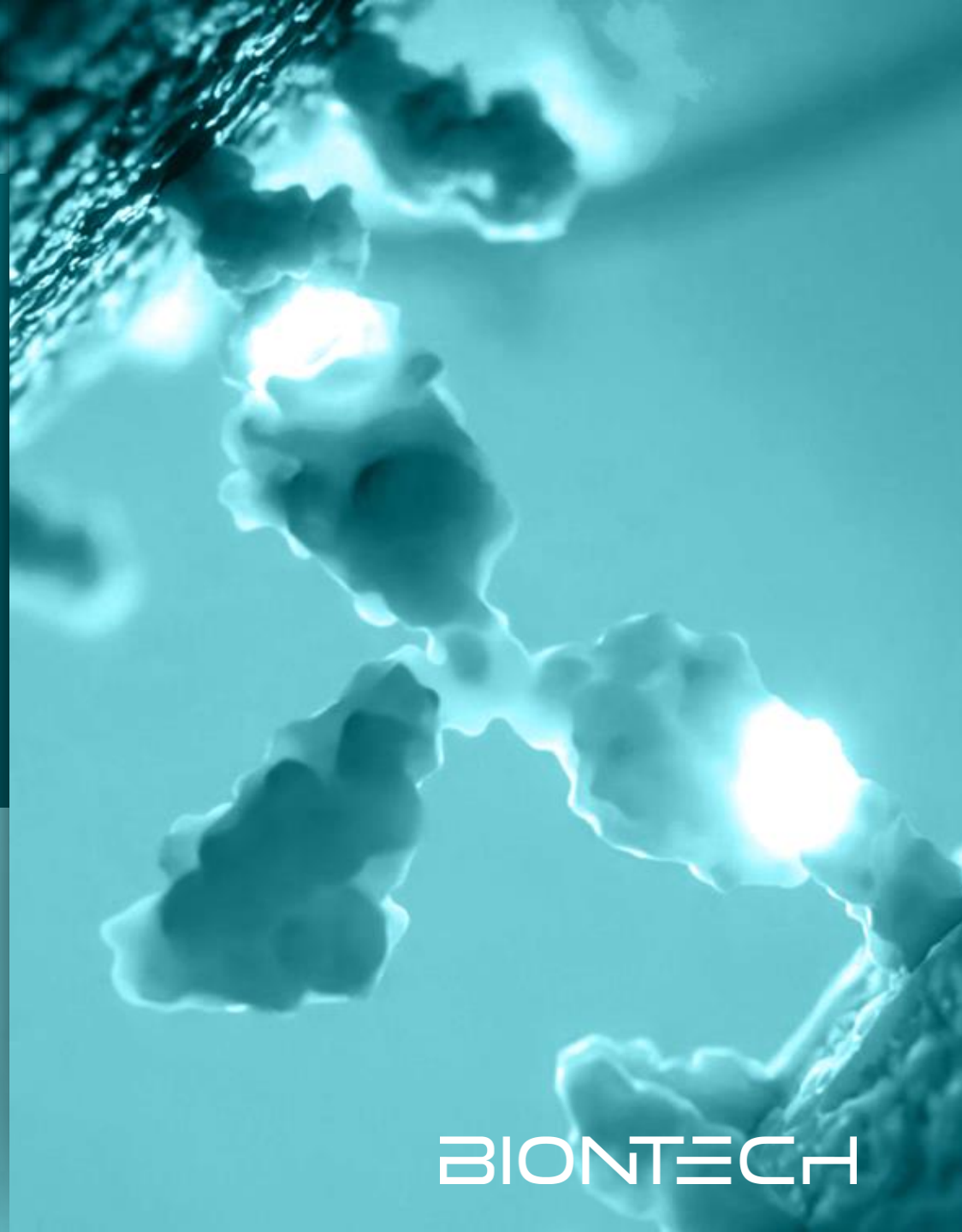
Innovation Series: R&D Day 2025

November 11th, 2025



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1 Introductory Remarks

Douglas Maffei, PhD,
Vice President, Strategy and
Investor Relations

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This Slide Presentation Includes Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements concerning: BioNTech's expected revenues and net profit/(loss) related to sales of BioNTech's COVID-19 vaccine, referred to as COMIRNATY where approved for use under full or conditional marketing authorization, in territories controlled by BioNTech's collaboration partners, particularly for those figures that are derived from preliminary estimates provided by BioNTech's partners; the rate and degree of market acceptance of BioNTech's COVID-19 vaccine and, if approved, BioNTech's investigational medicines; expectations regarding anticipated changes in COVID-19 vaccine demand, including changes to the ordering environment and expected regulatory recommendations to adapt vaccines to address new variants or sublineages; the initiation, timing, progress, results, and cost of BioNTech's research and development programs, including BioNTech's current and future preclinical studies and clinical trials, including statements regarding the expected timing of initiation, enrollment, and completion of studies or trials and related preparatory work and the availability of results, and the timing and outcome of applications for regulatory approvals and marketing authorizations; BioNTech's expectations regarding potential future commercialization in oncology, including goals regarding timing and indications; the targeted timing and number of additional potentially registrational trials, and the registrational potential of any trial BioNTech may initiate; discussions with regulatory agencies; BioNTech's expectations with respect to intellectual property; the impact of BioNTech's collaboration and licensing agreements, including BioNTech's partnership with BMS; BioNTech's planned acquisition of CureVac; the development, nature and feasibility of sustainable vaccine production and supply solutions; the deployment of AI across BioNTech's preclinical and clinical operations; BioNTech's expectations with respect to tariff policy; BioNTech's estimates of revenues, research and development expenses, selling, general and administrative expenses, and capital expenditures for operating activities; BioNTech's expectations regarding upcoming payments relating to litigation settlements; BioNTech's expectations for upcoming scientific and investor presentations; and BioNTech's expectations of net profit / (loss). In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words.

The forward-looking statements in this presentation are based on BioNTech's current expectations and beliefs of future events and are neither promises nor guarantees. You should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond BioNTech's control, and which could cause actual results to differ materially and adversely from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to: the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, projected data release timelines, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preclinical and clinical data, including the data discussed in this release, and including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; BioNTech's pricing and coverage negotiations regarding its COVID-19 vaccine with governmental authorities, private health insurers and other third-party payors; the future commercial demand and medical need for initial or booster doses of a COVID-19 vaccine; the impact of tariffs and escalations in trade policy; competition from other COVID-19 vaccines or related to BioNTech's other product candidates, including those with different mechanisms of action and different manufacturing and distribution constraints, on the basis of, among other things, efficacy, cost, convenience of storage and distribution, breadth of approved use, side-effect profile and durability of immune response; the timing of and BioNTech's ability to obtain and maintain regulatory approval for its product candidates; the ability of BioNTech's COVID-19 vaccines to prevent COVID-19 caused by emerging virus variants; BioNTech's and its counterparties' ability to manage and source necessary energy resources; BioNTech's ability to identify research opportunities and discover and develop investigational medicines; the ability and willingness of BioNTech's third-party collaborators to continue research and development activities relating to BioNTech's development candidates and investigational medicines; the impact of COVID-19 on BioNTech's development programs, supply chain, collaborators and financial performance; unforeseen safety issues and potential claims that are alleged to arise from the use of products and product candidates developed or manufactured by BioNTech; BioNTech's and its collaborators' ability to commercialize and market BioNTech's COVID-19 vaccine and, if approved, its product candidates; BioNTech's ability to manage its development and related expenses; regulatory and political developments in the United States and other countries; BioNTech's ability to effectively scale its production capabilities and manufacture its products and product candidates; risks relating to the global financial system and markets; and other factors not known to BioNTech at this time. You should review the risks and uncertainties described under the heading "Risk Factors" in BioNTech's Report on Form 6-K for the period ended September 30, 2025, and in subsequent filings made by BioNTech with the SEC, which are available on the SEC's website at www.sec.gov. These forward-looking statements speak only as of the date hereof. Except as required by law, BioNTech disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this presentation in the event of new information, future developments or otherwise.

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An abbreviation directory of defined terms can be found at the end of the presentation.

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Innovation Series R&D Day 2025 Agenda

1	**Introductory Remarks**	Douglas Maffei, PhD, Vice President, Strategy and Investor Relations
2	**BioNTech's Unique Approach to Innovation**	Prof. Uğur Şahin Co-founder and Chief Executive Officer
3	**BioNTech's Differentiated Clinical Strategy to Advance the Treatment of Solid Tumors**	Prof. Özlem Türeci, M.D. Co-founder and Chief Medical Officer
4	**Establishing Pumitamig[1] in Foundational Tumor Types**	Prof. Ilhan Celik, M.D. Vice President, Clinical Development Michael Wenger, M.D. Vice President, Clinical Development
5	**Innovating Early-Stage Cancer Treatment with mRNA Cancer Immunotherapies**	Prof. Özlem Türeci, M.D. Co-founder and Chief Medical Officer
6	**BioNTech's Path to Value Creation**	Ramón Zapata Chief Financial Officer
7	**Q&A Panel Discussion**	All Speakers Annemarie Hanekamp Chief Commercial Officer

1. Partnered with Bristol Myers Squibb.

2 BioNTech's Unique Approach to Innovation

Prof. Uğur Şahin
CEO and Co-founder

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Translating Science into Survival

Building a Global Immunotherapy Powerhouse

BioNTech – Disruptive Tech-Bio Company with Pioneering Technologies Developed Through Full AI Integration

Multiplatform oncology company

16 **Clinical programs**

>20 **Ongoing Phase 2 or 3 trials**

Bristol Myers Squibb™ · Genmab · DualityBio · MediLink Therapeutics · OncoC4 · Genentech · REGENERON

Infectious diseases pipeline

7 **Clinical programs** in high unmet need indications

Gates Foundation · CEPI

COVID-19 vaccine global impact

5 **Billion doses distributed**

Pfizer

Leader in integrated AI capabilities

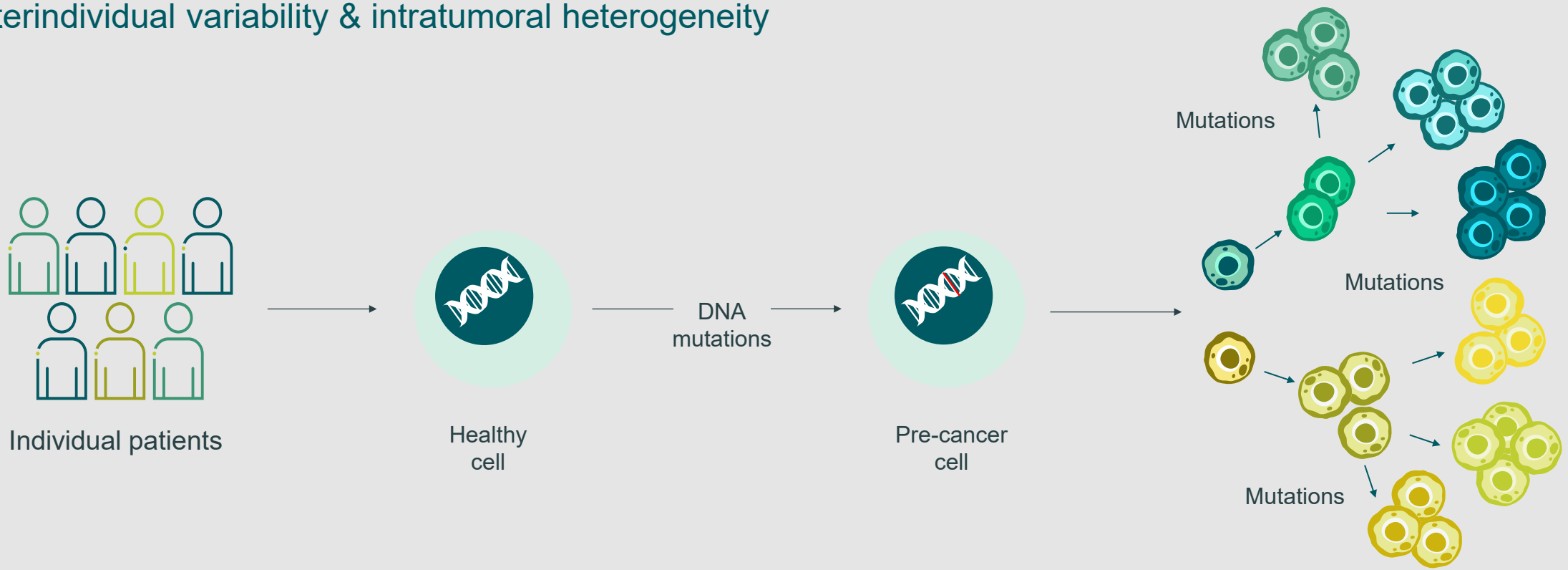
InstaDeep™ a BioNTech Company

In-house manufacturing

4 **Platforms** including individualized mRNA and bispecific antibodies

Root Cause of Cancer Treatment Failure

Interindividual variability & intratumoral heterogeneity



Cancer evolution 5-20 years – up to 10,000 mutations

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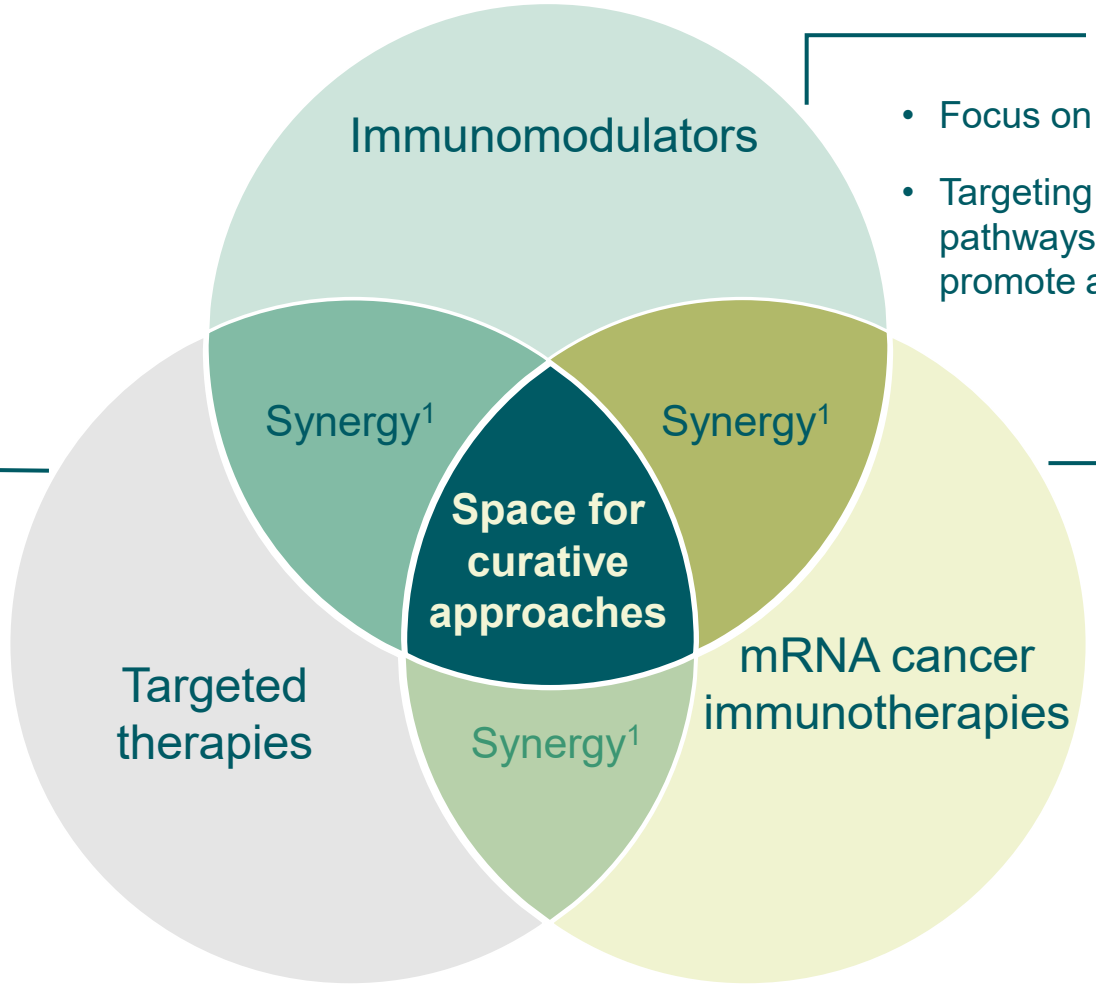
We Are Uniquely Positioned to Combine Approaches to Transform Cancer Care

Immunomodulators

- Focus on the critical IO pathways
- Targeting different complementary pathways in cancer immunity cycle may promote a durable anti-tumor effect



Targeted therapies

- Precise and potent modalities for fast onset tumor reduction
- ADC as potential “augmenters” of immunomodulators and mRNA cancer immunotherapies
- HER2, TROP2, B7H3, HER3, EGFRxHER3, ADCs as combination partners

mRNA cancer immunotherapies

- Eliminate polyclonal residual disease with multi-antigen and individualized approaches
- Polyspecific activity by targeting multiple antigens at once
- Establish long-lasting immunological memory to prevent relapses

1. Synergistic potential.

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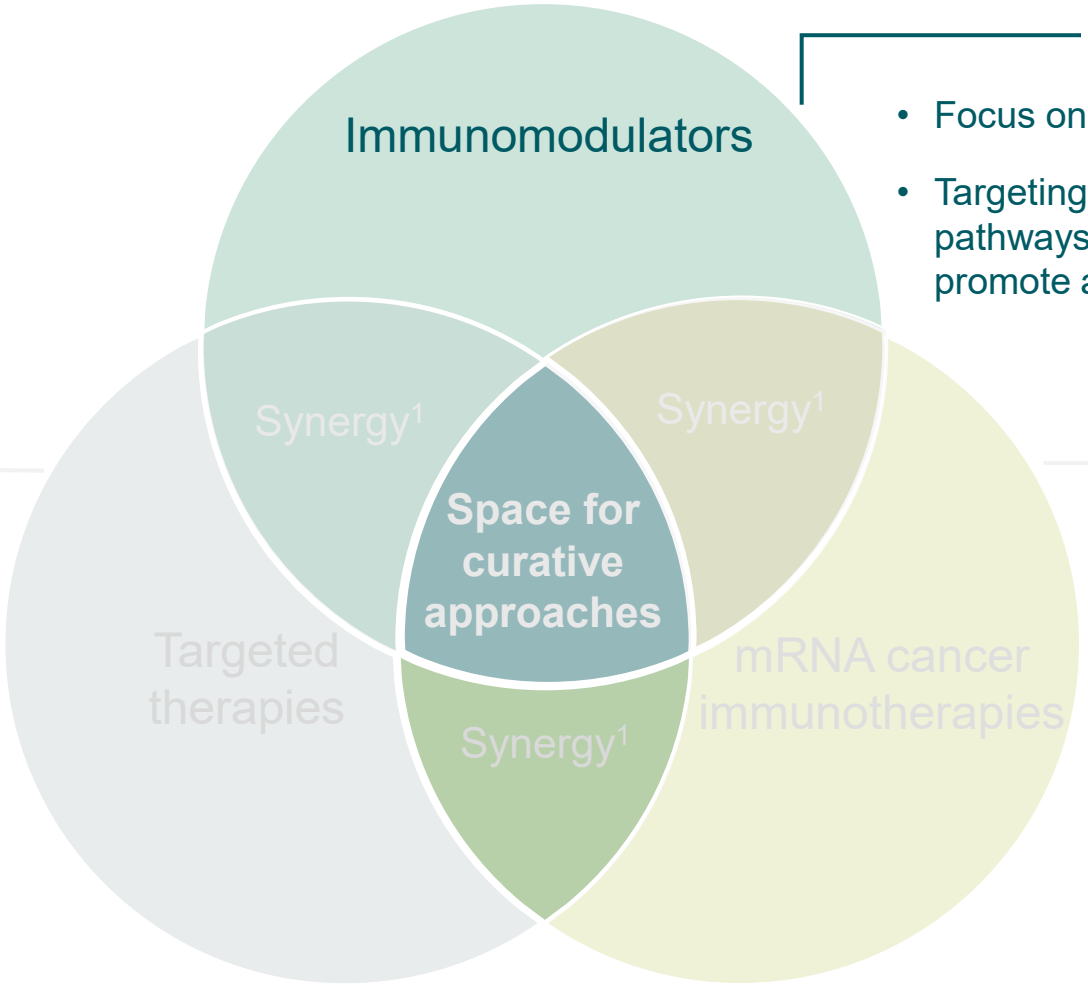

Immunomodulators

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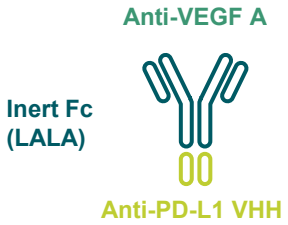
Prioritized Immunomodulator Pipeline

Pumitamig[1]

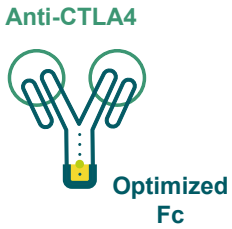


PD-L1 expression or upregulation in tumors may enrich **VEGF neutralization** into the TME which **inhibits angiogenesis**.

Clinical status

- **Registrational trials** ongoing in 1L SCLC, NSCLC, TNBC and initiating in CRC, gastric
- 12+ studies combining with chemotherapy
- 10+ novel combinations

Gotistobart[2]



Monospecific antibody with **optimized Fc** targeting CTLA-4 and **selectively depleting tumor-infiltrating Tregs** in the TME but not in the periphery due to a pH driven mechanism.

Clinical status

- **Ph3** in 2L+ sqNSCLC
- Ph2 in PROC
- Ph1/2 in mCRPC
- Ph1/2 in multiple solid tumors

BNT314/ GEN1059[3]

BNT317

BNT3213

Clinical status

Phase 1, Phase 1/2, exploratory trials ongoing

Exploratory exercise: More novel next-gen IO molecules to come

1. Partnered with Bristol Myers Squibb; 2. Partnered with OncoC4; 3. Partnered with Genmab.

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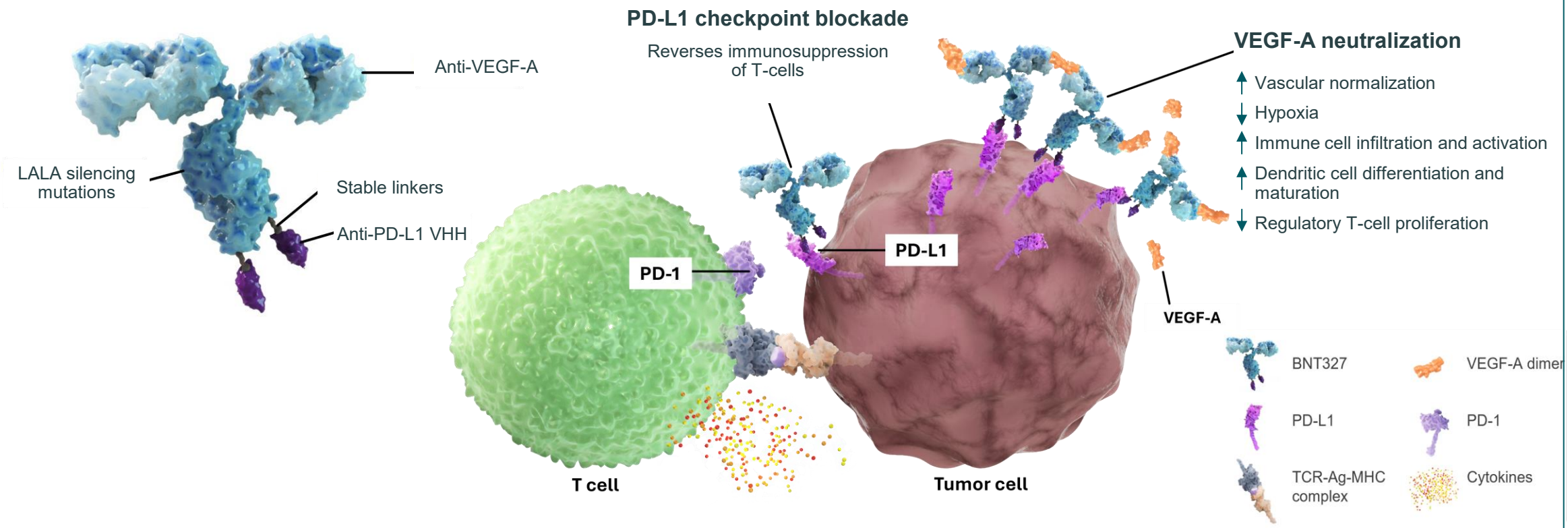
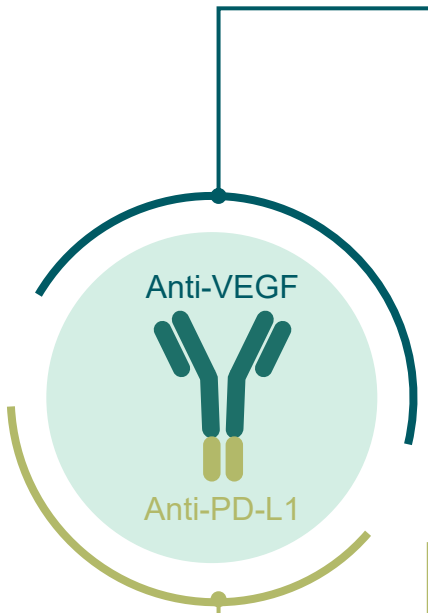
Pumitamig[1]: PD-L1 x VEGF-A Bispecific Antibody

Pumitamig is an investigational bispecific antibody, targeting both PD-L1 and VEGF-A. Binding to PD-L1 is intended to restore effector T-cell function and localize VEGF-A neutralization within the TME, reversing the negative impact of VEGF signaling on immune cell infiltration and activation and normalizing tumor vasculature, leading to tumor growth inhibition.

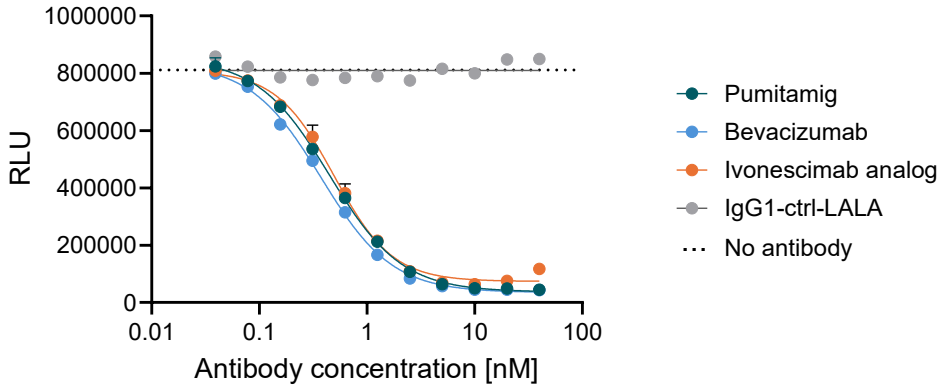


Miao X et al. AACR 2025. Poster #6061; 1. Partnered with Bristol Myers Squibb

Pumitamig[1]: Potent VEGF-A Neutralization and PD-1/PD-L1 Checkpoint Blockade



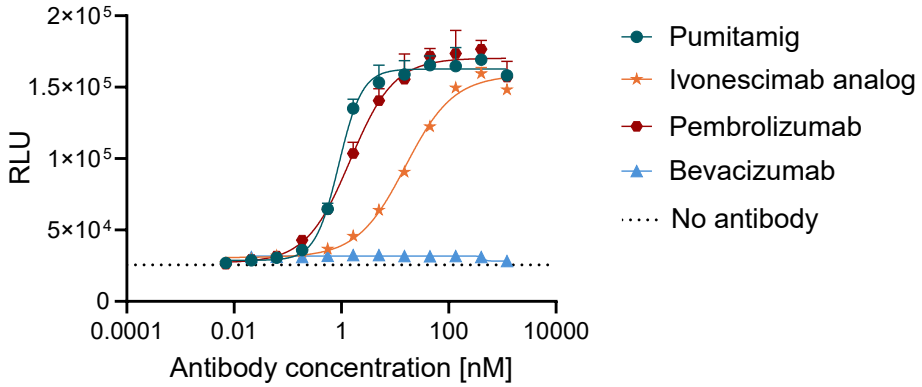
Pumitamig dose-dependently inhibited functional VEGF-A / VEGFR2 engagement



VEGF-A neutralization assay[2]

Antibody	IC_{50} ± SD (nM)
Pumitamig (n=5)	0.53 ± 0.06
Bevacizumab (n=4)	0.42 ± 0.05
Ivonescimab analog (n=4)	0.56 ± 0.05

Pumitamig dose-dependently blocked the PD-1 / PD-L1 checkpoint



PD-1/PD-L1 blockage bioassay[2]

Antibody	IC_{50} ± SD (nM)
Pumitamig (n=6)	0.84 ± 0.06
Pembrolizumab (n=6)	1.17 ± 0.17
Ivonescimab analog (n=5)	16.08 ± 1.76

Data on file. 1. Partnered with Bristol Myers Squibb; 2. Luciferase-based reporter assays are commercially available from Promega.

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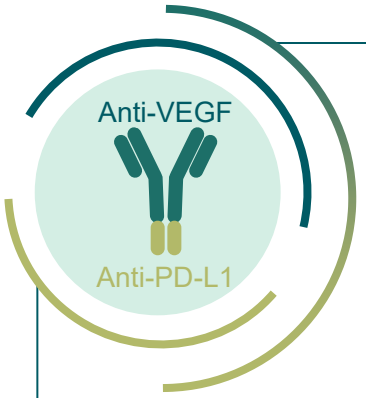
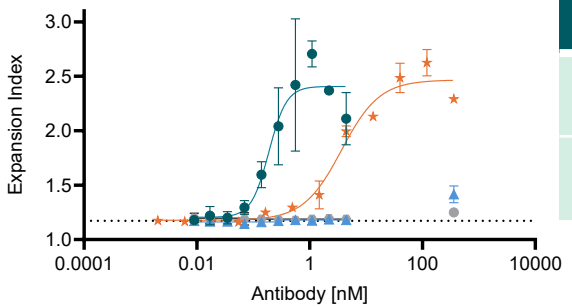
Pumitamig[1]: Combined Effect of Anti-Angiogenesis and Checkpoint Blockade Through One Molecule Leads to Immune Invigoration

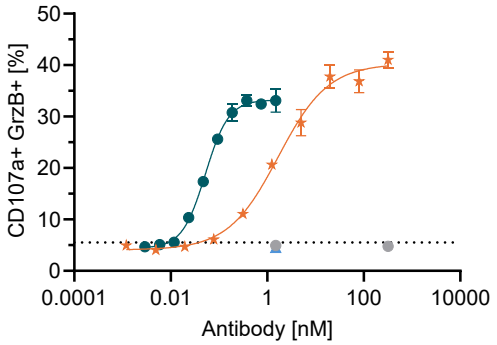


T cell Expansion



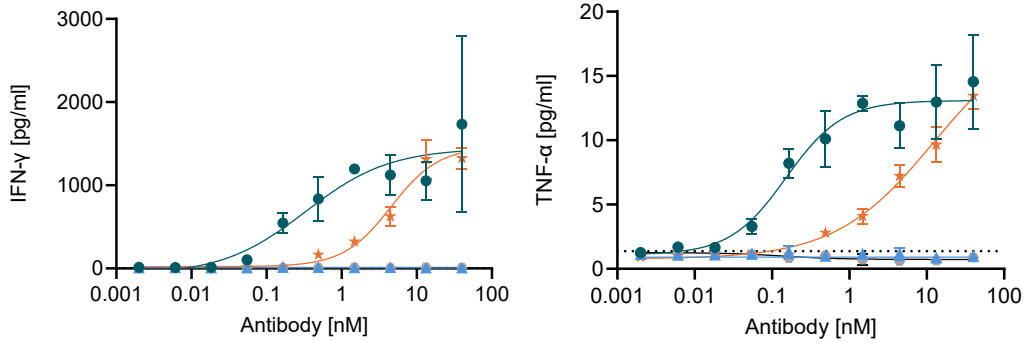
Antibody	IC_{50} ± SD (nM)
Pumitamig (n=7)	0.21 ± 0.09
Ivonescimab analog (n=4)	2.47 ± 0.95

CD107 Expression

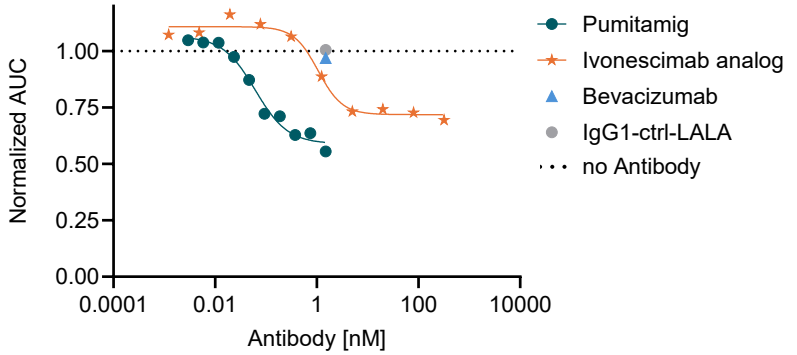


Antibody	IC_{50} ± SD (nM)
Pumitamig (n=6)	0.058 ± 0.01
Ivonescimab analog (n=4)	1.202 ± 0.57

Cytokine secretion



Tumor Cell Killing



Antibody	IC_{50} ± SD (nM)
Pumitamig (n=6)	0.069 ± 0.03
Ivonescimab analog (n=4)	0.746 ± 0.24

Immune-invigorating: Pumitamig[1] enhances expression of cytotoxic molecules, cytokine secretion, CD8+ T-cell expansion, and CD8+ T-cell mediated tumor-cell killing

Data on file. 1. Partnered with Bristol Myers Squibb

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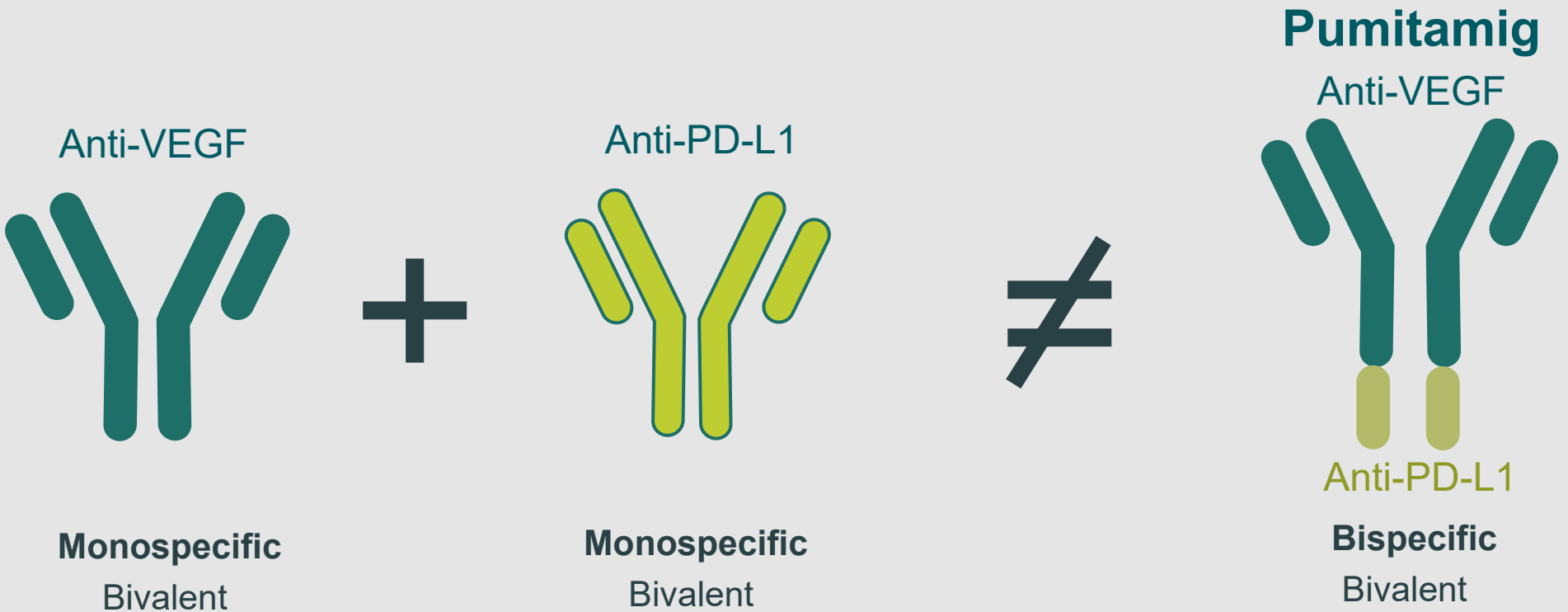
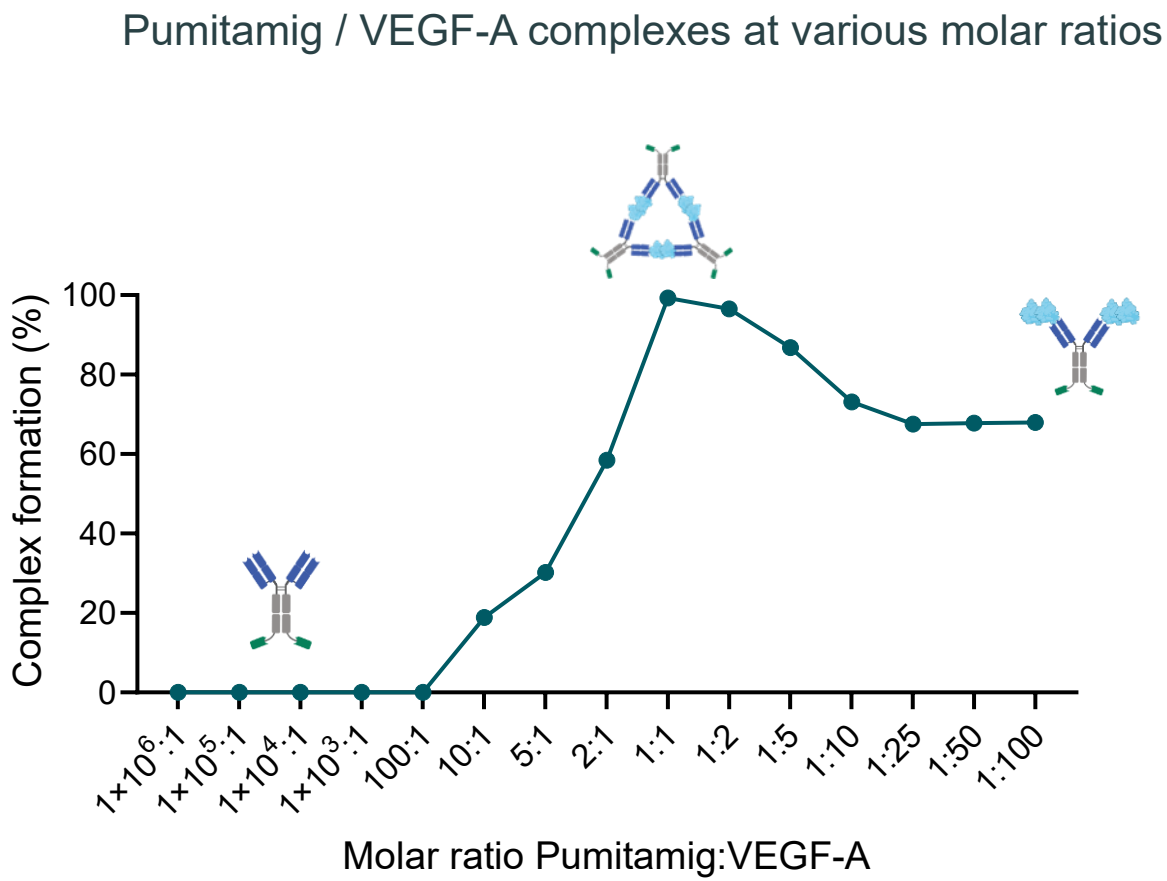
Pumitamig[1] is More than the Sum of Two Monospecific Antibodies



1. Partnered with Bristol Myers Squibb

VEGF-A / Bispecific Antibody Complex Formation is a Function of Antibody-to-VEGF-A Molar Ratio

Complex formation occurs at optimal antibody-to-VEGF-A molar ratios in a bell-shaped response curve



Data on file.

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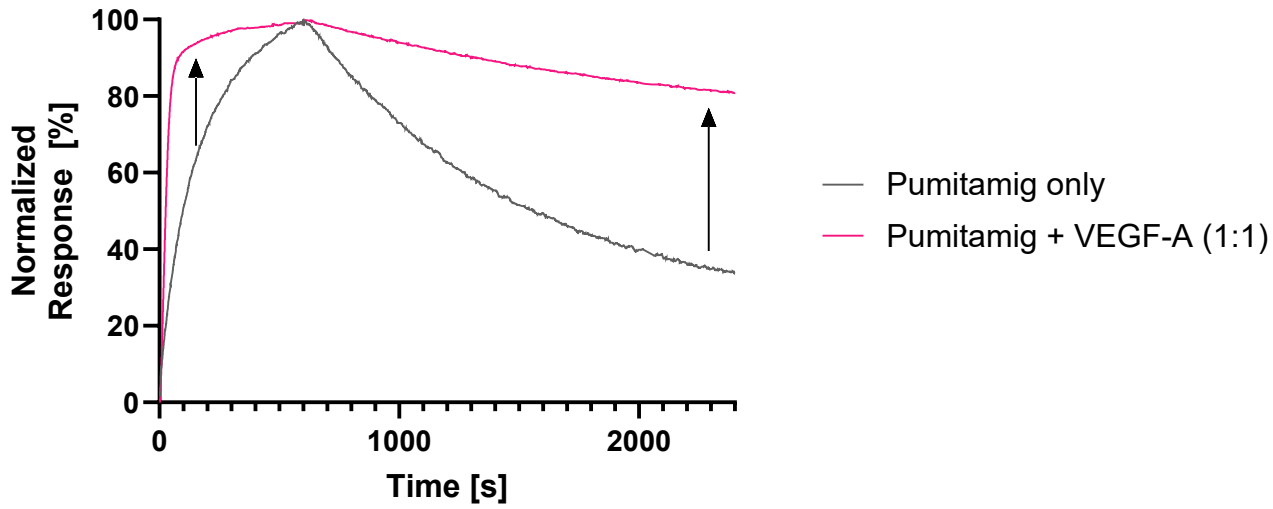
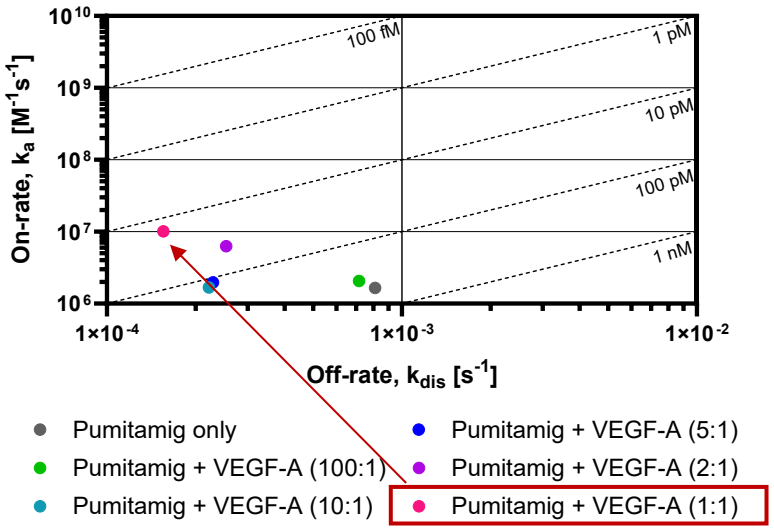
Pumitamig[1] / VEGF-A Complexation Leads to Enhanced Binding Affinity to PD-L1

At equimolar pumitamig-to-VEGF-A ratio, pumitamig shows increased On-rate and decreased Off-rate

A. Normalized SPR sensorgrams



B. Isoaffinity graph



C. K_D values and association (k_a) /dissociation (k_{dis}) rates for pumitamig

Pumitamig:VEGF-A molar ratio	K_D (Binding affinity) [M]	k_a [$M^{-1}s^{-1}$]	k_{dis} [s^{-1}]	Fold differences
Pumitamig only	4.915×10^{-10}	1.651×10^{6}	8.114×10^{-4}	
100:1	3.468×10^{-10}	2.063×10^{6}	7.153×10^{-4}	1.4
10:1	1.317×10^{-10}	1.684×10^{6}	2.217×10^{-4}	3.7
5:1	1.158×10^{-10}	1.977×10^{6}	2.289×10^{-4}	4.2
2:1	0.4029×10^{-10}	6.299×10^{6}	2.538×10^{-4}	12.2
1:1	**0.1537×10^{-10}**	**1.011×10^{7}**	**1.555×10^{-4}**	**32**

32-fold enhanced binding affinity of pumitamig to immobilized PD-L1 by complexation of pumitamig with equimolar VEGF-A, indicative of cooperative binding

Data on file. 1. Partnered with Bristol Myers Squibb

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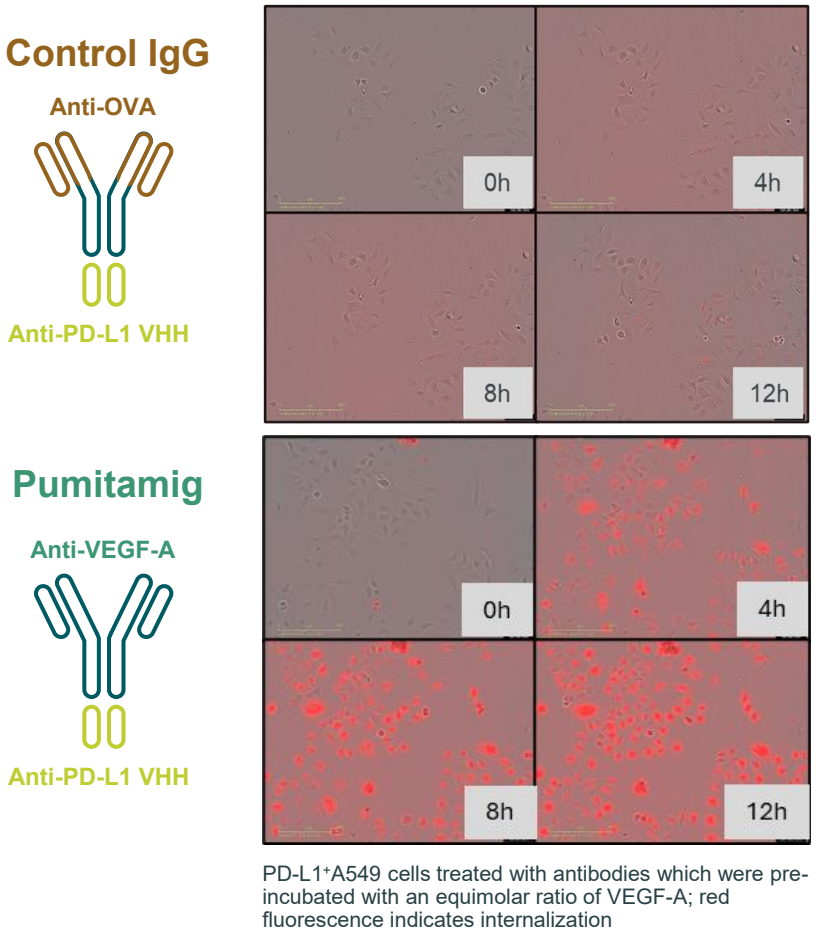
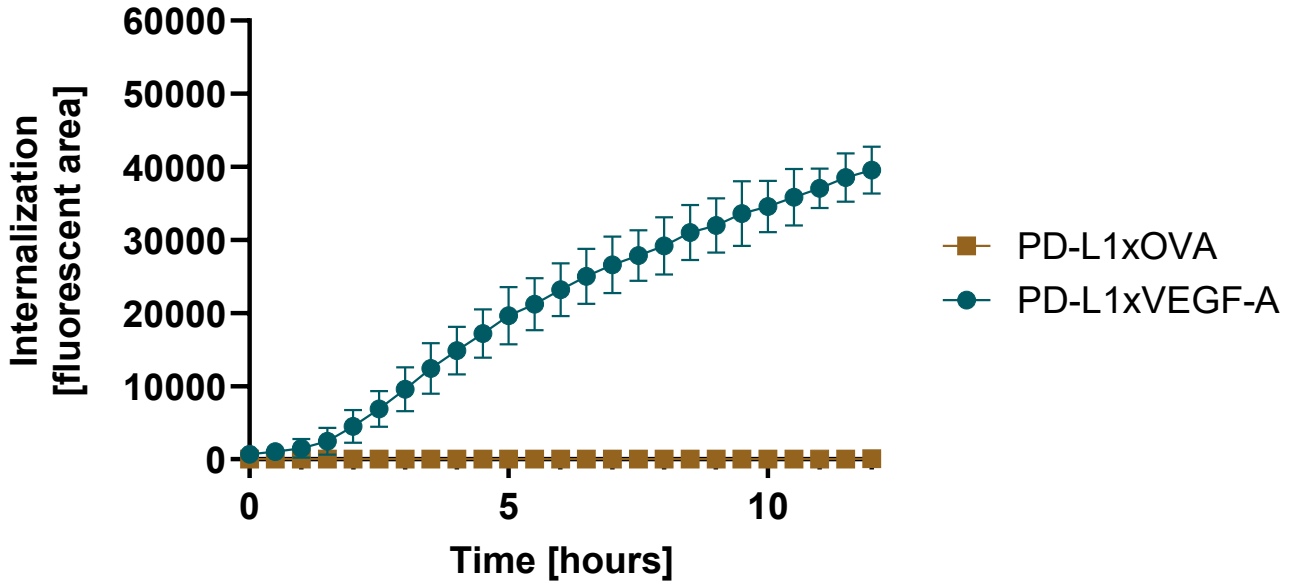
Rapid anti-VEGF-A Dependent Internalisation of Pumitamig[1] Upon Binding to PD-L1+ Cells



PD-L1+A549 cells treated with antibodies which were pre-incubated with an equimolar ratio of VEGF-A; red fluorescence indicates internalization



Rapid PD-L1 internalization may contribute to enhanced T cell activation in the presence of Pumitamig / VEGF-A complexes

Data on file. 1. Partnered with Bristol Myers Squibb

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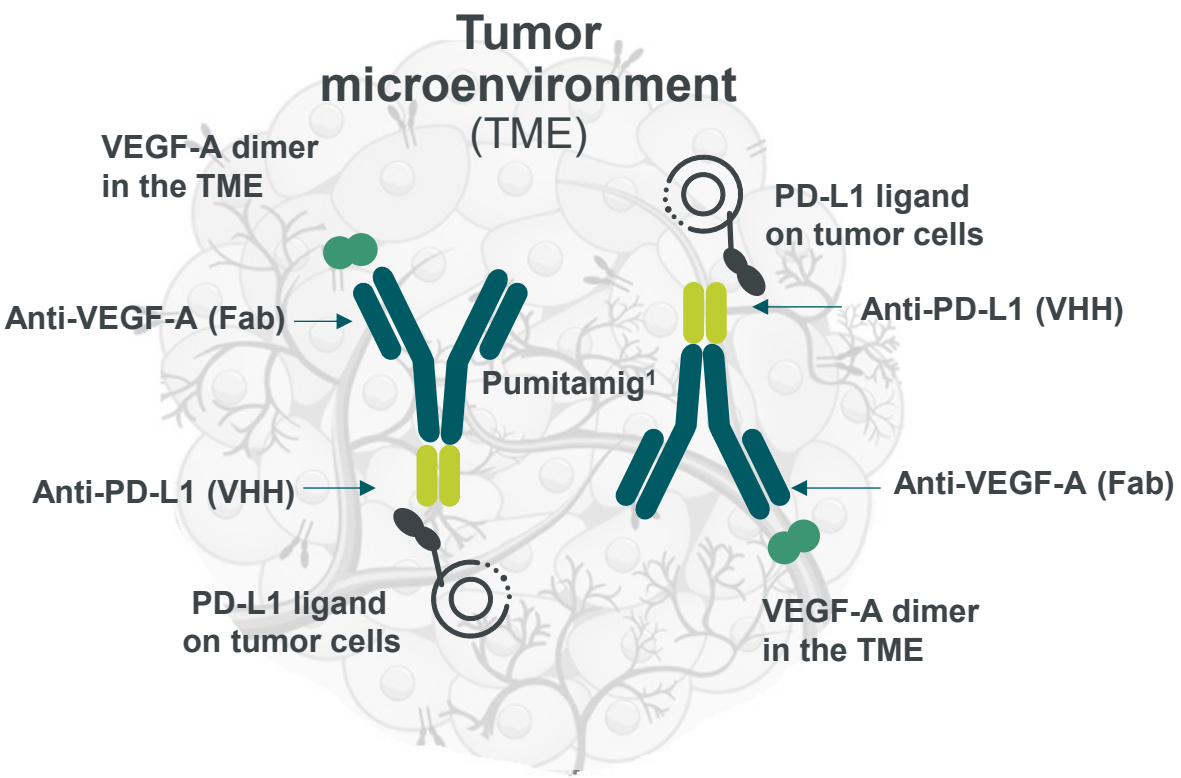
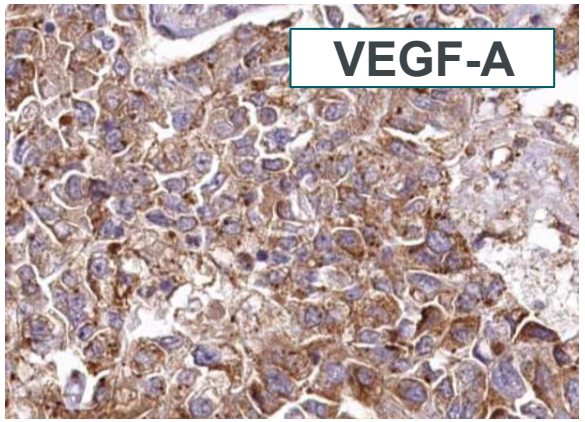
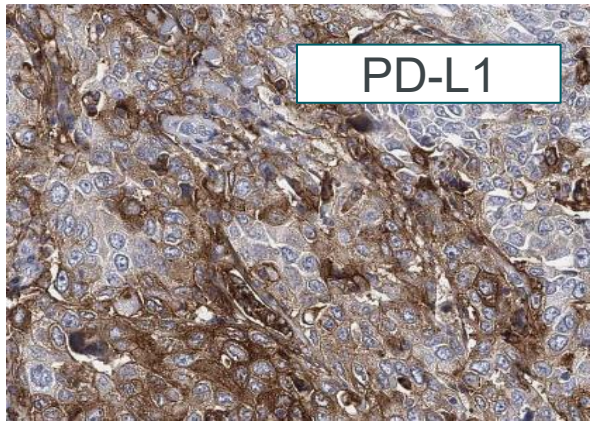
Pumitamig[1]: Synergistic Targeting of PD-L1 and VEGF-A

Pumitamig characteristics: combined tumor targeting[2]



Selected NSCLC IHC[3]





Bispecific MOA

Targeting of PD-1/PD-L1 blockade to VEGF-A high tumors

Targeting of VEGF-A neutralization to PDL1 high tumors

1. Partnered with Bristol Myers Squibb; 2. Khan KA Nat Rev Clin Oncol 2018; 3. IHC data: Human Protein Atlas.

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Differentiation of Pumitamig[1] by Binding to PD-L1 Aims Targeting to Tumor Site

	Blocking of PD-1/PD-L1 signaling	Neutralization of VEGF	Cooperative effect linking PD-L1 and VEGF binding	TME Targeting by anti-PD-L1
Pumitamig PD-L1/VEGF Bispecific	YES	YES	YES	YES
PD-1/VEGF Bispecific	YES	YES	YES	NO
PD(L)1 + VEGF Monospecific	YES	YES	NO	NO

Pumitamig[1]

Dual targeting of TME

VEGF targeted PD-L1 inhibition

Anti-VEGF-A

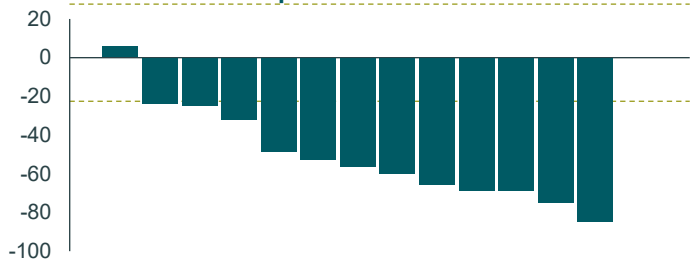
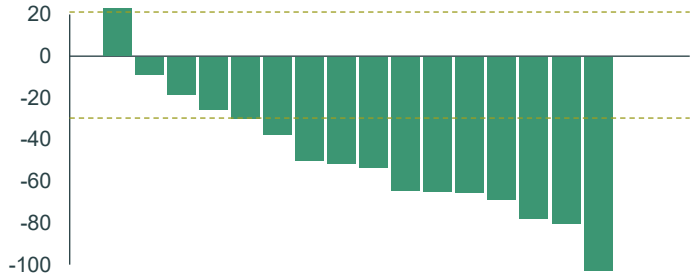
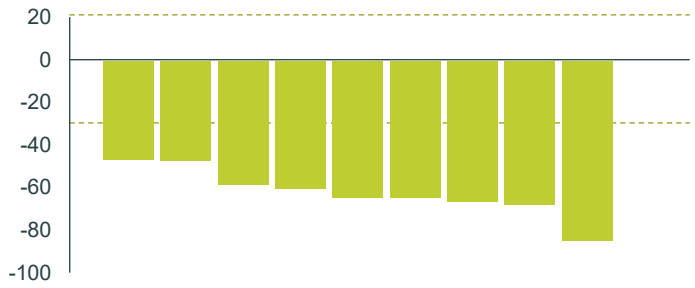
Anti-PD-L1

PD-L1 targeted VEGF neutralization

1. Partnered with Bristol Myers Squibb.

Pumitamig[1] May Drive Clinical Benefit Irrespective of PD-L1 Status

Pumitamig[1] + chemo in 1L **TNBC,** Y. Meng et al. ESMO 2024 384MO

PD-L1 status	Waterfall plots	ORR Objective response rate
PD-L1 negative[2]		**76.9%**
PD-L1 low[2]		**56.3%**
PD-L1 high[2]		**100.0%**

Pumitamig[1] has the potential to become a backbone IO therapy for significant patient populations currently not addressed by existing IO therapies

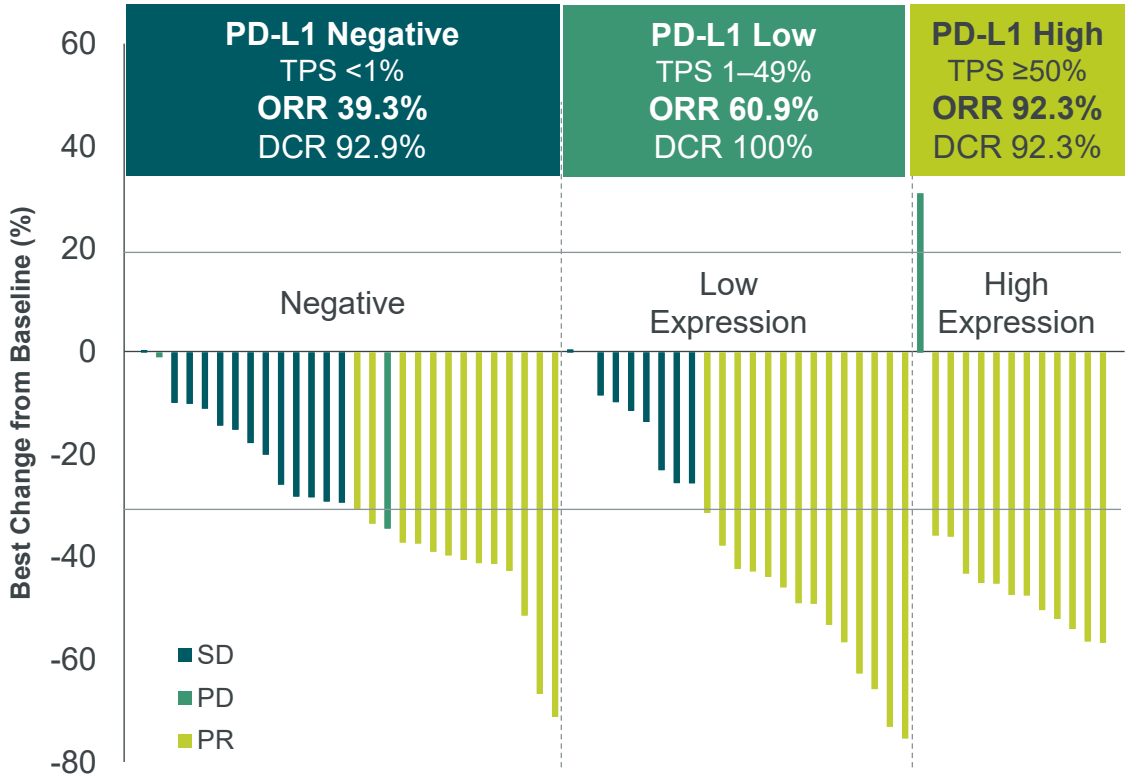
1. Partnered with Bristol Myers Squibb; 2. PD-L1 status in TNBC: negative= CPS<1; low= 1≤CPS<10; high= CPS≥10

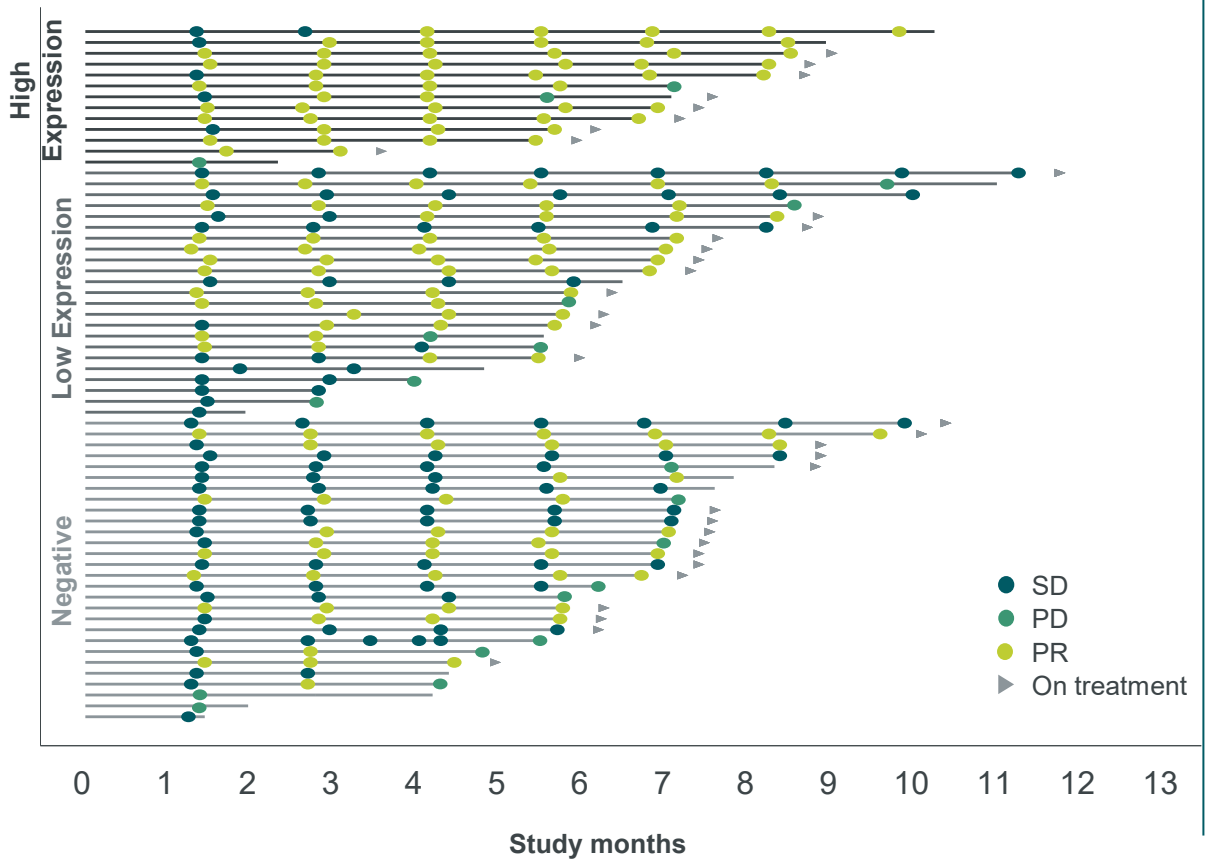
BIONTECH

Pumitamig[1] in Combination with Chemo Shows Efficacy in EGFRm NSCLC Irrespective of PD-L1 Status

Phase 2 study* of pumitamig + carbo/pem in **EGFRmut NSCLC** post EGFR TKI

Adapted from Wu YL et al. ESMO 2024 1255MO





Median follow-up time: 7.7 months

1. Partnered with Bristol Myers Squibb; *NCT05756972

BIONTECH

Broad Combination Strategy Across Indications Aiming to Establish Next-Generation IO-Backbone

REPLACE

Anti-PD-(L)1 approved

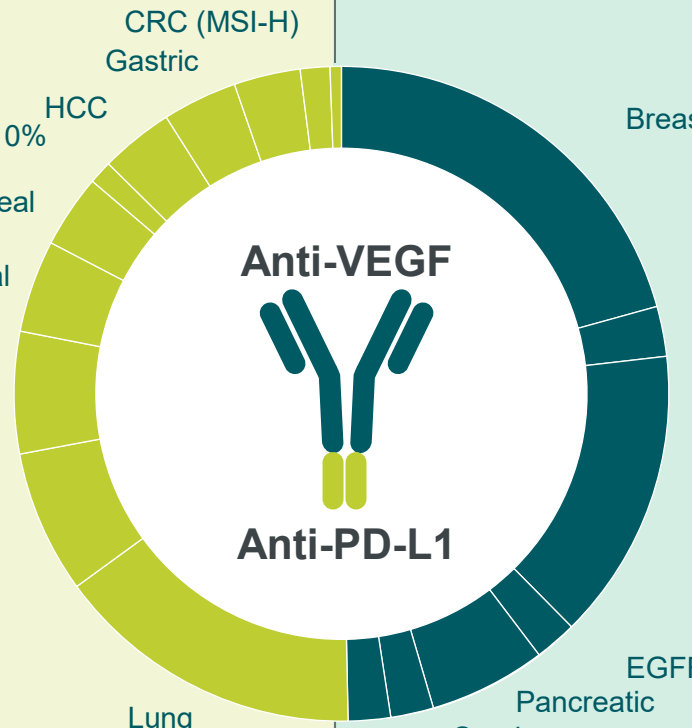
Anti-PD-(L)1 therapy addresses

~1.5 M

new cancer cases
in the US and EU annually
with medical need remaining
high (5-year survival < 50%)[1]

EXPAND

Anti-PD-(L)1 not approved



US and EU Cancer Incidence[2]

>1.4 M

estimated new cancer cases
in the US and EU annually
that cannot be addressed
by current IO therapies

1. NCI SEER https://training.seer.cancer.gov/index.html. 2.US incidence source: NIH and American Cancer Society data EU incidence source: European Cancer Information System

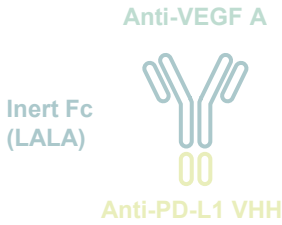
BIONTECH

Pumitamig[1]: Executing a Parallel Three-Wave Strategy to Build a Proprietary IO Franchise

Partnered with 1. Bristol Myers Squibb.

Prioritized Immunomodulator Pipeline

Pumitamig[1]

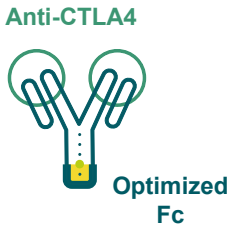


PD-L1 expression or upregulation in tumors may enrich **VEGF neutralization** into the TME which **inhibits angiogenesis**.

Clinical status

- **Registrational trials** ongoing in 1L SCLC, NSCLC, TNBC and initiating in CRC, gastric
- 12+ studies combining with chemotherapy
- 10+ novel combinations

Gotistobart[2]



Monospecific antibody with **optimized Fc** targeting CTLA-4 and **selectively depleting tumor-infiltrating Tregs** in the TME but not in the periphery due to a pH driven mechanism.

Clinical status

- **Ph3** in 2L+ sqNSCLC
- Ph2 in PROC
- Ph1/2 in mCRPC
- Ph1/2 in multiple solid tumors

BNT314/ GEN1059[3]

BNT317

BNT3213

Clinical status

Phase1, Phase 1/2, exploratory trials ongoing

Exploratory exercise: More novel next-gen IO molecules to come…

1. Partnered with Bristol Myers Squibb; 2. Partnered with OncoC4; 3. Partnered with Genmab.

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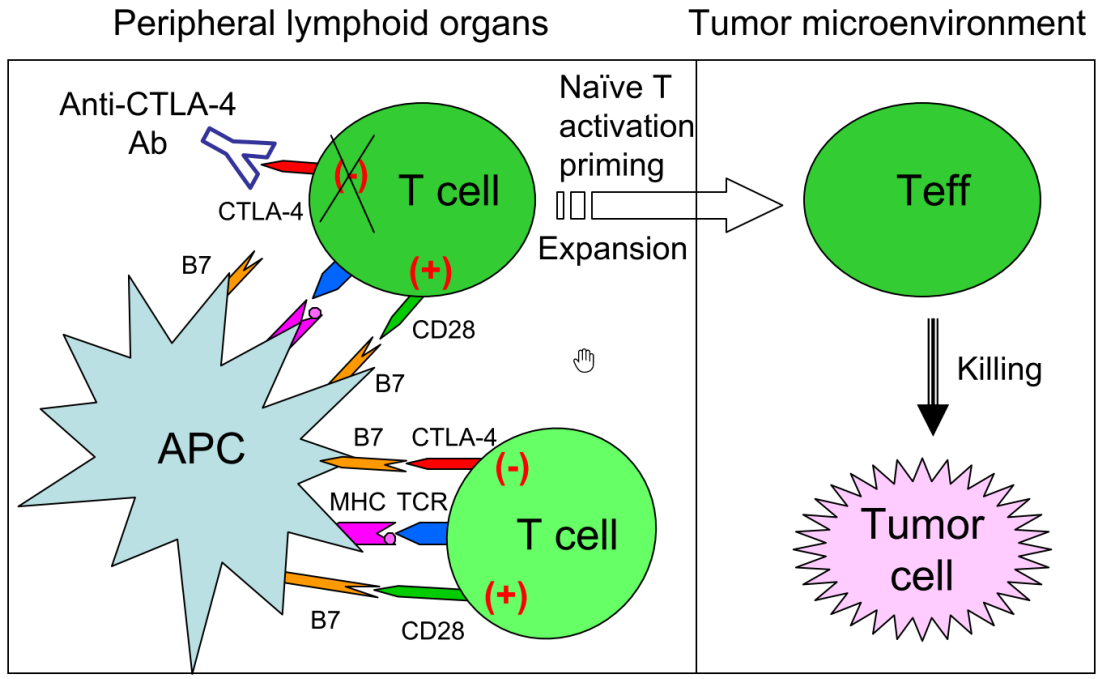
Anti-CTLA4 as a Target for Cancer Immunotherapy

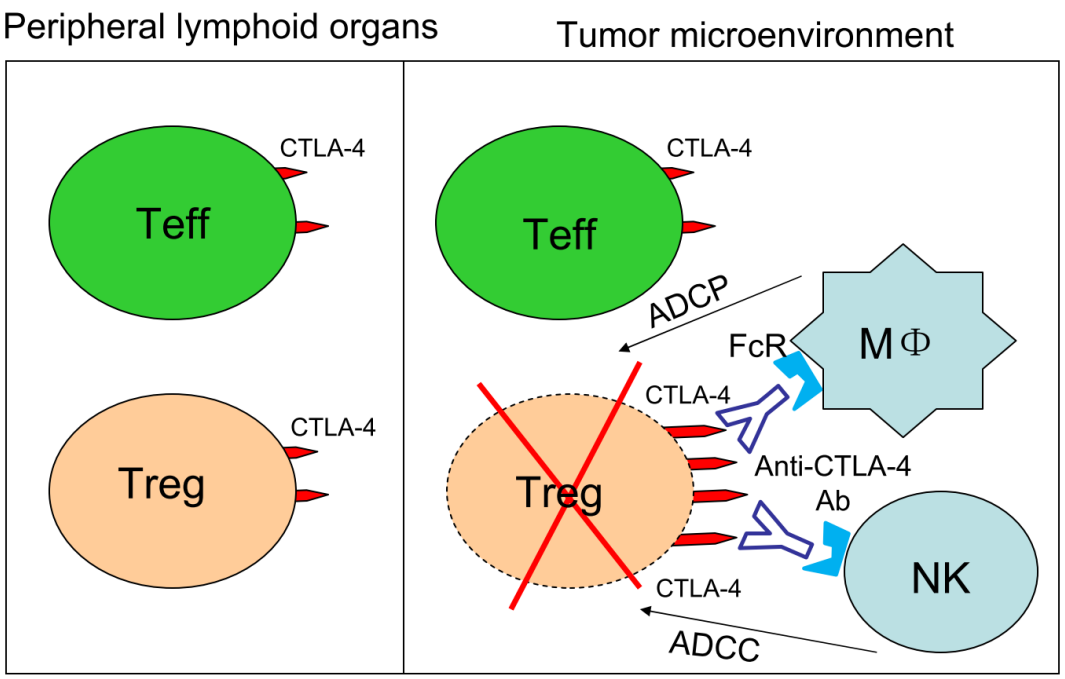
Prevailing View: CTLA-4 Blockade



Antitumor response intrinsically linked to concomitant autoimmunity, constraining the therapeutic window

Yang Liu, Pan Zheng et al British Medical Journal, 2018

The Novel Concept: Selective Depletion of Tregs in the TME



Opportunity for better therapeutic index by tumor selectivity

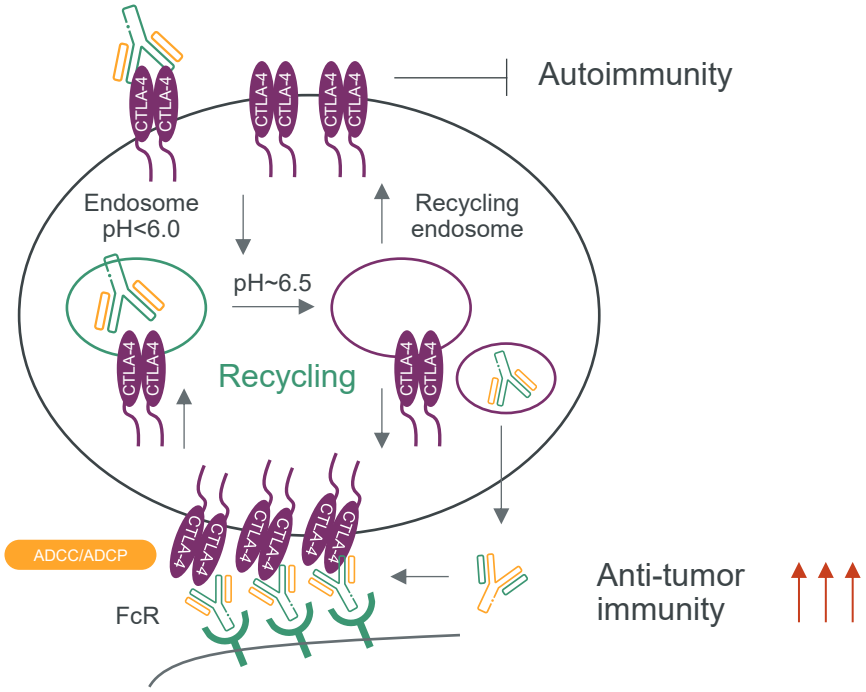
BIONTECH

Gotistobart:[1] Differentiated Mechanism with Potential to Become Best-in-Class Anti-CTLA-4 Antibody

Avoiding lysosomal degradation of CTLA-4 for safer and more effective immunotherapy may lead to uncoupling cancer therapeutic effect from immunotherapy-related adverse effects

Gotistobart[1] designed to:

- Allow regular recycling and enrichment of antibody and CTLA-4 molecule
- Selectively kill Tregs in the tumor microenvironment
- Improve therapeutic index (efficacy/toxicity ratio)
- Enhance anti-tumor immunity
- Allow prolonged, repeated dosing

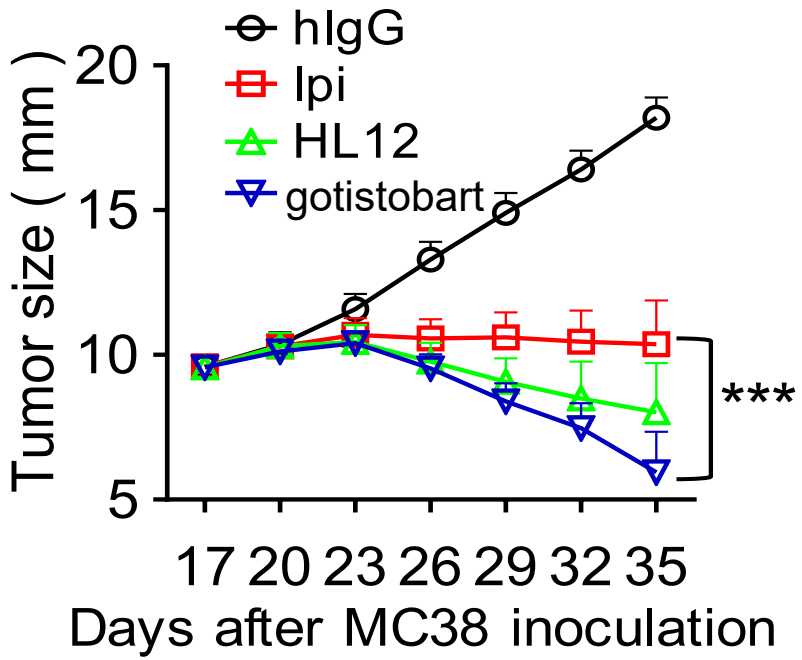


Liu Y. et al. SITC 2021 # 231; Du et al. Cell Res. 2018 Apr; 28(4): 416–432; Du et al. Cell Res. 2018 Apr; 28(4): 433–447.

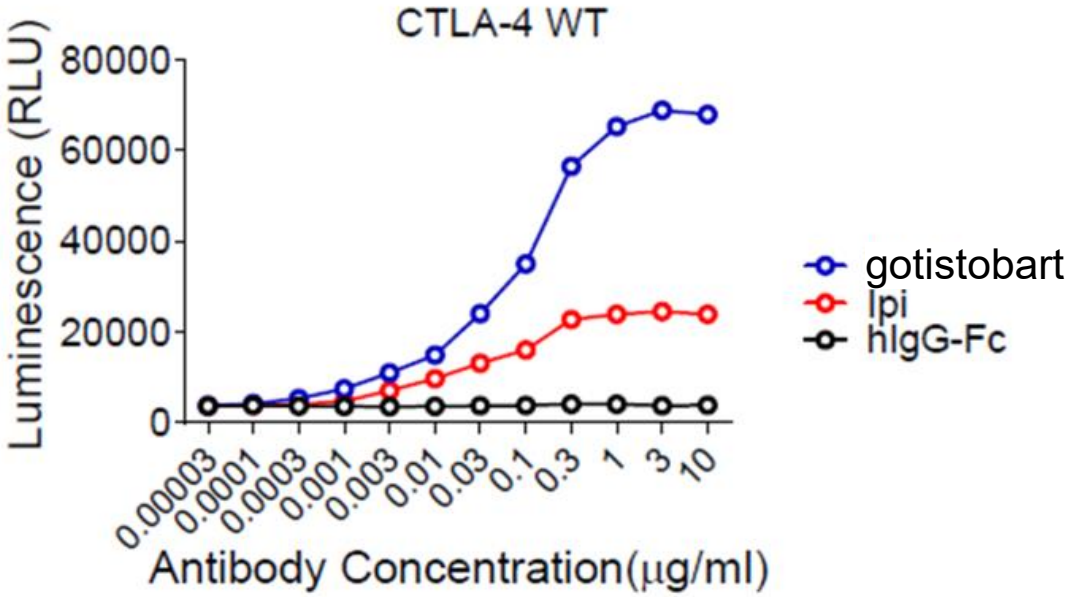
1. Partnered with OncoC4.

BIONTECH

Preclinical Data Demonstrate Improved Therapeutic Index of Gotistobart[1]



Zhang *et al.* Cell Research 2019



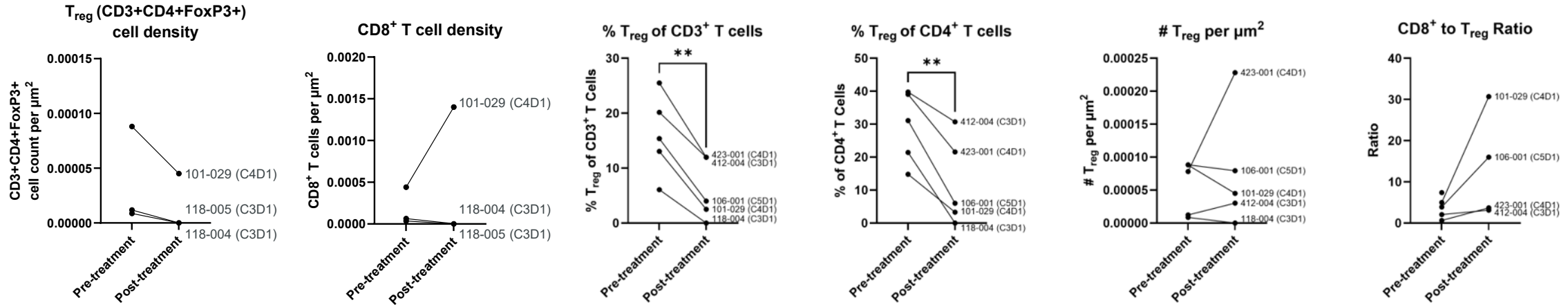
Data on file.

1. Partnered with OncoC4.

BIONTECH

CD3+, CD4+ and FoxP3+ Treg Concentrations Decrease with Gotistobart[1] Treatment

PRESERVE-001 Phase 1/2 Trial: gotistobart monotherapy treatment in multiple tumor types, including sarcoma, pancreatic cancer, melanoma and ovarian cancer



1. Partnered with OncoC4. Data on file

BIONTECH

Pivotal Development of Gotistobart[1] in 2L Squamous Non-Small Cell Lung Cancer

Seamless Phase 3 two-stage, randomized trial evaluating gotistobart versus docetaxel in 600 patients

Key Inclusion Criteria

- stage IV, metastatic NSCLC
- Prior PD-(L)1 +/- platinum-based chemotherapy
- Prior IO-IO allowed
- RECIST 1.1 measurable lesions

Stratification Factors

- Histology (Squamous or Non-Squamous) in Stage I
- Presence of brain metastases
- ECOG score (0 or 1)
- Region (US or ex-US)

Stage 1: Dose confirmation in squamous and non-squamous NSCLC

R 1:1:1

- **Gotistobart** 6 mg/kg with 2 loading doses of 10 mg/kg, Q3W (n=103)
- **Gotistobart** 3 mg/kg, Q3W (n=10)
- **Docetaxel** 75 mg/kg, Q3W (N=104)

Phase 3 Stage 1 data to be presented at NACLC on December 6, 2025

Stage 2: Pivotal part in squamous NSCLC

R 1:1

- **Gotistobart** 6 mg/kg with 2 loading doses of 10 mg/kg, Q3W (n=239)
- **Docetaxel** 75 mg/kg, Q3W (n=239)

Key Endpoints

Primary: OS
Secondary: PFS, safety

Benchmark Data for 2L sqNSCLC

Regimen	ORR	mPFS	mOS	Benchmark study
Docetaxel	12.7%	3.9 mo	9.4 mo	TROPION-Lung01 sq population[2]

1. Partnered with OncoC4 . 2. Ahn et al. J Clin Oncol 43, 260-272(2025); NCT05671510

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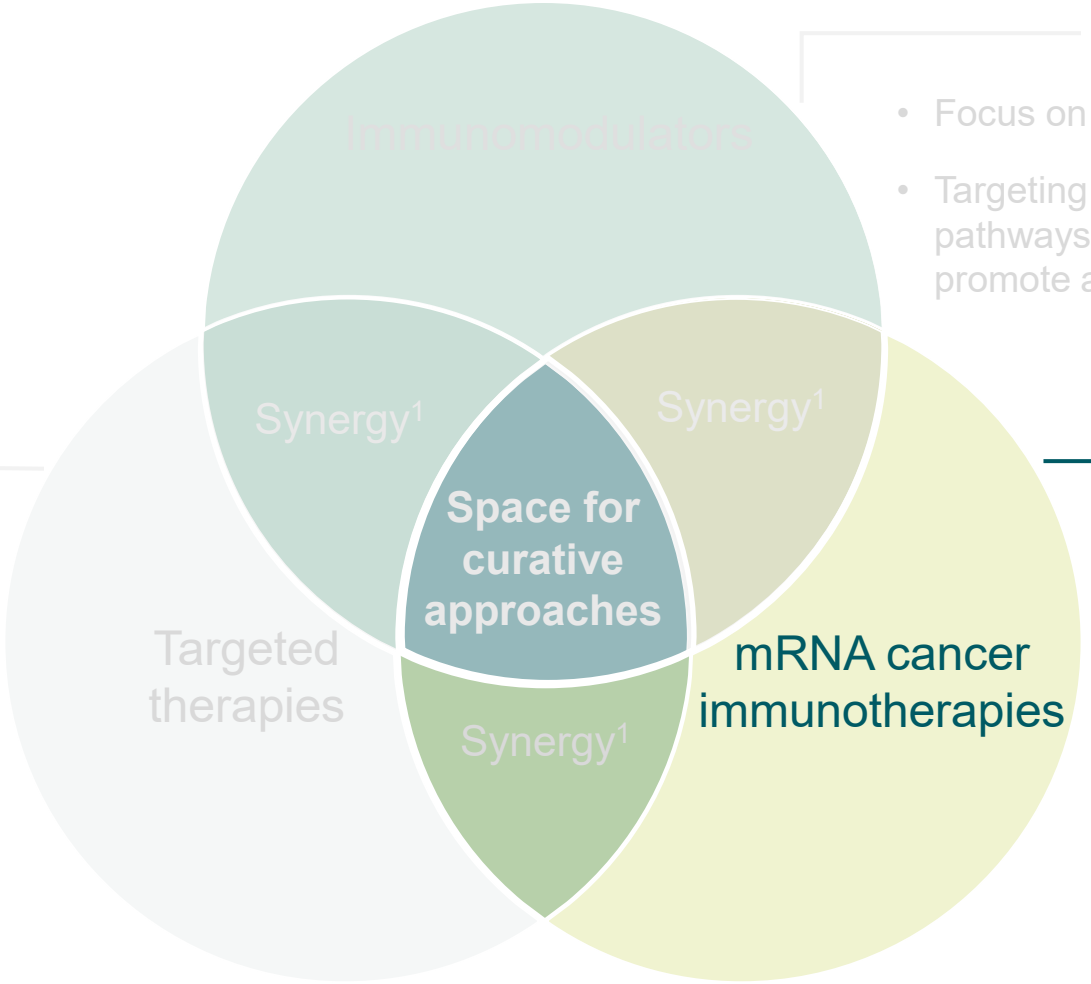
We are Uniquely Positioned to Combine Approaches to Transform Cancer Care

Immunomodulators

- Focus on the critical IO pathways
- Targeting different complementary pathways in cancer immunity cycle may promote a durable anti-tumor effect

Targeted therapies

- Precise and potent modalities for fast onset tumor reduction
- ADC as potential “augmenters” of immunomodulators and mRNA cancer immunotherapies
- HER2, TROP2, B7H3, HER3, EGFRxHER3 ADCs as combination partners



mRNA cancer immunotherapies

- Eliminate polyclonal residual disease with multi-antigen and individualized approaches
- Polyspecific activity by targeting multiple antigens at once
- Establish long-lasting immunological memory to prevent relapses

1. Synergistic potential.

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mRNA-Technology Toolbox

mRNA formats

Uridine mRNA

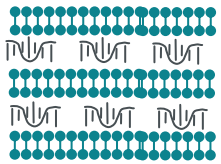
Pseudo-uridine mRNA

Self-amplifying mRNA

Trans-amplifying mRNA

Circular RNA,
chemically synthesized mRNA

Nanoparticles

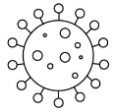


Lipoplex nanoparticles

Lipid nanoparticles

Polymer nanoparticles

Encoded drugs

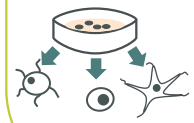


Vaccines
(e.g. cancer, infectious disease, autoimmunity)

Antibodies
(e.g. receptor blockade)

Signaling molecules
(e.g. cytokine)

Enzymes
(e.g. CRISPR/CAS)



Transcription factors
(e.g. Yamanaka factors)

Local
Tissue-specific
Systemic

Multimodal optimization of mRNA potency and performance over decades (>10,000x)

Holtkamp et al. Blood 2006; Kuhn et al. Gene Therapy 2010; Sahin, Türeci & Kariko Nat Drug Discovery 2014; Vogel et al. Mol Therapy 2018; Beissert et al. Mol Therapy 2020.

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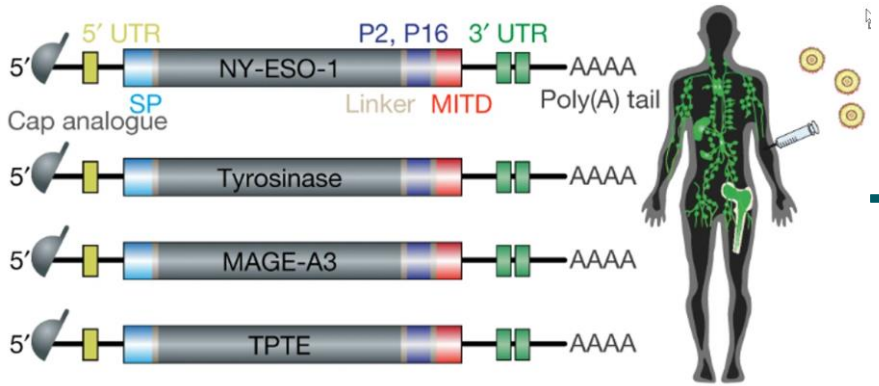
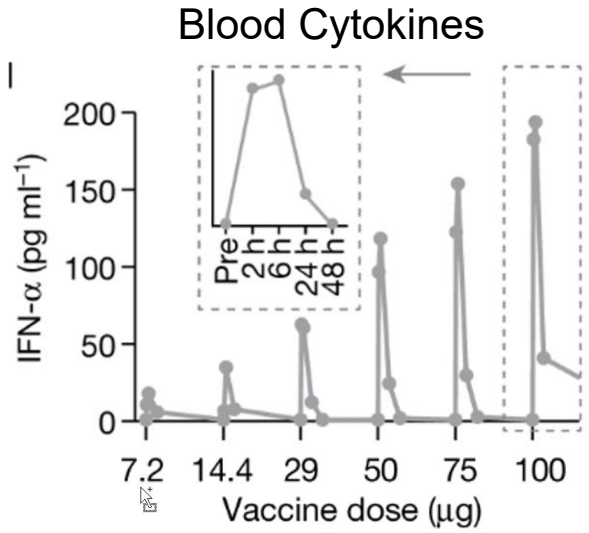
Nanoparticulate mRNA Vaccines

BNT111 mRNA LPX Vaccine

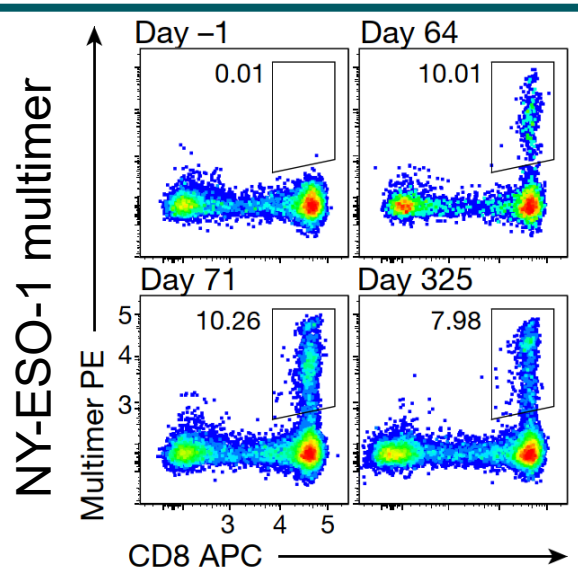


Systemic Targeting to Lymphoid Dendritic Cells

Kranz, Diken et al., Nature 2016



Type-I Interferon Innate immune Response



Induction of Antigen Specific Immunity

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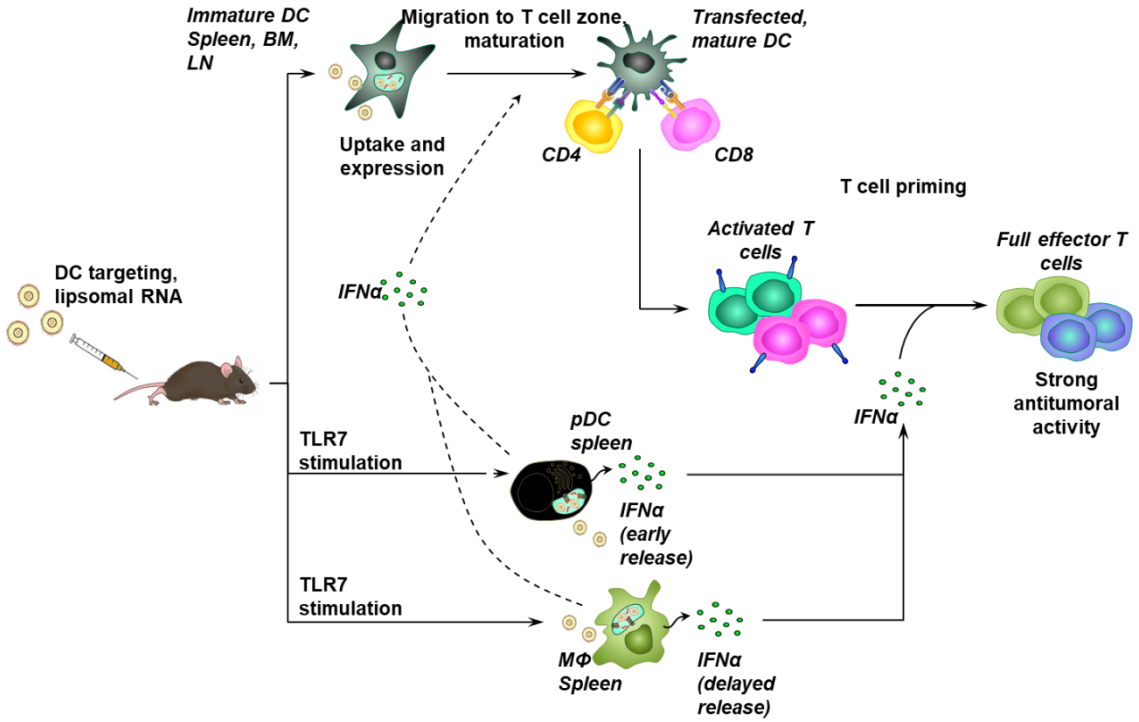
Nanoparticulate mRNA-LPX Vaccines for Cancer Immunotherapy



Systemic RNA delivery to dendritic cells exploits antiviral defence for cancer immunotherapy

Lena M. Kranz[1,2*], Mustafa Diken[1,3*], Heinrich Haas[3], Sebastian Kreiter[1,3], Carmen Loquai[4], Kerstin C. Reuter[3], Martin Meng[3], Daniel Fritz[3], Fulvia Vascotto[1], Hossam Hefesha[3], Christian Grunwitz[2,3], Mathias Vormehr[2,3], Yves Hüsemann[3], Abderraouf Selmi[1,2], Andreas N. Kuhn[3], Janina Buck[3], Evelyna Derhovanessian[3], Richard Rae[1], Sebastian Attig[1,2], Jan Diekmann[3], Robert A. Jabulowsky[3], Sandra Heesch[3], Jessica Hassel[5], Peter Langguth[6], Stephan Grabbe[4], Christoph Huber[1,3], Özlem Türeci[7§] & Ugur Sahin[1,2,3§]

- RNA-LPX vaccine targeting dendritic cells
- TLR7 driven adjuvant effect
- Type-I Interferon driven innate & adaptive immune stimulation
- Universally applicable for almost all type of tumor antigens
- Overcomes tolerance against self-antigens
- Excellent immunogenicity *in vivo*
- Preclinical activity against advanced tumors

BIONTECH

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Targeted therapies

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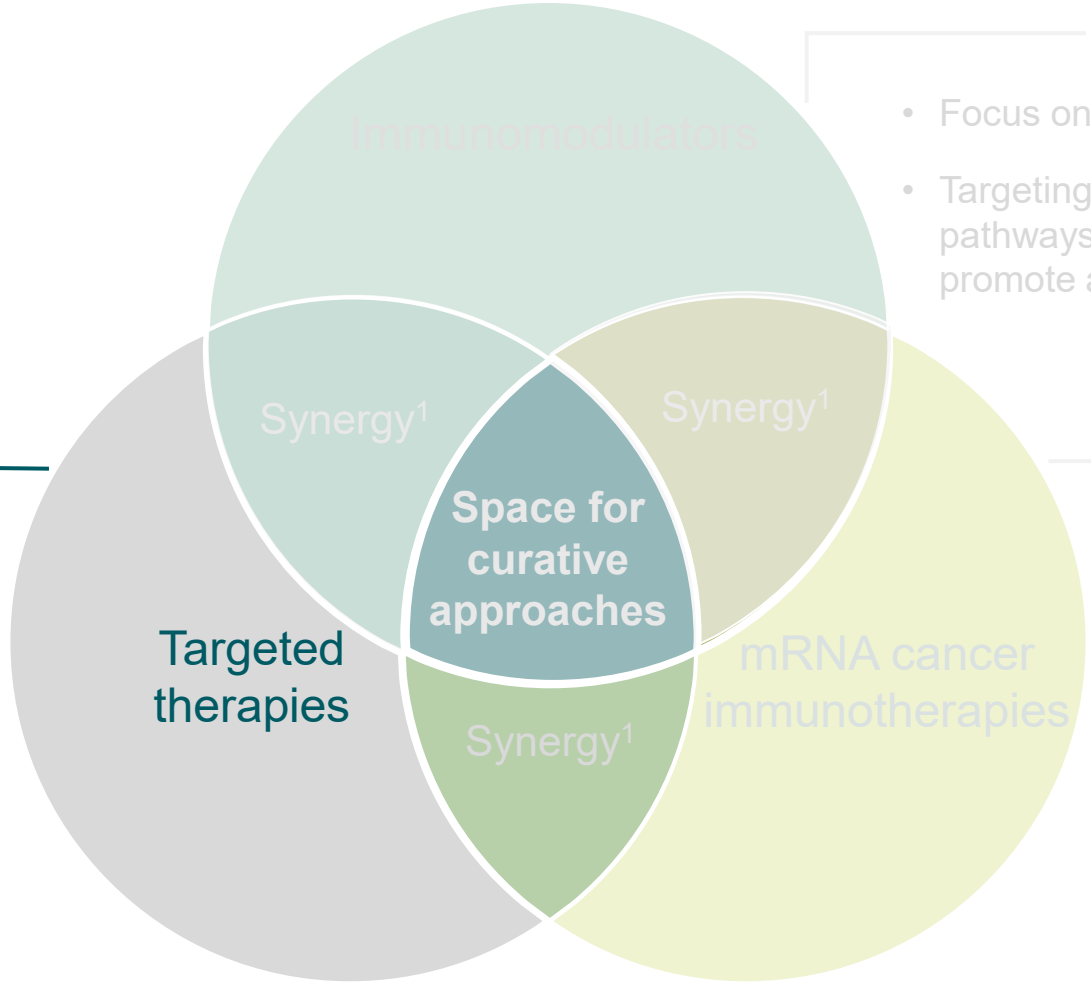
- ADC as potential “augmenters” of immunomodulators and mRNA cancer immunotherapies
- HER2, TROP2, B7H3, HER3, EGFRxHER3 ADCs as combination partners



Immunomodulators

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- Targeting different complementary pathways in cancer immunity cycle may promote a durable anti-tumor effect

mRNA cancer immunotherapies

- Eliminate polyclonal residual disease with multi-antigen and individualized approaches
- Polyspecific activity by targeting multiple antigens at once
- Establish long-lasting immunological memory to prevent relapses

1. Synergistic potential.

BIONTECH

ADC Innovation Cycle is Just Beginning

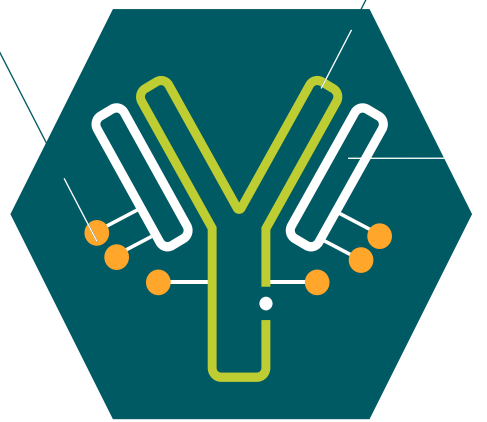
BioNTech is driving the development of next-generation ADCs

Distinguished ADC linker technology
- Stability improving safety profile
- Higher efficacy

Novel mechanisms of actions
- Tumor specific activation
- Improved and novel payloads

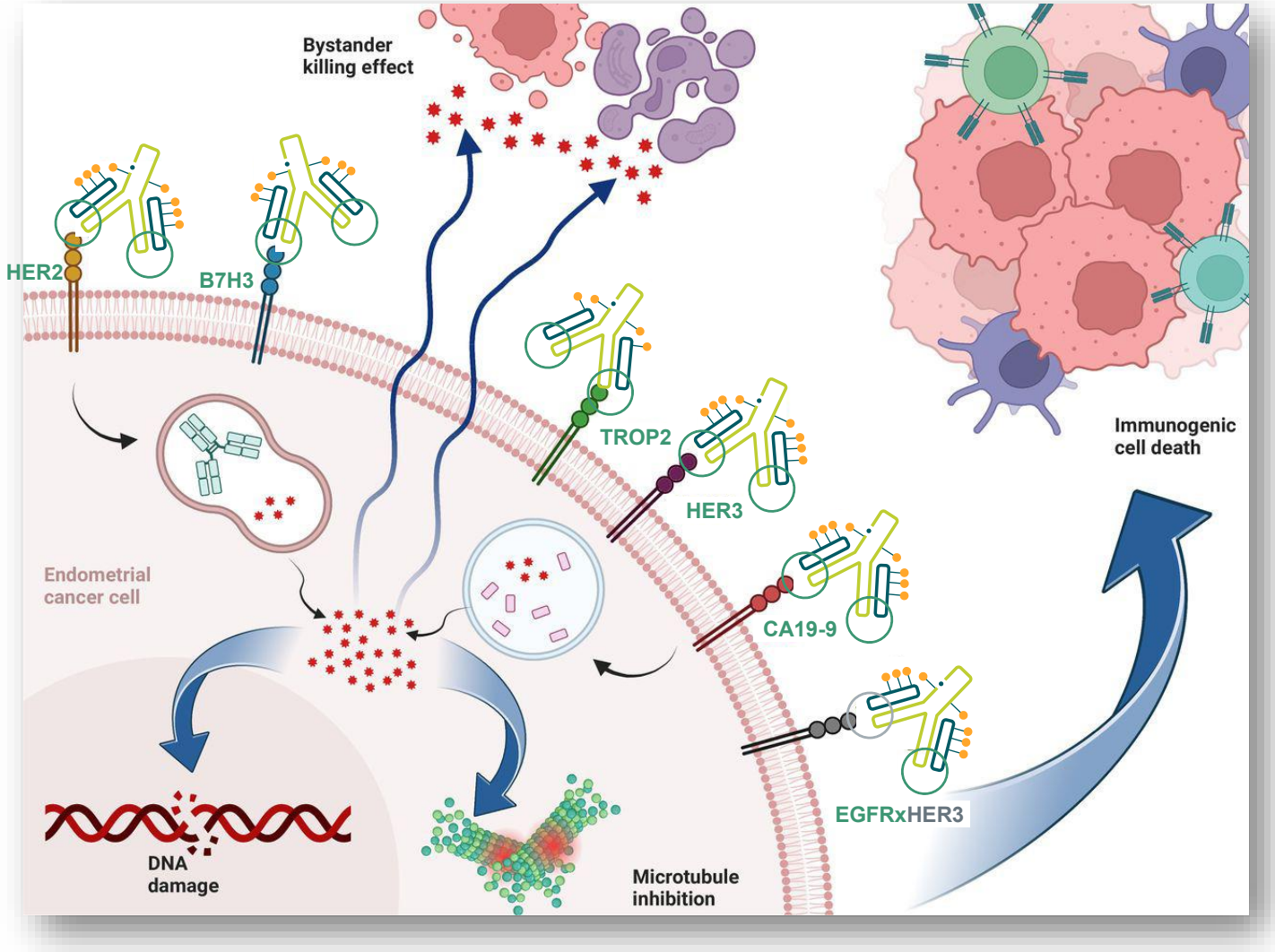
Novel targets and novel epitopes
- Targeting broader spectrum of tumors
- Higher specificity

BioNTech is developing ADCs against novel targets



Our deep understanding of ADC targets and immunology distinctively positions us to consolidate and maximize the substantial therapeutic window offered by the next-gen ADC technology

ADC Driven Mechanisms May Synergize with Other Immune Mechanisms



Targeted Tumor Cell Killing

Bystander Tumor Cell Killing

Immunogenic Cell Death Promoting Innate and Adaptive Immunity

Opportunity for Synergy with Immunotherapy Compounds

Adapted from Fucà G, et al. Int J Gynecol Cancer. 2024 Nov

BIONTECH

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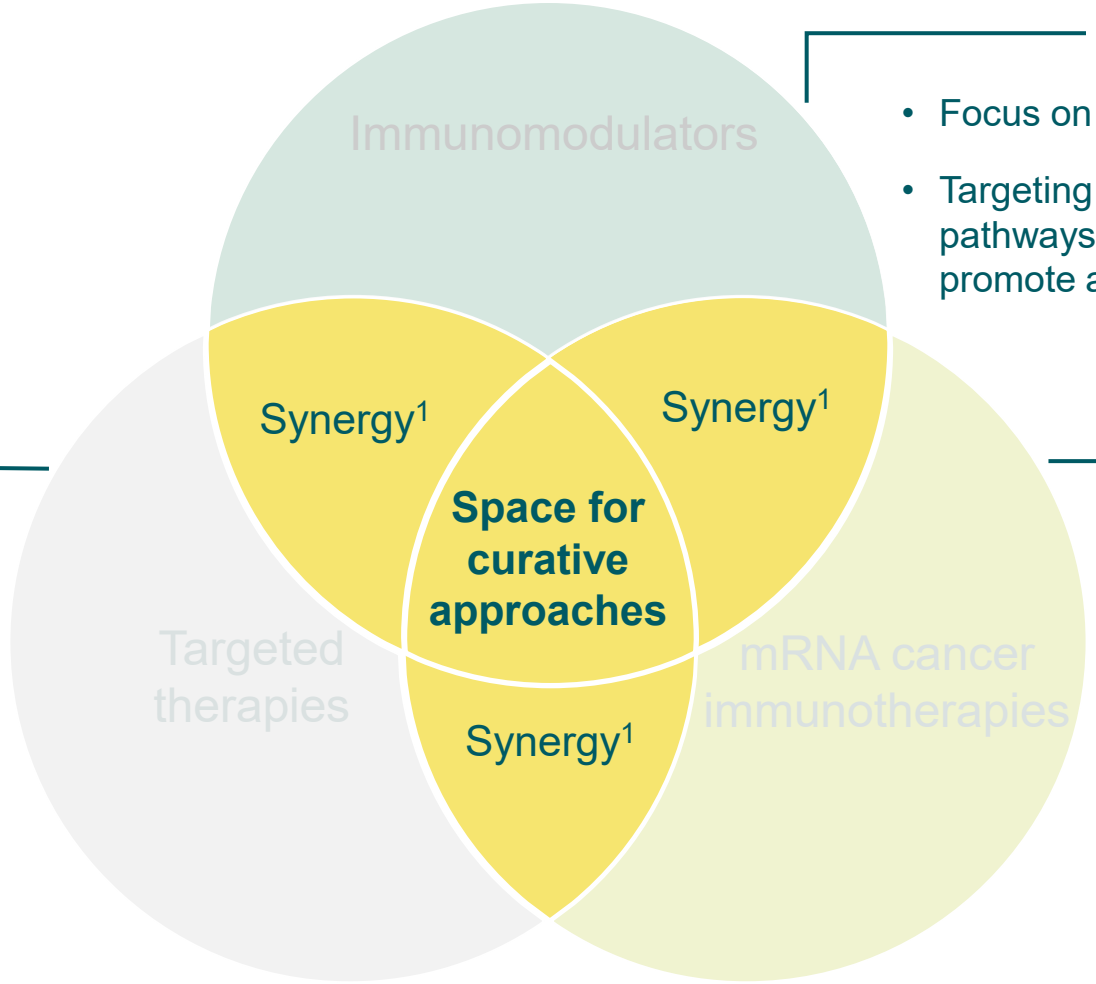

mRNA cancer immunotherapies

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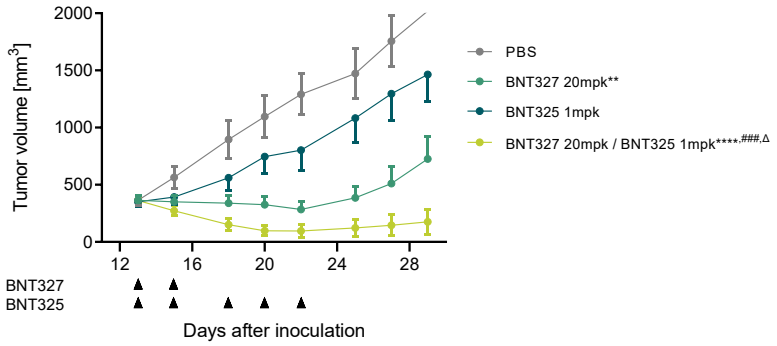
BIONTECH

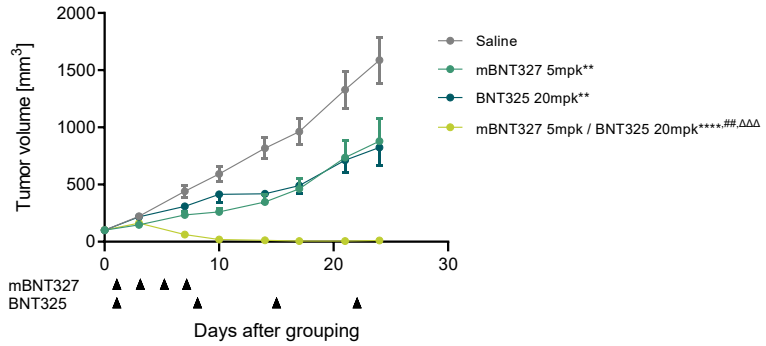
Pumitamig[1] in Combination with ADCs Showed Superior Anti-Tumor Activity Compared with Each Treatment Alone in Pre-Clinical Tumor Models

Pumitamig[1] + BNT325/DB-1305

hTROP2-A375:hPBMC co-injection xenograft model

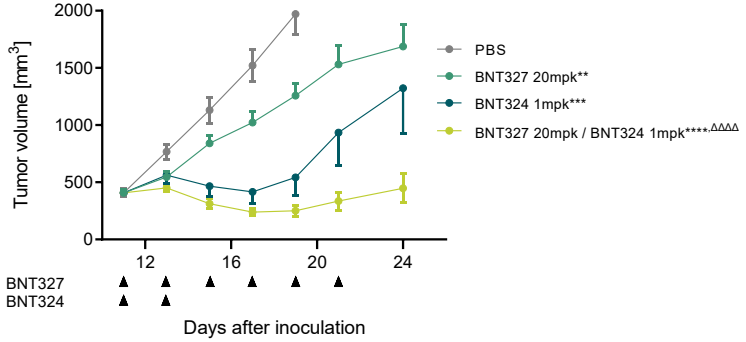


B-hTROP2 MC38 in wt mice

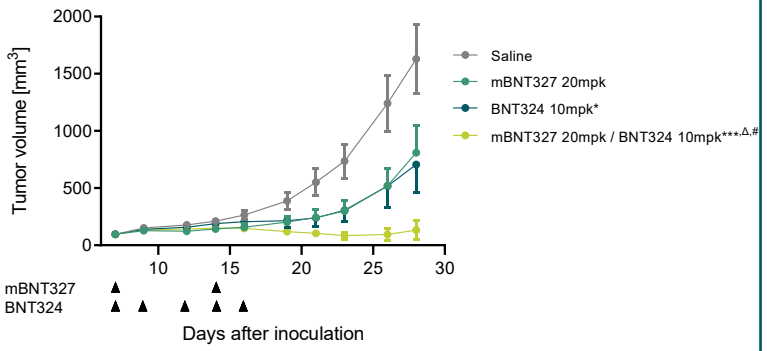


Pumitamig[1] + BNT324/DB-1311

A375:hPBMC co-injection xenograft model

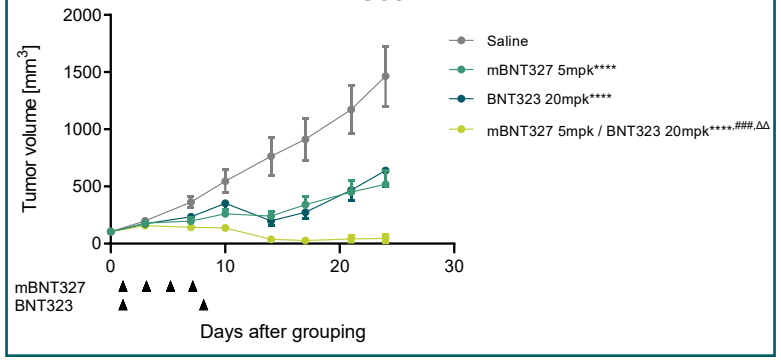


hB7H3-CT26 in wt mice



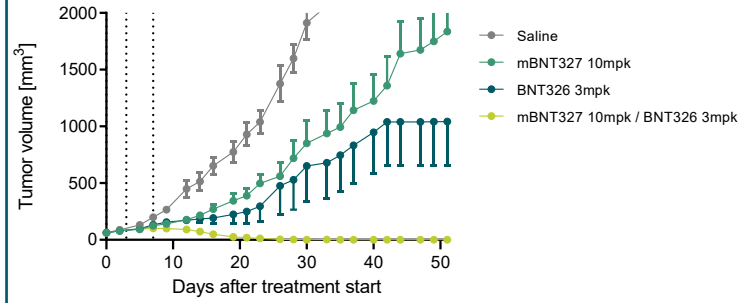
Pumitamig[1] + trastuzumab-pamirtecan

B-hHER2 MC38 in wt mice



Pumitamig[1] + BNT326/YL202

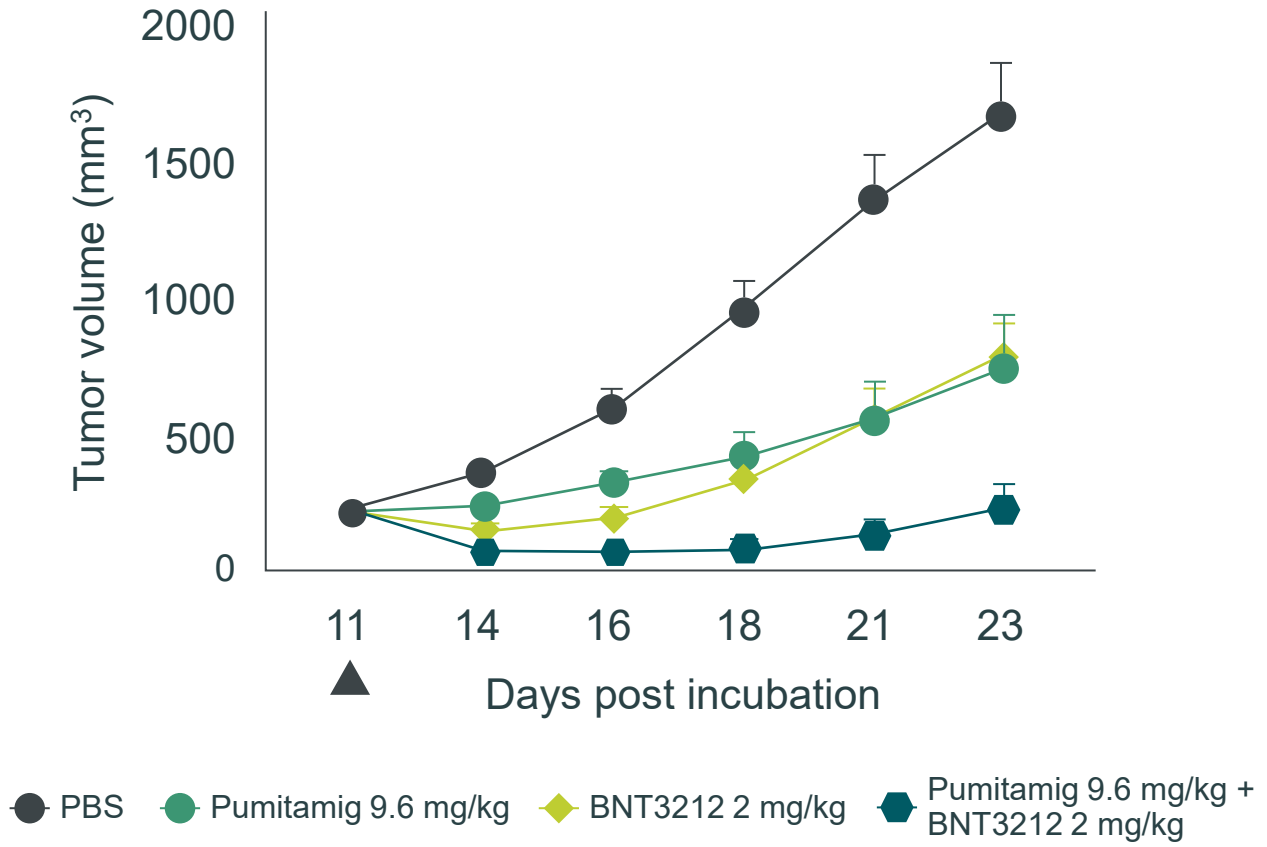
hHER3-MC38 in wt mice



Pumitamig refers to the total mouse surrogate Pumitamig antibody that binds murine VEGF-A/PD-L1 targets; Data shown represents mean±SEM;
Statistical significance testing was performed comparing treatment groups with PBS/saline (*, **, ***, ****), with ADC-monotherapy (#, ##, ###, ####) or with (m)Pumitamig-monotherapy (Δ, ΔΔ, ΔΔΔ, ΔΔΔΔ,)
Source: https://doi.org/10.1158/1538-7445.AM2025-648

BIONTECH

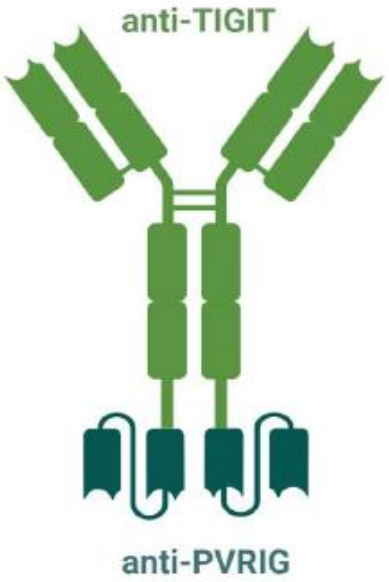
Pumitamig[1] in Combination with BNT3212 Showed Synergistic Anti-Tumor Activity



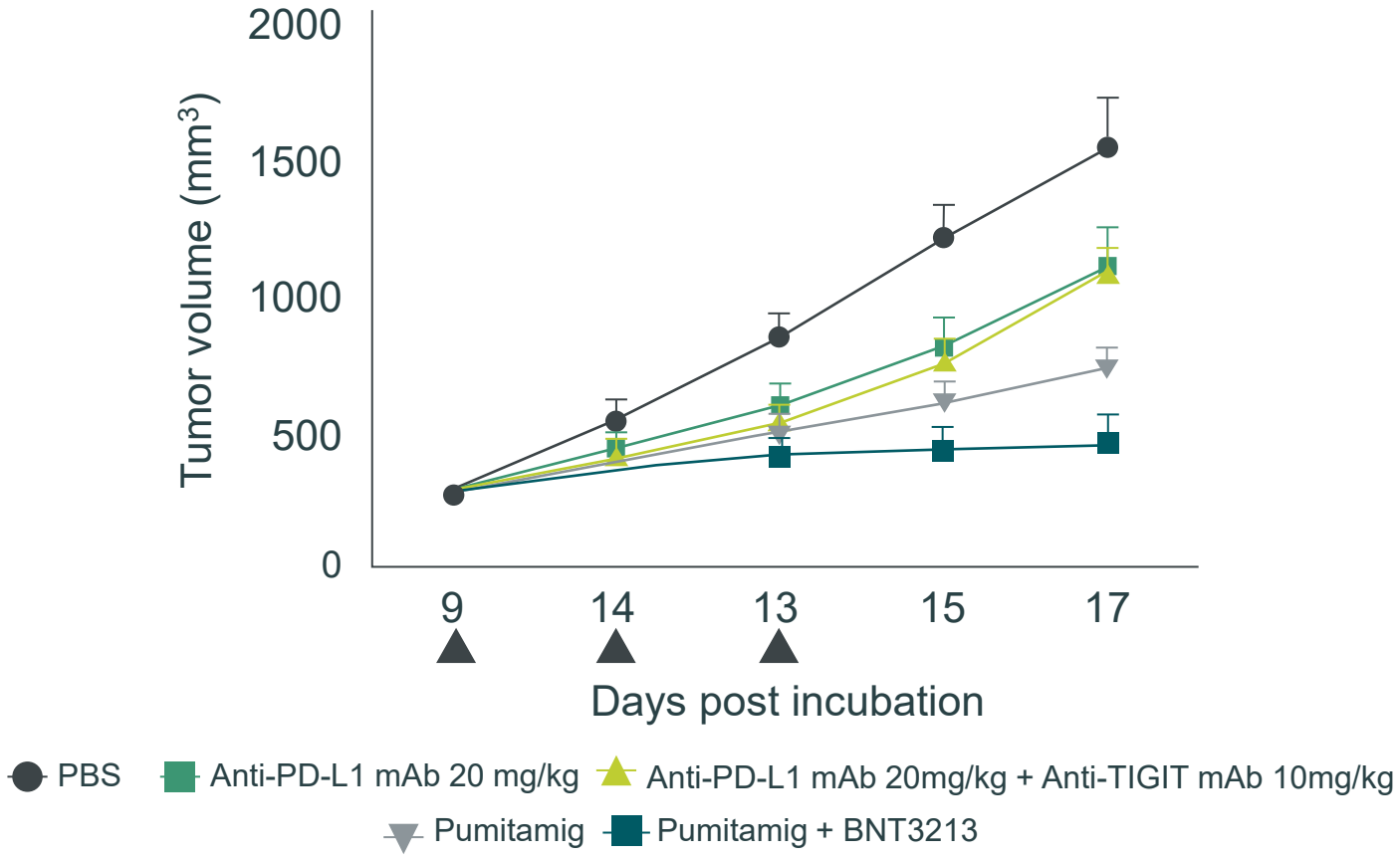
1. Partnered with Bristol Myers Squibb. A375 tumor cells and human PBMCs were co-implanted subcutaneously in B-NDG B2M KO Plus mice.

BIONTECH

BNT3213 and Pumitamig[1] Showed Superior Anti-Tumor Activity Compared with Each Treatment Alone in Pre-Clinical Tumor Models



BNT3213
Anti-TIGIT x PVRIG bsAb



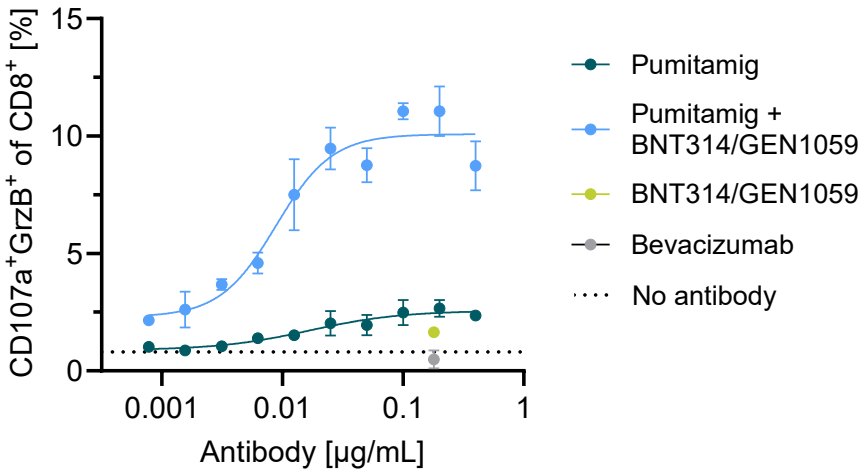
1. Partnered with Bristol Myers Squibb; A375 tumor cells and human PBMCs were co-implanted subcutaneously in NOD-SCID mice.

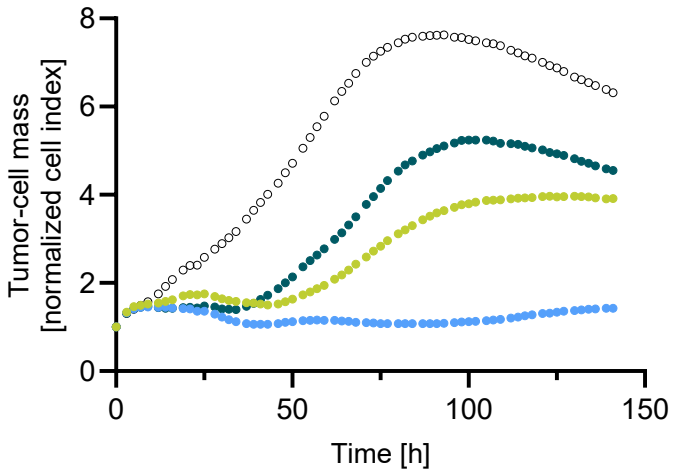
BIONTECH

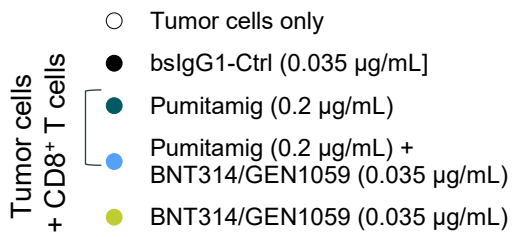
Combined Checkpoint Inhibition and 4-1BB Agonism of Pumitamig[1] plus BNT314/GEN1059[2] In Vitro

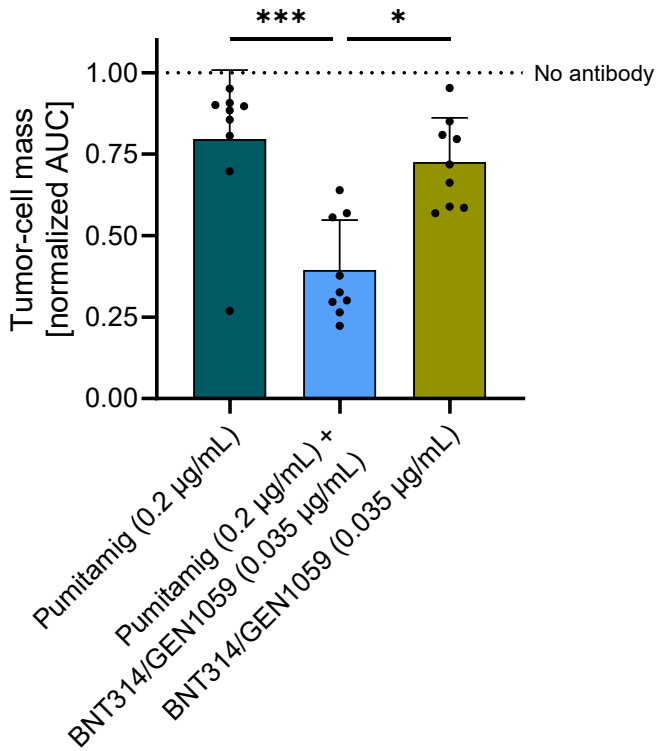
Pumitamig[1] + BNT314/GEN1059[2] enhanced expression of cytotoxic markers and cytotoxic activity of CD8⁺ T cells compared to single-agent treatments *in vitro*

Imle et al. SITC 2025. P652









1. Partnered with Bristol Myers Squibb; 2. Partnered with Genmab. ***, P<0.001; **, P<0.01; *, P<0.05

Novel Combination Trials Across Multiple Tumor Types

	Combination Partners		Indications
Next Gen IO + ADC	Pumitamig[1]	+ T-Pam[2]	HR+ HER2-low, ultra-low/null BC or TNBC
		+ BNT324/DB-1311[2]	NSCLC, SCLC, HCC, melanoma, HNSCC, PROC
		+ BNT325/DB-1305[2]	TNBC, NSCLC, OC
		+ BNT326/YL202[3]	NSCLC, EGFRm NSCLC, HER2-neg BC, melanoma, other solid tumors
		+ BNT3212	Multiple solid tumors
Next Gen IO + IO	Pumitamig[1]	+ BNT314/GEN1059[4]	MSS-CRC
		+ BNT3213	HCC[6]
Next Gen IO + mRNA	Pumitamig[1]	+ BNT116	NSCLC
	Gotistobart[5]	+ BNT116	NSCLC
mRNA + ADC	BNT116	+ BNT324/DB-1311[2]	NSCLC
		+ BNT326/YL202[3]	NSCLC

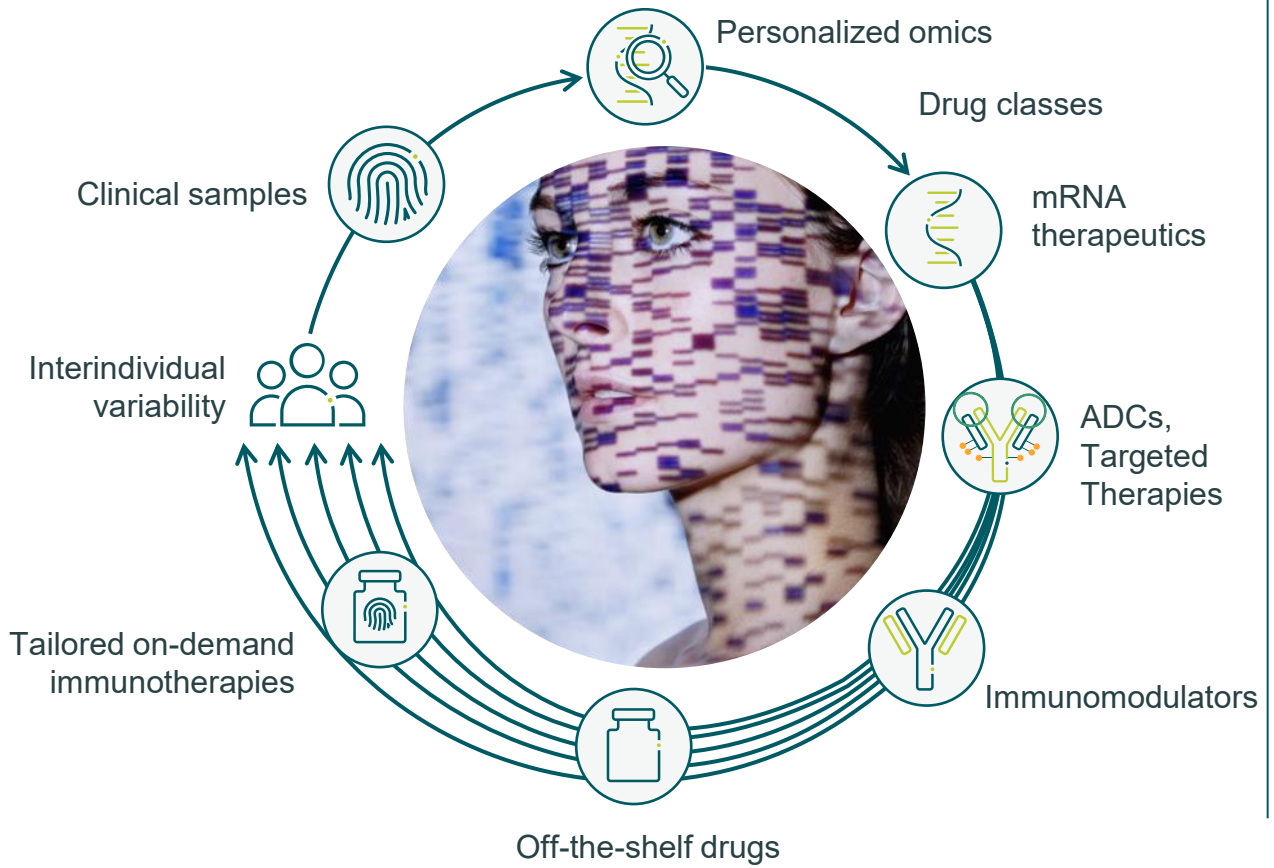
Partnered with: 1. Bristol Myers Squibb; 2. DualityBio ; 3. MediLink; 4. Genmab; 5. Onco C4; 6. Trial ongoing in China.

BioNTech: Advancing Tomorrow's Personalized Precision Medicine with Integrated Capabilities Under One Roof

Fully-integrated tech-bio company

- Deep genomics & immunology expertise to analyze patient data
- Individualized treatment platforms to address inter-individual variability
- AI-infused & digitally-integrated target & drug discovery and development
- Automated in-house manufacturing to serve patients on time and globally

Capabilities to build tomorrow's personalized precision medicines



BioNTech Operating from Position of Strength

2026

Key Areas of Focus

1

Combination Therapy Momentum

Anticipate additional datasets from novel-novel combination trials with pumitamig

2

Modalities to Disease Areas

2026 marks BioNTech's movement to a focused disease area specific approach

3

Late-Stage Acceleration

Expect key late-stage data readouts for initial wave of oncology assets

BIONTECH

3 BioNTech's Differentiated Clinical Strategy to Advance the Treatment of Solid Tumors

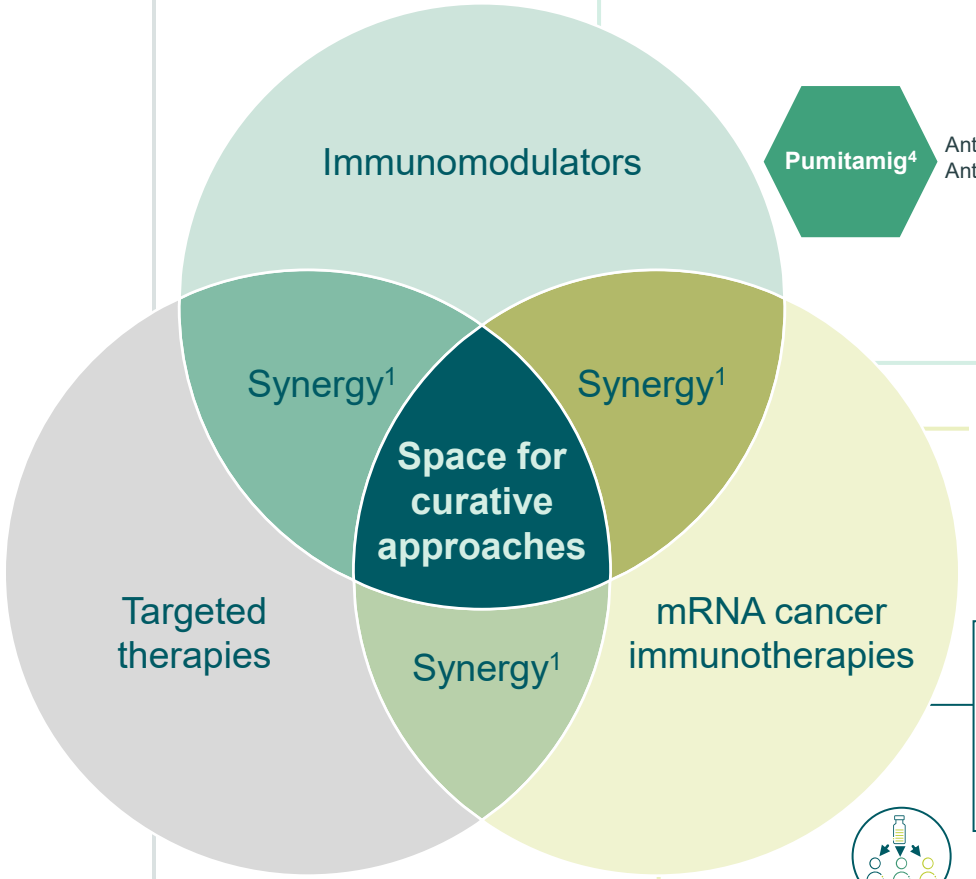
Prof. Özlem Türeci, M.D.
Chief Medical Officer and Co-founder

BIONTECH

BioNTech's Current Priority Programs

Targeted therapies

- **Trastuzumab pamirtecan**[2] — Anti-HER2 ADC
- **BNT324/ DB-1311**[2] — Anti-B7-H3 ADC
- **BNT325/ DB-1305**[2] — Anti-TROP2 ADC
- **BNT326/ YL202**[3] — Anti-HER3 ADC
- **BNT3212** — Anti-EGFR / HER3 ADC



Immunomodulators

- **Pumitamig**[4] — Anti-PD-L1/ Anti-VEGF
- **BNT314/ GEN1059**[6] — Anti-EpCAM/ Anti-4-1BB
- **BNT317** — Anti-PD-1/ Anti-CD39
- **Gotistobart**[7] — Anti-CTLA4
- **BNT3213** — Anti-TIGIT/ Anti-PVRIG

mRNA cancer immunotherapies

- **iNeST** — individualized Neoantigen-Specific immunoTherapy
  - **Autogene cevumeran**[5]
    - Adj. CRC
    - Adj. Pancreatic Cancer
    - Adj. Bladder Cancer
- **FixVac**
  - **BNT113** HNSCC
  - **BNT116** Lung Cancer

1. Synergistic potential. Partnered with 2. DualityBio; 3. MediLink; 4. Bristol Myers Squibb; 5. Genentech, a member of the Roche Group; 6. Genmab; 7. OncoC4.

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Pumitamig:Executing a Parallel Three-Wave Strategy to Build a Proprietary IO Franchise

Establish

SCLC
- 1L Ph3 (Global) ROSETTA LUNG-01
- 2L Ph3 (China)
- 1L/2L Ph2 (Global)

NSCLC
- 1L Ph2/3 (Global) ROSETTA LUNG-02
- 2L Ph2 (Global)
- 2L EGFRmut Ph2 (China)
- IIT neoadjuvant (China)

TNBC
- 1L Ph3 trial (Global) ROSETTA BREAST-01
- 1L Ph3 (China)

Expand

Registrational-Intent
- 1L Gastric Ph2/3 (Global) ROSETTA GASTRIC-204
- 1L CRC Ph2/3 (Global) ROSETTA CRC-203

Signal-Seeking
- 1L PDAC Ph2 (Global) ROSETTA PDAC-109
- 1L PDAC Ph2 (China)
- 1L GBM Ph2 (Global) ROSETTA GBM-110
- 1L GBM Ph2 (China)
- 1L CRC Ph2 (China)
- 1L HCC Ph2 (China)
- 1L MPM Ph2 (China)
- 1L NEN Ph2 (China)
- HNSCC, RCC, CC, PROC, EC, Melanoma Ph1/2 (China)

Elevate

- **Combining with our ADCs targeting**
  - HER2
  - HER3
  - TROP2
  - EGFR x HER3
  - B7H3
  - Novel targets
- **Exploring potential synergies with our IO agents**
  - EpCam x 4-1BB
  - TIGIT x PVRIG
  - mRNA cancer immunotherapy

Potential New Standards of Care
10+ Novel-Novel Combinations

Broad Pan-Tumor Applicability With Standard-of-Care Chemotherapy
12+ Studies Exploring Pumitamig[1] in 10+ New Indications

Foundational Registrations
Registrational Trials with Pumitamig[1] Ongoing in 3 High-Impact Tumors

Partnered with 1. Bristol Myers Squibb.

Clinical Stage ADC Program

T-Pam[1]

HER2

Target: HER2
Payload: topo I inhibitor

Clinical status
- 1,100+ patients dosed
- Ph3: HR+HER2-low mBC
- Ph1/2: multiple solid tumors (EC cohort fully recruited)
- Ph1/2: pumitamig combo (HR+ and HR- HER2+, low and null BC)

BNT324/DB-1311[1]

B7H3

Target: B7H3
Payload: topo I inhibitor

Clinical status
- 600+ patients dosed
- Ph1/2: multiple solid tumors
- Ph1/2: combo wiith pumitamig and BNT325

BNT325/DB-1305[1]

TROP2

Target: TROP2
Payload: topo I inhibitor

Clinical status
- 500+ patients dosed
- Ph1/2: multiple solid tumors
- Ph2: combo with pumitamig and BNT324

BNT326/YL202[2]

HER3

Target: HER3
Payload: topo I inhibitor

Clinical status
- 600+ patients dosed
- Ph1/2: multiple solid tumors
- Ph1/2: combo with pumitamig (NSCLC, other solid tumors).

BNT329

CA19-9

Target: CA19-9
Payload: topo I inhibitor

Clinical status
- Ph1/2: multiple solid tumors

More novel next-gen ADCs to come…

BNT3212

EGFRxHER3

Target: EGFRxHER3
Payload: topo I inhibitor

Clinical status
- Ph1/2: multiple solid tumors
- Ph1/2: pumitamig combo

Expression level by indication[3]

High
Medium / Low
Very low / None

Target	NSCLC	SCLC	HER2+ BC	HR+ BC	TNBC	CRC	Gastric	Ovarian	PDAC	HNSCC	Prostate	Other high expression indications
HER2												Gynecologic
TROP2												
B7H3												UC, EC
HER3												
CA19-9												UC, BTC, EC
EGFR												GBM, UC, RCC

Broad ADC coverage across all relevant tumors provides **optionality** for selecting the most suitable therapeutic approach per indication

1. Partnered with DualityBio; 2. Partnered with MediLink. 3. Human Protein Atlas. ADC structures shown for illustration-purpose only

BIONTECH

Pumitamig[1] Extensively Studied as Monotherapy and SOC Chemo Combo

Indication / Regimen	Lung cancers			Breast cancers		Gyn cancers			GI cancers				GU cancers		Other cancers		
	NSCLC AGA-	NSCLC EGFRm	SCLC	TNBC	HR+/ HER2- BC	Endometrial	Cervical	OC	GC/GEJ	CRC	PDAC	HCC	RCC	Prostate	GBM	HNSCC	Melanoma
Pumitamig[1] Monotherapy	■	■				■	■	■				■	■		■	■	■
Pumitamig[1] + Chemo	■	■	■	■					■	■	■	■			■		

■ Registrational trial ■ Phase 1/2 trial

Over 1,400 patients* dosed across pumitamig monotherapy and chemo combination studies

1. Partnered with Bristol Myers Squibb *Patient number include both China and ex-China studies, sponsored by BioNTech or partners.
Pumitamig is also being investigated in BTC (mono), MPM (chemo combo), and NEN (mono, chemo combo).

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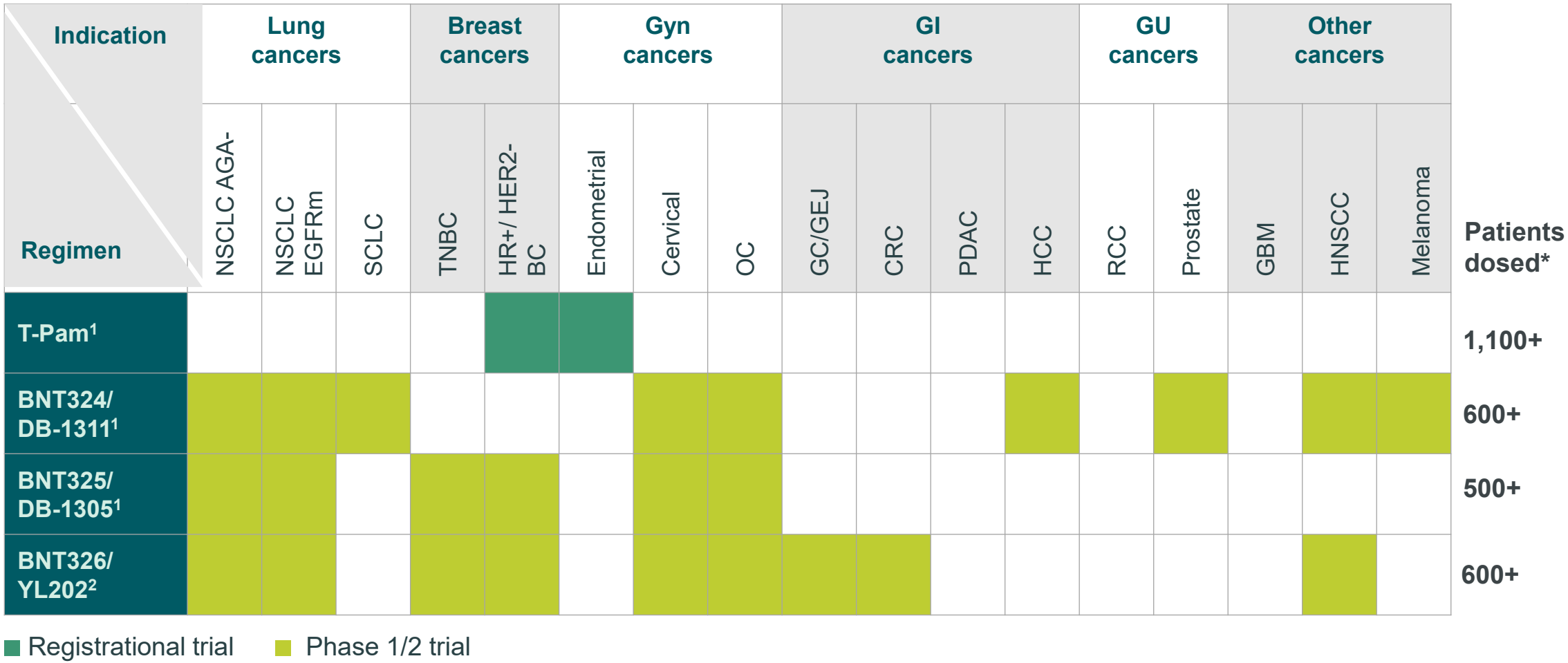
Single Activity of ADCs Being Explored Across Indications



Partnered with 1. DualityBio; 2. MediLink *Patient number include both China and ex-China studies, sponsored by BioNTech or partners.

BIONTECH

Expanding Pumitamig[1] Opportunity with Ongoing Novel ADC Combinations

Regimen \ Indication	Lung cancers			Breast cancers		Gyn cancers			GI cancers				GU cancers		Other cancers		
	NSCLC AGA-	NSCLC EGFRm	SCLC	TNBC	HR+/ HER2- BC	Endometrial	Cervical	OC	GC/GEJ	CRC	PDAC	HCC	RCC	Prostate	GBM	HNSCC	Melanoma
Pumitamig[1] Chemo combo	■		■	■					■	■	▪				▪		
Pumitamig[1] + T-Pam[2]				■	▪												
Pumitamig[1] + BNT324/DB-1311[2]	▪	▪	▪				▪	▪				▪				▪	▪
Pumitamig[1] + BNT325/DB-1305[2]	▪	▪		▪			▪	▪									
Pumitamig[1] + BNT326/YL202[3]	▪	▪		▪	▪												▪

■ Registrational trial ▪ Phase 1/2 trial

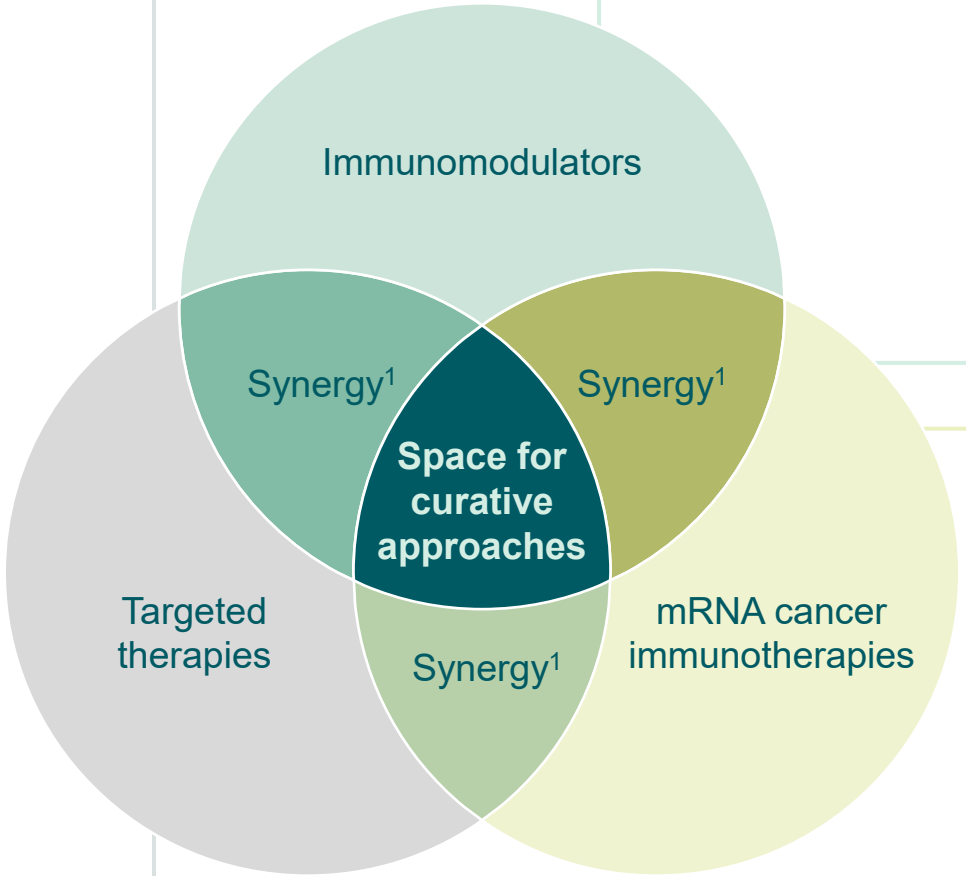
Partnered with 1. Bristol Myers Squibb; 2. DualityBio; 3. MediLink *Patient number include both China and ex-China studies, sponsored by BioNTech or partners.

BIONTECH

Our Diverse Lung Cancer Pipeline

Targeted therapies

- BNT324/ DB-1311[2] — Anti-B7H3 ADC
- BNT326/ YL202[3] — Anti-HER3 ADC
- BNT325/ DB-1305[2] — Anti-TROP2 ADC



Immunomodulators

- Pumitamig[4] — Anti-PD-L1/ Anti-VEGF
- Gotistobart[5] — Anti-CTLA-4

mRNA cancer immunotherapy

FixVAC Off-the-shelf mRNA → BNT116

1. Synergistic potential; Partnered with 2 DualityBio; 3. MediLink; 4. Bristol Myers Squibb; 5. OncoC4.

BIONTECH

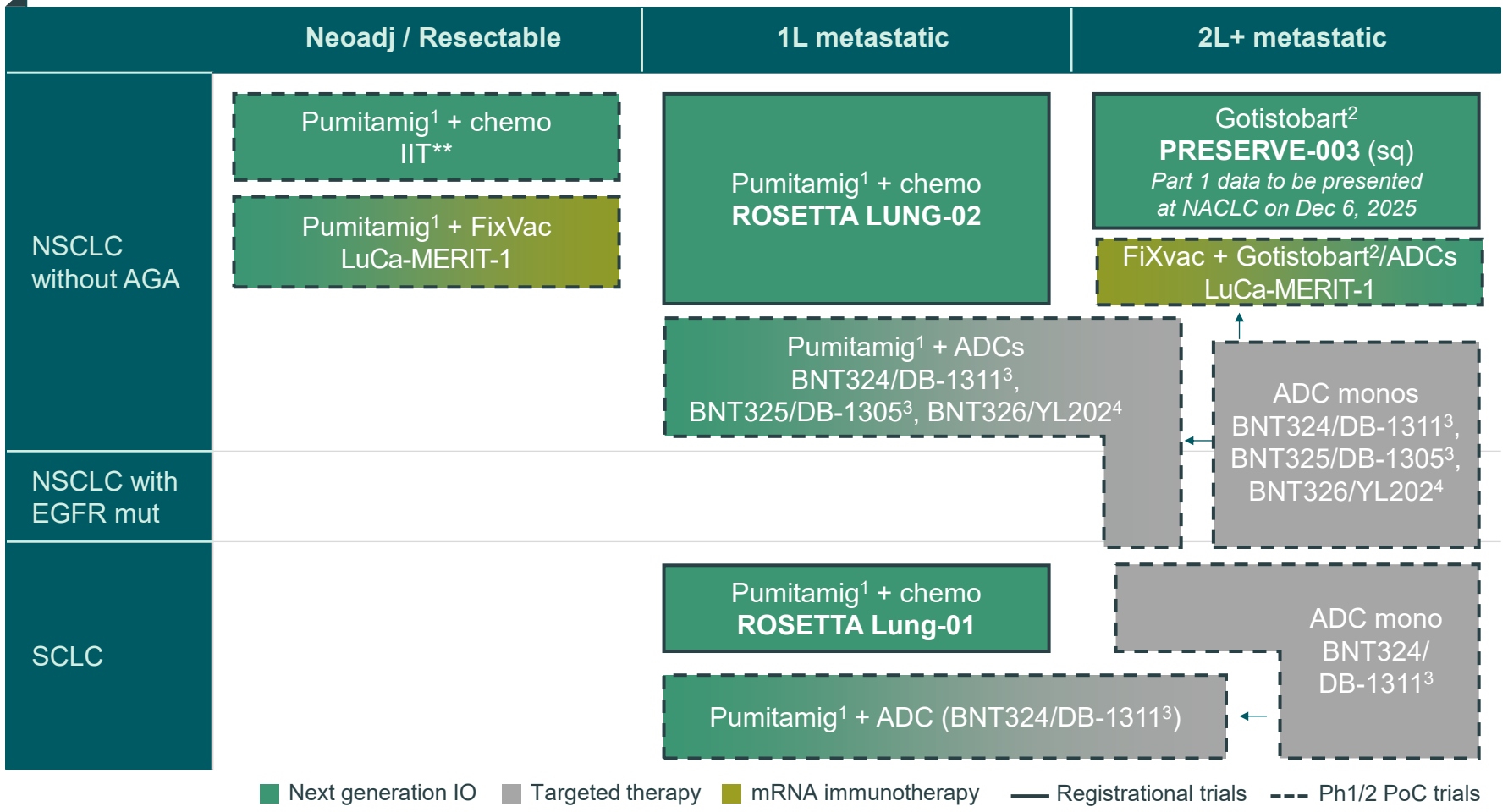
BioNTech's Currently Ongoing Trials* in Lung Cancer

Registrational trials in metastatic Lung Cancer with next-generation IO

- Pumitamig[1] aiming to improve over SoC in 1L NSCLC and ES-SCLC
- Gotistobart[2] to provide IO option for 2L NSCLC Sq (high unmet need)

PoC trials with ADC mono and novel combinations to inform future registrational trials

- ADC mono and FixVac data provided confidence to start combination PoC trials
- Multiple Pumitamig + ADC PoC trials ongoing for data-driven decision making and inform future registrational trials in the 1L setting

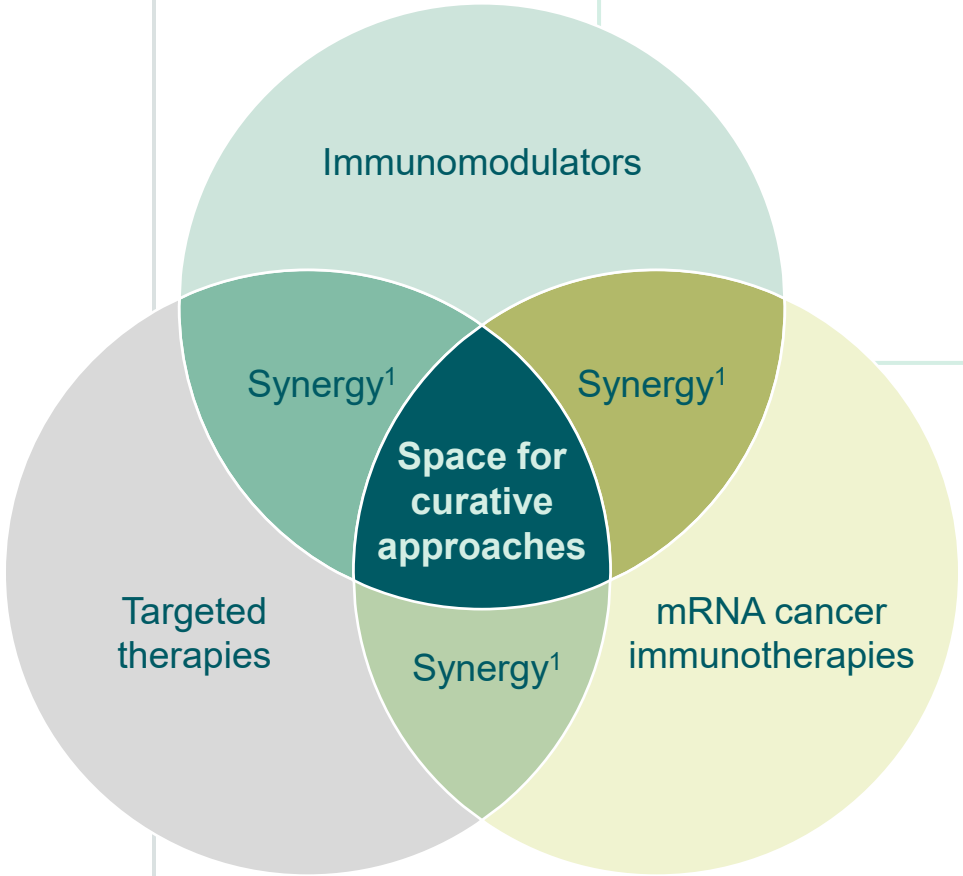


Partnered with: 1. Bristol Myers Squibb; 2. OncoC4; 3. DualityBio; 4. MediLink; *As of November 2025; **being conducted in China

Our Diverse Breast Cancer Pipeline

Targeted therapies

- Trastuzumab pamirtecan[2] — Anti-HER2 ADC
- BNT325/ DB-1305[2] — Anti-TROP2 ADC
- BNT326/ YL202[3] — Anti-HER3 ADC



Immunomodulators

- Pumitamig[4] — Anti-PD-L1/ Anti-VEGF

1. Synergistic potential; Partnered with 2. DualityBio; 3. MediLink; 4. Bristol Myers Squibb.

BIONTECH

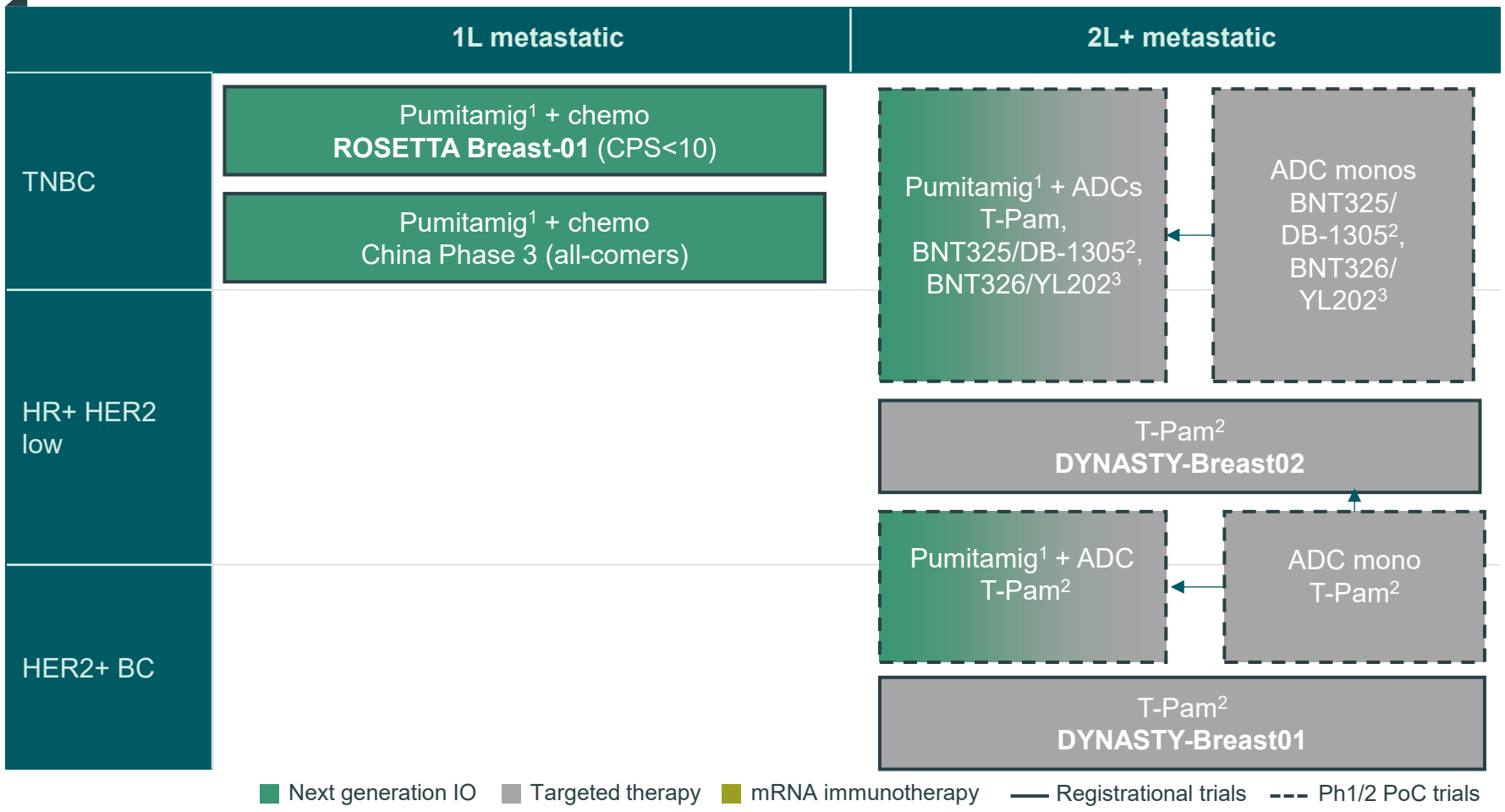
BioNTech's Currently Ongoing Trials* in Breast Cancer

Registrational trials in metastatic Breast Cancer

- Pumitamig[1] aiming to improve on SoC in 1L TNBC CPS<10, (historically insensitive to PD-(L)1)
- Trastuzumab pamirtecan mono Ph1/2 data informed pivotal trial in HER2 low BC enabling first potential BNT approval in BC

PoC trials with ADC mono and novel combinations to inform future registrational trials

- Emerging data from multiple BNT ADCs in breast cancer informed Pumitamig + ADC PoC trials
- Parallelly exploring multiple combinations to inform the right combination for the right patient segment & accelerate registrational trial



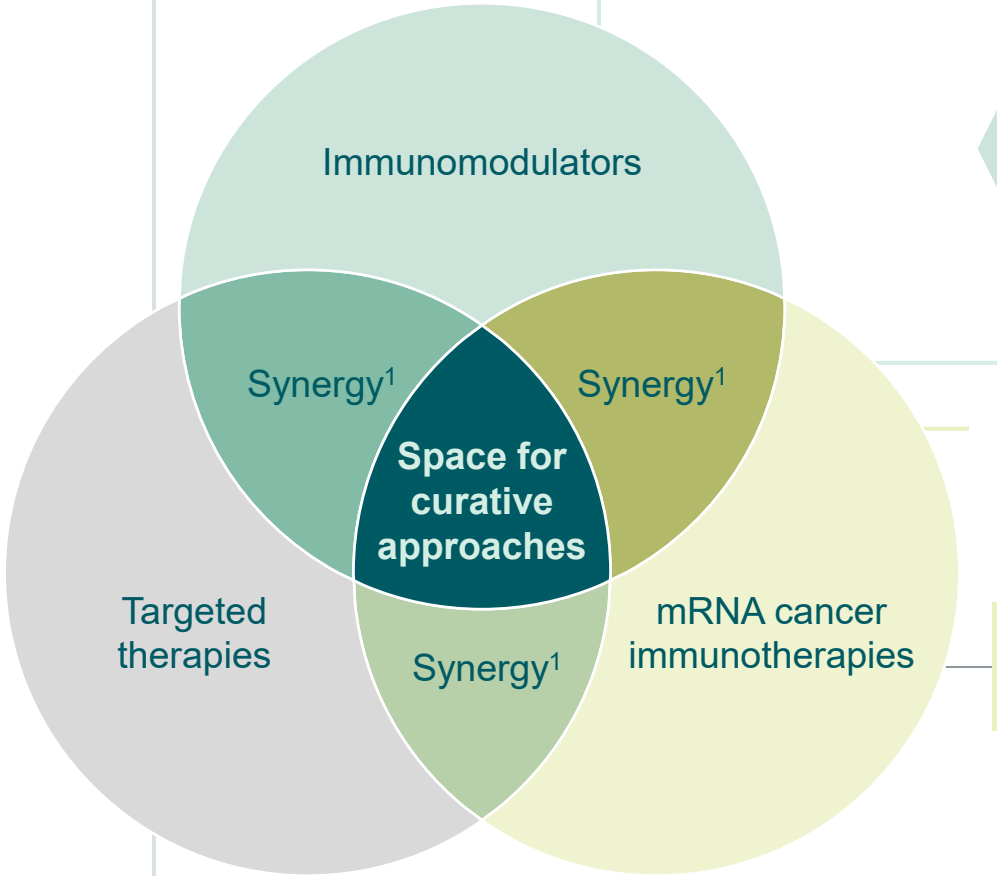
Partnered with: 1. Bristol Myers Squibb; 2. DualityBio; 3. MediLink *As of November 2025

Our Diverse GI Cancer Pipeline

Targeted therapies

BNT324 /DB-1311[2]
Anti-B7H3 ADC

BNT326 /YL202[3]
Anti-HER3 ADC



Immunomodulators

Pumitamig[4]
Anti-PD-L1/ Anti-VEGF

BNT314 /GEN1059[5]
Anti-EpCAM/ Anti-4-1BB

mRNA cancer immunotherapy

iNeST
Fully individualized immunotherapy

→ Autogene cevumeran[6]

1. Synergistic potential. Partnered with 2. DualityBio; 3. MediLink; 4. Bristol Myers Squibb; 5. Genmab; 6. Genentech, a member of the Roche Group.

BIONTECH

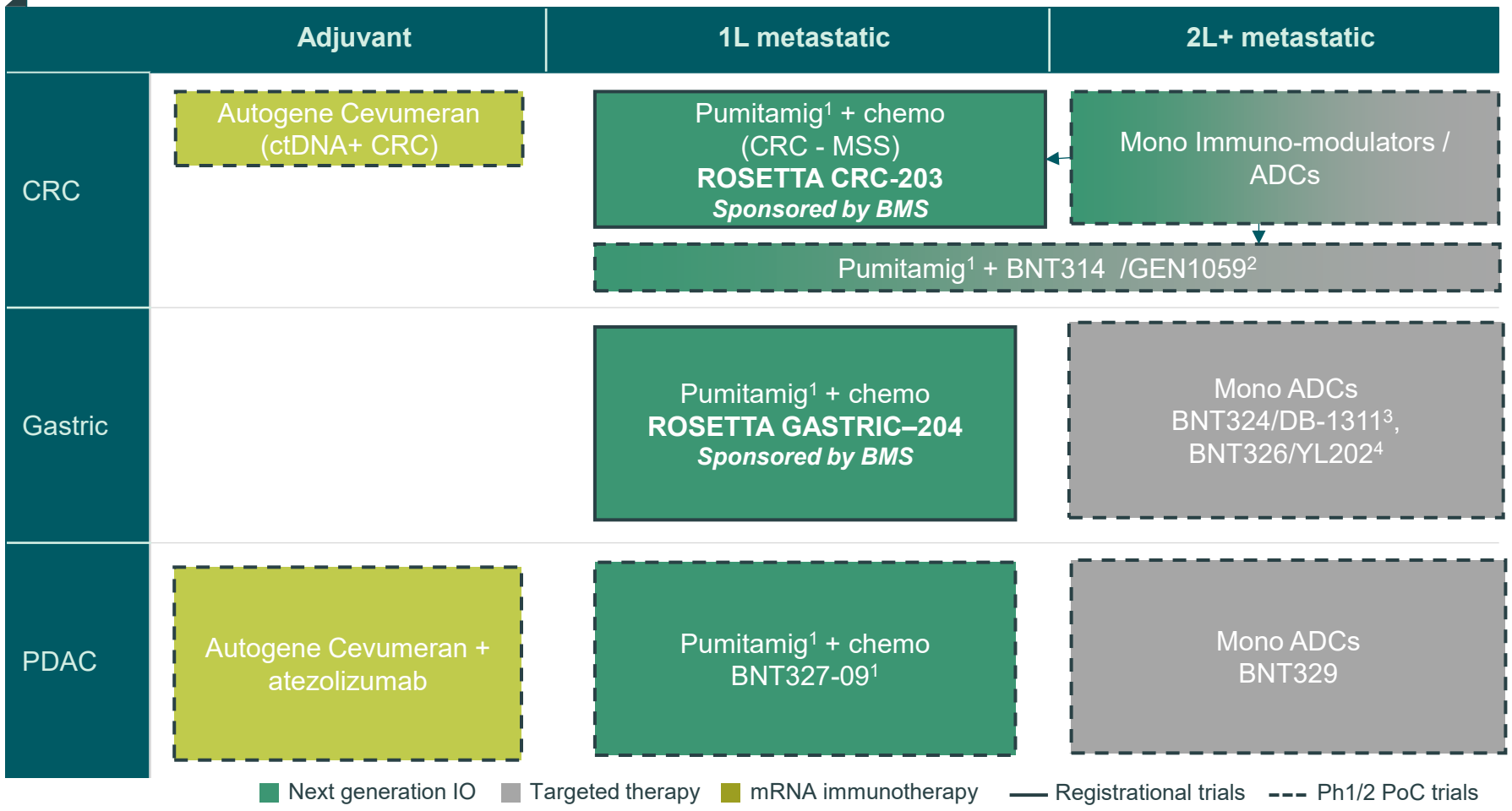
BioNTech's Currently Ongoing Trials* in GI Cancers

Registrational trials in metastatic GI cancers

- Pumitamig[1] aiming to provide IO option in CRC-MSS
- Pumitamig[1] aiming to improve upon SoC in Gastric Cancer

PoC trials with novel combinations to inform future registrational trials

- Mono data being generated in 2L+ settings with ADCs and immunomodulators
- In parallel, combination trials will start to generate indication specific data
- mRNA cancer immunotherapies being evaluated in randomized clinical trials in the adjuvant setting



Partnered with: 1. Bristol Myers Squibb; 2. Genmab; 3. DualitiyBio; 4. MediLink.*As of November 2025

4 Establishing Pumitamig in Foundational Tumor Types

Prof. Ilhan Celik, M.D.
Vice President, Clinical Development

Michael Wenger, M.D.
Vice President, Clinical Development

BIONTECH

Thoracic Cancer

BIONTECH

Our Diverse Lung Cancer Pipeline

Targeted therapies

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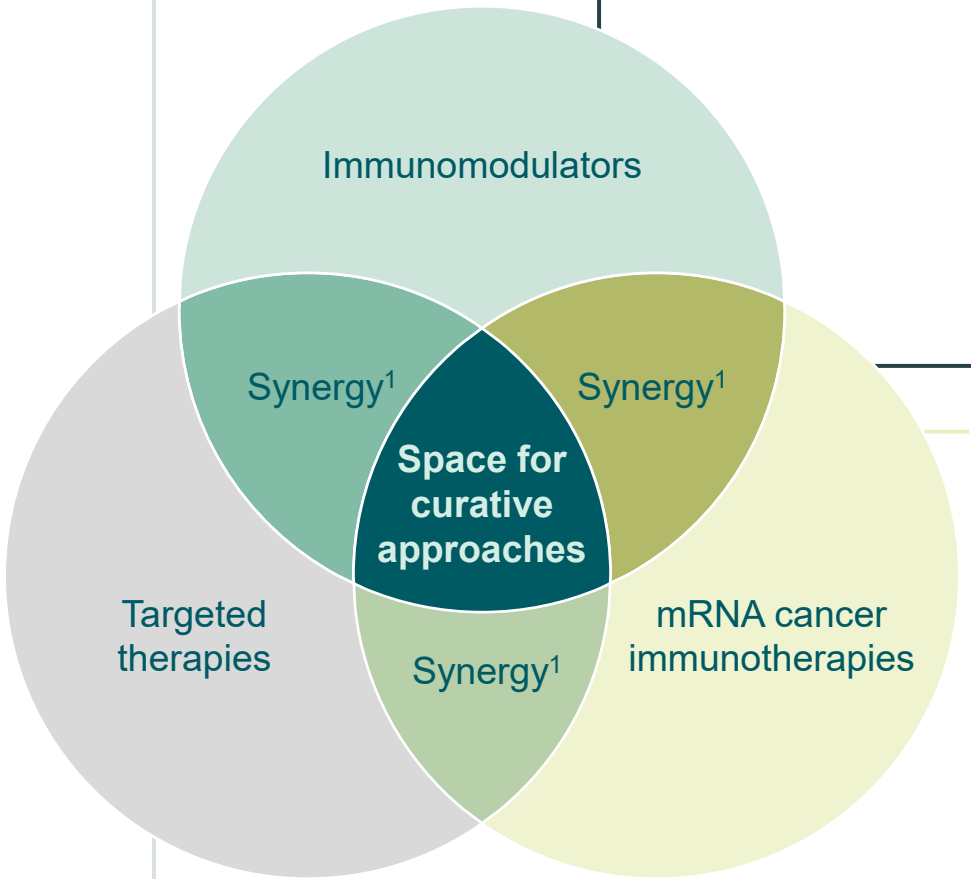
- BNT326/ YL202[3] — Anti-HER3 ADC
- BNT325/ DB-1305[2] — Anti-TROP2 ADC



Immunomodulators

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mRNA cancer immunotherapy

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1. Synergistic potential; Partnered with 2 DualityBio; 3. MediLink; 4. Bristol Myers Squibb; 5. OncoC4.

BIONTECH

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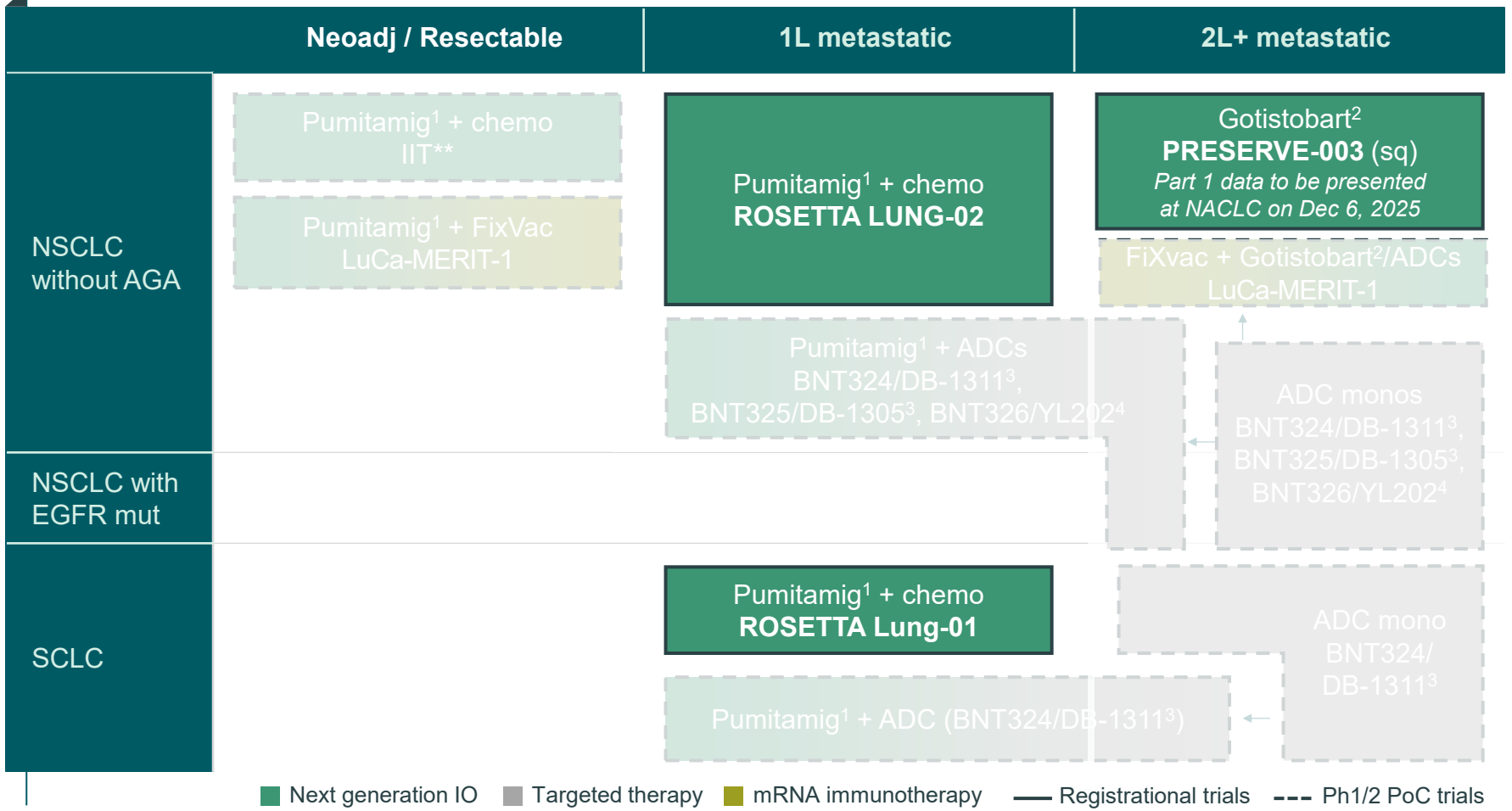
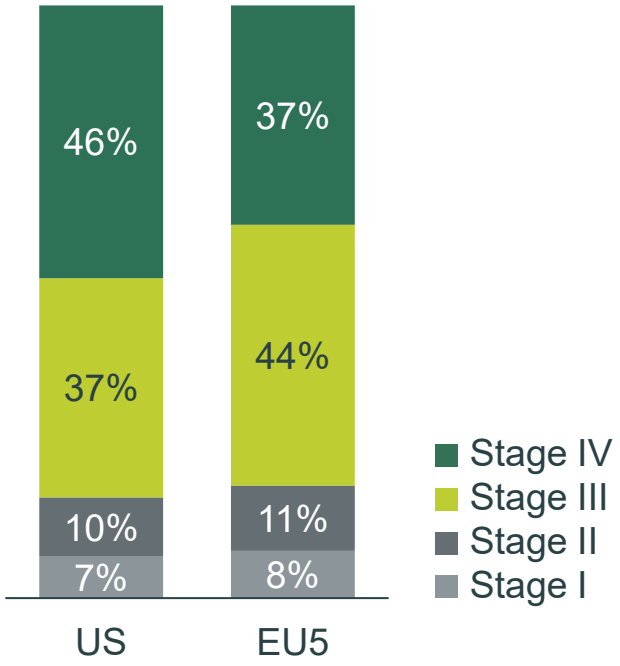


Partnered with: 1. Bristol Myers Squibb; 2. OncoC4; 3. DualityBio; 4. MediLink; *As of Nov 2025; **being conducted in China

Non-Small Cell Lung Cancer is One of the Highest Incidence Cancers Globally[1]

2030 U.S., EU4, U.K. NSCLC incidence[1] **~415k**

NSCLC staging distribution[2]



Treatment outcomes vary based on histology and PD-L1 levels in 1L NSCLC patients without actionable genomic alterations

	Non-squamous (~ 70%)[3]	Squamous (~ 30%)[3]
PD-L1 ≥ 50% (~ 25 - 30%)[4,5]	**5-year OS:** 30% (KN-189)[6]	**5-year OS:** 23% (KN-407)[7]
PD-L1 1 - 49% (~ 30 - 40%)[4,5]	**5-year OS:** 20% (KN-189)[6]	**5-year OS:** 21% (KN-407)[7]
PD-L1 < 1% (~ 30 - 40%)[4,5]	**5-year OS:** 10% (KN-189)[6]	**5-year OS:** 11% (KN-407)[7]

1. Globocan – Cancer Tomorrow. 2. CancerMPact® 2024 Treatment Architecture EU5 and US; Note that 5-year survival reported includes all comer NSCLC population ie including with actionable genetic alterations. 3. Ganti AK, et al. JAMA Oncol. 2021 Dec; 4. Mansour MSI et al. Int J Mol Sci. 2022 Apr 19;23(9):4517; 5. Saez de Gordoa, K. et al. Diagnostics 2021, 11, 1452; 6. Garassino MC, et al. J Clin Oncol. 2023 Apr 10;41(11):1992-1998; 7. Silvia Novello et al. JCO 41, 1999-2006(2023).

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Pumitamig[1] in Non-Small Cell Lung Cancer

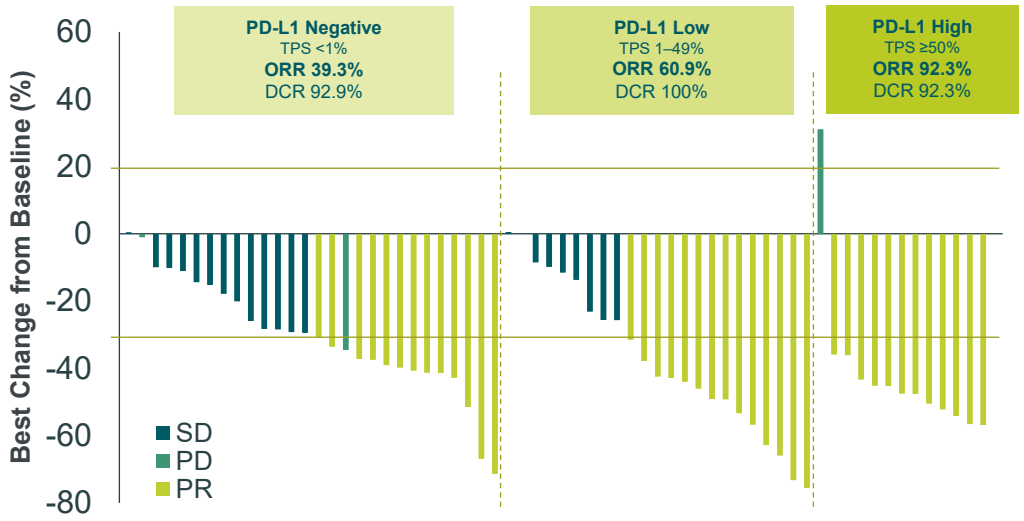
Efficacy
Efficacy observed in patients with and without driver mutations and irrespective of PD-L1 levels

Safety Profile
Manageable safety profile with low rates of discontinuation

Focused Execution
ROSETTA Lung-02 ongoing in both non-squamous and squamous histologies. Phase 2 part completed. Phase 3 recruiting.

Patient Population	1L EGFR/ALK WT PD-L1+ (TPS≥1) NSQ NSCLC 20 mg/kg	2L/3L EGFR mut TKI-experienced NSQ NSCLC 20 mg/kg	2L EGFR/ALK WT PD-(L)1 r/r NSQ NSCLC 20 mg/kg	2L/3L EGFR-mutated TKI-experienced NSQ NSCLC 30 mg/kg
N	17	36	8	64
cORR (%)	**47.1**	**19.4**	**12.5**	**57.8**
DCR (%)	**100.0**	**69.4**	**62.5**	**95.3**
mPFS (months)	**13.6**	**5.5**	**6.7**	-
mOS (months)	**13.9**	**15.1**	**9.4**	-
Congress	ASCO 2024			ESMO 2024

Yi-Long Wu, et. al. ESMO 2024 1255MO (pumitamig + chemotherapy)



Benchmark Data[2] 1L NSCLC

Indication	Benchmark regimen	ORR	mPFS	mOS	Study
1L NSCLC (PD-L1 ≥ 50%)	**Pembro mono**	46%	7.7 mo	26.3 mo	KEYNOTE-024[3]
1L NSQ NSCLC	**Pembro + chemo**	48%	9.0 mo	22.0 mo	KEYNOTE-189[4]
1L SQ NSCLC	**Pembro + chemo**	62%	8.0 mo	17.2 mo	KEYNOTE-407[5]

1. Partnered with Bristol Myers Squibb; 2. This benchmarking is not based on head-to-head trials between BioNTech's investigational candidates and other products or product candidates. Furthermore, definitive conclusions cannot be drawn from cross-trial comparisons or anticipated data, as they may be confounded by various factors, and should be interpreted with caution; 3.Reck et al, NEJM 2016; 4. Garassino et al, J Clin Oncol, 2023 5. Novello et al, J Clin Oncol, 2023

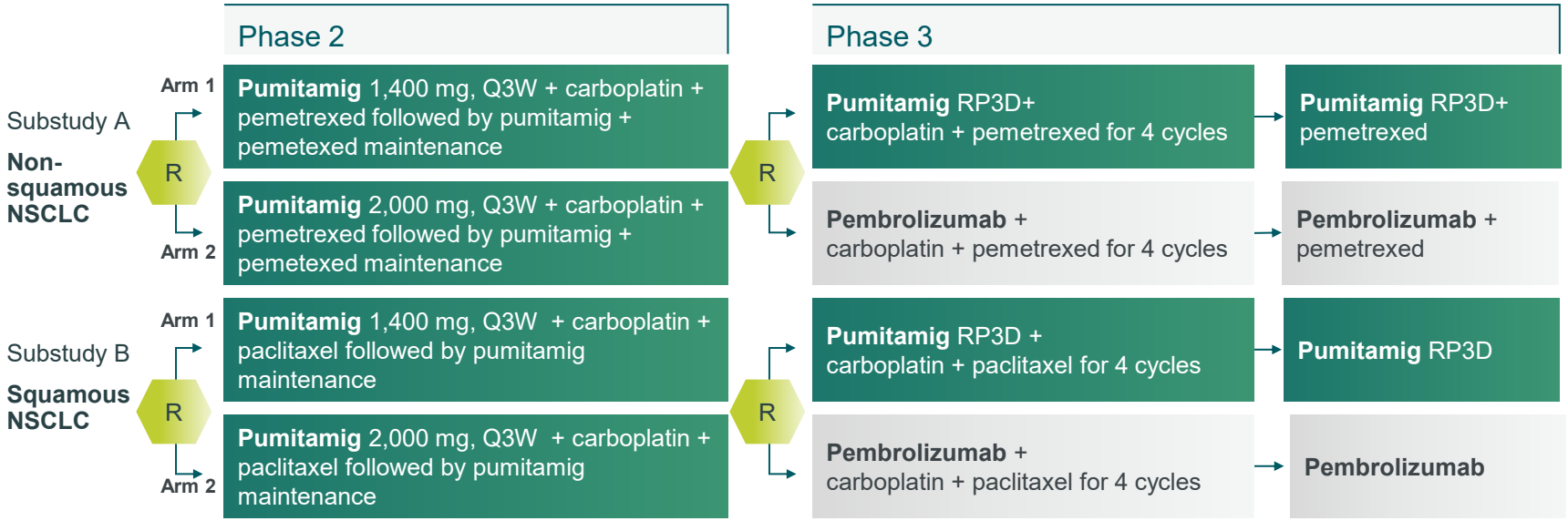
Global Phase 2/3 Trial to Establish Pumitamig[1] in NSCLC

ROSETTA LUNG-02

Seamless Phase 2/3 multi-site, randomized trial of pumitamig in combination with chemotherapy in 1L NSCLC

Key Inclusion Criteria

- Treatment naïve Stage IIIB/IIIC or IV NSCLC
- RECIST 1.1 measurable disease
- ECOG PS 0 or 1
- PD-L1 all-comers



Key Endpoints

Primary: PFS (BICR), OS
Secondary: PFS (inv), ORR

Benchmark Data 1L NSCLC

Histologies	Regimen	ORR	mPFS	mOS	Study
NSQ NSCLC	Pembro + chemo[2]	48%	9.0 mo	22.0 mo	KEYNOTE-189[4]
SQ NSCLC	Pembro + chemo[3]	62%	8.0 mo	17.2 mo	KEYNOTE-407[5]

1. Partnered with Bristol Meyer Squibb; 2.Carboplatin + pemetrexed→pemetrexed maintenance. 3. carboplatin + paclitaxel / nab-paclitaxel. 4. Garassino et al, J Clin Oncol, 2023 5. Novello et al, J Clin Oncol, 2023; NCT06712316.

BIONTECH

Squamous NSCLC Remains an Area of High Unmet Need

By 2030

55k ***squamous*** patients start in 1L (non-AGA population) [1]

~30% continue into 2L treatment and are IO addressable

Amongst NSCLC, metastatic squamous NSCLC is seen as **#1 area of unmet need** for improving treatment amongst NSCLC[2]

Limited treatment options for patients without actionable genetic alterations in squamous NSCLC

In 2L, current chemo-based SOC shows 10 months median OS in clinical trials

<25% respond to 2L chemo-based SOC (docetaxel ± ramucirumab)

Multiple efforts failed to improve therapeutic outcome in 2L squamous NSCLC in recent years

1. CancerMPact; 2. Clarivate / Clarivate Survey|

Data Support Initiation of Pivotal Phase 3 Trial Evaluating Gotistobart[1] in CPI-resistant NSCLC

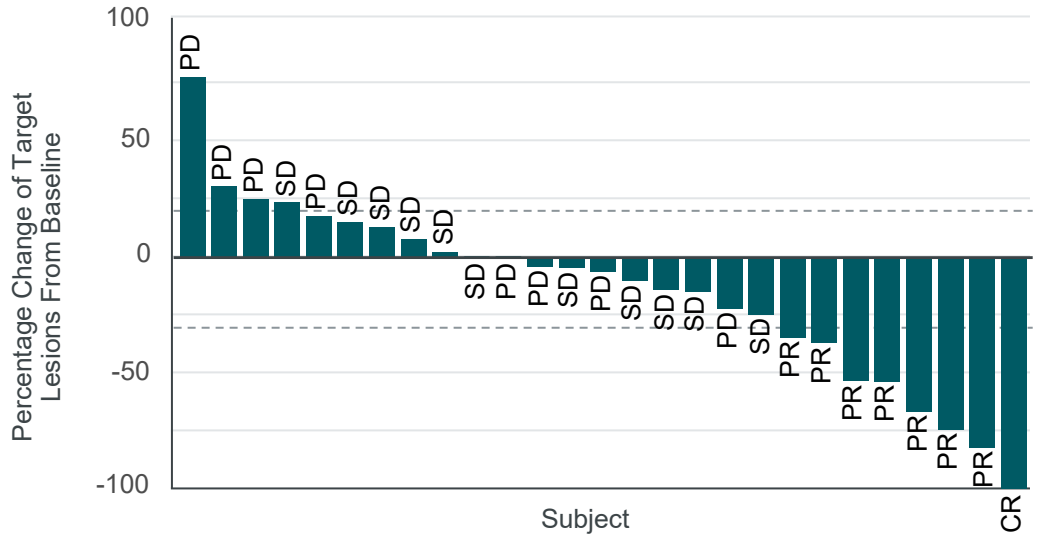
PRESERVE-001: Phase 1/2 multicenter, non-randomized, open-label, multiple-dose, FIH trial

He K. et al. ASCO 2023 #9024.

Anti-tumor activity observed in ICI-resistant NSCLC patients (n=27)	**ORR: 29.6%** (22.2% confirmed & 7.4% unconfirmed) **DCR: 70.4%**	**Manageable adverse events**

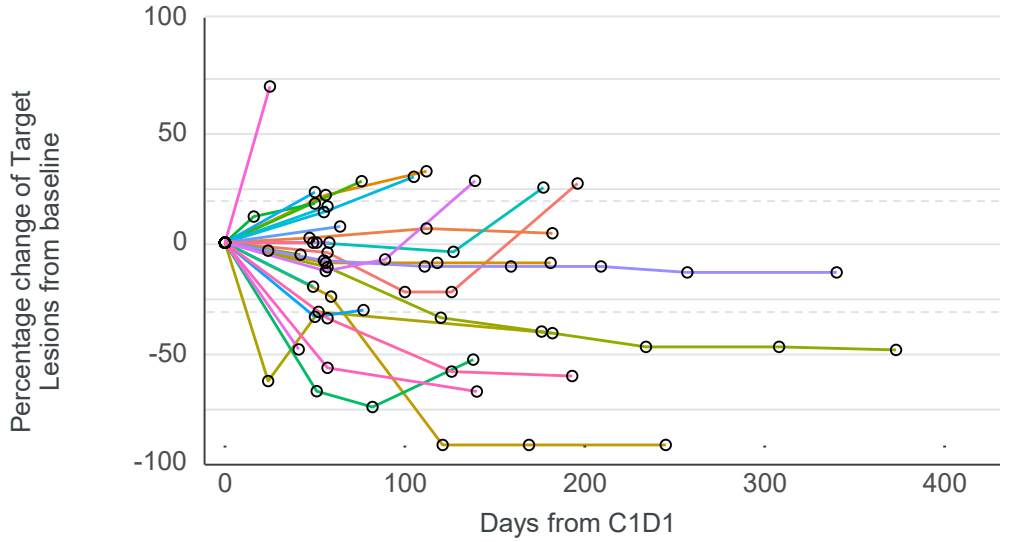
Target lesion best overall response (n=27 evaluable)

Dosing 10 mg/kg x 2, then 6 mg/kg, q3w (2 pts.: 10 mg/kg x 4, q3w)



Target lesion percentage change over time (n=27 evaluable)

Dosing; 10 mg/kg x 2, then 6 mg/kg, q3w (2 pts.: 10 mg/kg x 4, q3w)



1.Partnered with OncoC4; *NCT04140526.

BIONTECH

Pivotal Development of Gotistobart[1] in 2L Squamous Non-Small Cell Lung Cancer

Seamless Phase 3 two-stage, randomized trial evaluating gotistobart versus docetaxel in 600 patients

Key Inclusion Criteria

- stage IV, metastatic NSCLC
- Prior PD-(L)1 +/- platinum-based chemotherapy
- Prior IO-IO allowed
- RECIST 1.1 measurable lesions

Stratification Factors

- Histology (Squamous or Non-Squamous) in Stage I
- Presence of brain metastases
- ECOG score (0 or 1)
- Region (US or ex-US)

Stage 1: Dose confirmation in squamous and non-squamous NSCLC

R 1:1:1

- **Gotistobart** 6 mg/kg with 2 loading doses of 10 mg/kg, Q3W (n=103)
- **Gotistobart** 3 mg/kg, Q3W (n=10)
- **Docetaxel** 75 mg/kg, Q3W (n=104)

Phase 3 Stage 1 data to be presented at NACLC on December 6, 2025

Stage 2: Pivotal part in squamous NSCLC

R 1:1

- **Gotistobart** 6 mg/kg with 2 loading doses of 10mg/kg, Q3W (n=239)
- **Docetaxel** 75 mg/kg, Q3W (n=239)

Key Endpoints

Primary: OS
Secondary: PFS, safety

Benchmark Data for 2L sqNSCLC

Regimen	ORR	mPFS	mOS	Study
Docetaxel	12.7%	3.9 mo	9.4 mo	TROPION-Lung01 sq population[2]

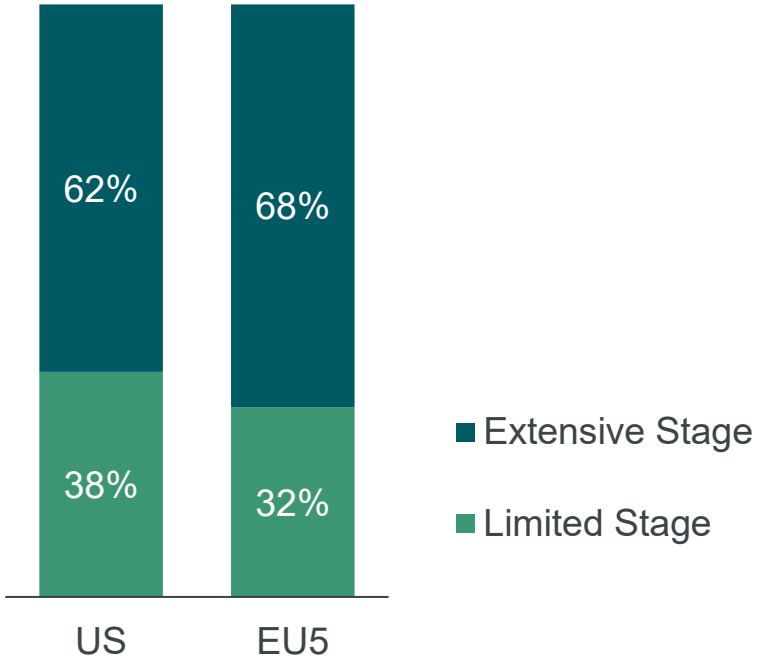
1. Partnered with OncoC4 . 2. Ahn et al. J Clin Oncol 43, 260-272(2025); NCT05671510

BIONTECH

Extensive-Stage Small Cell Lung Cancer is a High-Incidence Cancer with Poor Long-term Survival Rates

2030 U.S., EU4, U.K. SCLC incidence[1] **~60k**

SCLC staging distribution[2]



High unmet need for ES-SCLC patients as long-term survival outcomes remain very poor

	Limited-Stage SCLC	Extensive-Stage SCLC
mOS	**cCRT: ~25 – 30 mos** (CONVERT)[3] **Durva consolidation: 56 mos** (ADRIATIC)[4]	**Atezo + chemo: 12.3 mos** (IMPower133)[5,6]
24 mos OS	**cCRT: ~ 50%** (CONVERT)[3] **Durva consolidation: 68%** (ADRIATIC)[4]	**Atezo + chemo: ~ 25%** (IMPower133)[5,6]
5-year survival[2]	**20%**	**3%**

1. Incidence from: SEER data for diagnosed SCLC incidence in US; Cancer Research UK; Zentrum für Krebsregisterdaten; Sante Publique; AIOM; EPDATA. 2 Statistics from Dayen et al (2019); CancerMPact® Patient Metrics US & EU5, accessed February 2024. *Due to limited survival data in EU5, U.S. survival data is reported; 3 Walls, Gerard M. et al. International Journal of Radiation Oncology, Biology, Physics, Volume 119, Issue 5, 1386 – 1390; 4. Cheng et al., N Engl J Med 2024;391:1313-27. 5 L. Horn et al, N. Engl. J. Med., 379 (2018), pp. 2220-2229; 6 Stephen V. Liu et al., JCO 39, 619-630(2021).

BIONTECH

Expeditious Set Up of Global Phase 2 Trial To Confirm Optimal Dose For Pivotal Development

Fully enrolled Global Phase 2 dose-optimization of pumitamig[1] + chemotherapy in patients with 1L/2L SCLC

Key Inclusion Criteria

- Cohort 1: Untreated ES-SCLC or LS-SCLC with TFI≤6 months since last treatment

Pumitamig (30 mg/kg Q3W) + chemotherapy

Pumitamig (20 mg/kg Q3W) + chemotherapy

Treatment continued until disease progression or intolerable toxicity

- **Three cohorts** based on previous treatment for patients and chemo option used to combine with pumitamig
- Each cohort randomized to receive two different dose levels pumitamig with chemo

Key Endpoints

Primary: ORR, safety
Secondary: PFS, OS

1. Partnered with Bristol Myers Squibb; 2. L. Horn et al. N. Engl. J. Med., 379 (2018), pp. 2220-2229; NCT06449209.

Pumitamig[1] Combined with Chemotherapy Indicated Encouraging Efficacy in 1L ES-SCLC in Phase 2 Study

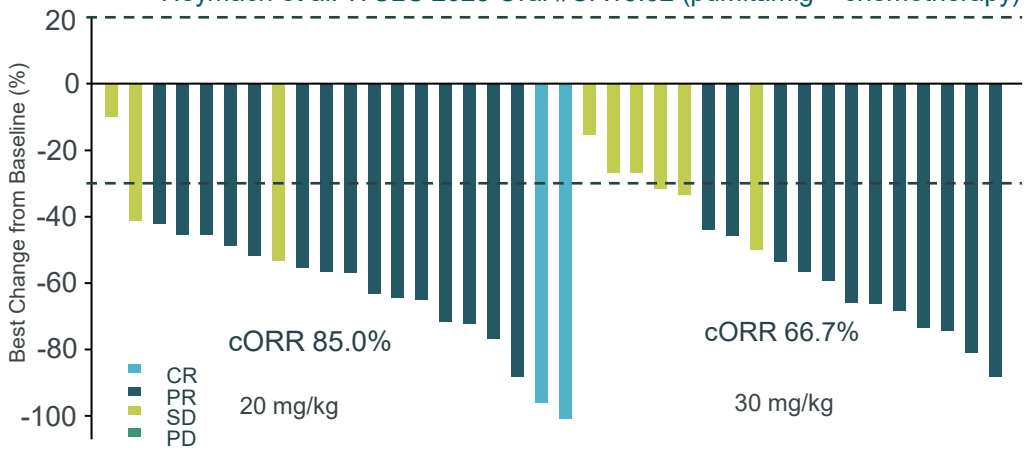
Efficacy
Encouraging efficacy observed across treatment lines, including >95% disease control rates in 1L-ESCLC

Safety Profile
Consistent and manageable safety profile across studies with low discontinuation rates and no new safety concerns

Consistent Clinical Profile
Activity and safety confirmed in China and global datasets, supporting frontline benefit

Patient Population	2L SCLC China IO Naïve 30 mg/kg Q3W	2L SCLC China IO Treated 30 mg/kg Q3W	1L ES-SCLC China 30 mg/kg Q3W	1L ES-SCLC Global 20 mg/kg Q3W	1L ES-SCLC Global 30 mg/kg Q3W
N	22	43	48	20	18
cORR (%)	**50.0**	**37.2**	**85.4**	**85.0**	**66.7**
DCR (%)	**81.8**	**90.7**	**97.9**	**100**	**100**
mPFS (months)	**5.5**	**5.4**	**6.9**	**6.3**	**7.0**
mOS (months)	**14.7**	**14.3**	**16.8**	-	-
Congress	ELCC 2025		ELCC 2025	WCLC 2025	

Heymach et al. WCLC 2025 Oral #OA13.02 (pumitamig + chemotherapy)



Benchmark data[2] 1L ES-SCLC

Regimen	ORR	mPFS	mOS	Study
Atezo + Chemo	60%	5.2 mo	12.3 mo	IMpower133[3]
Durva + Chemo	68%	5.1 mo	12.9 mo	CASPIAN[4]

1. Partnered with Bristol Myers Squibb; 2. This benchmarking is not based on head-to-head trials between BioNTech's investigational candidates and other products or product candidates. Furthermore, definitive conclusions cannot be drawn from cross-trial comparisons or anticipated data, as they may be confounded by various factors, and should be interpreted with caution; 3. Horn et al., New England Journal of Medicine, 2018; 4. Paz-Ares et al., The Lancet, 2019.

Pumitamig[1] Shows Early Signs Of Durable Antitumor Activity in SCLC

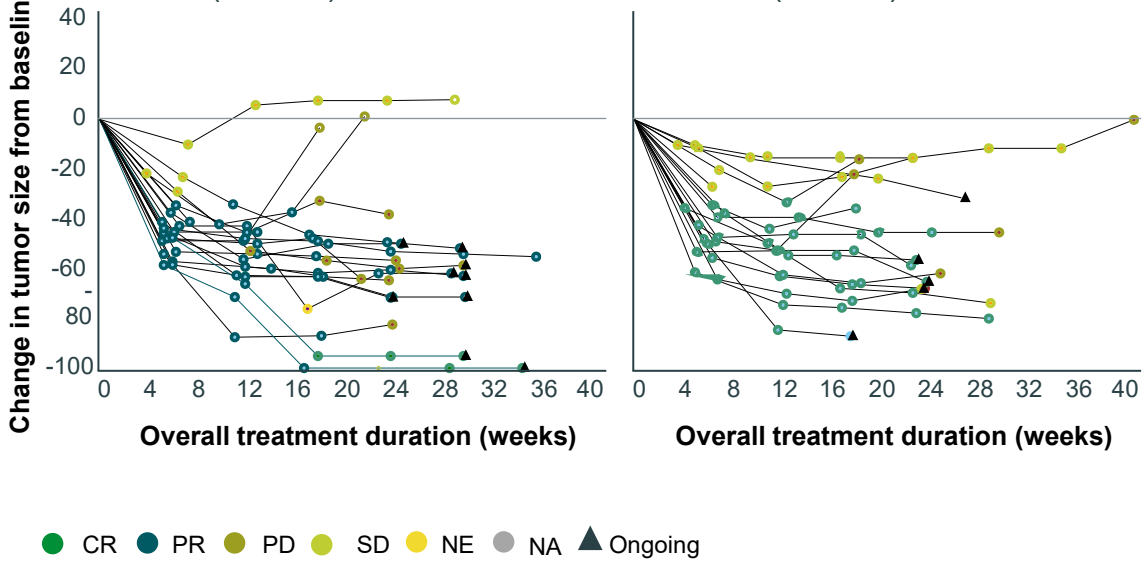
mDoR: **4.9** months (overall)

Pumitamig 20 mg/kg + EC

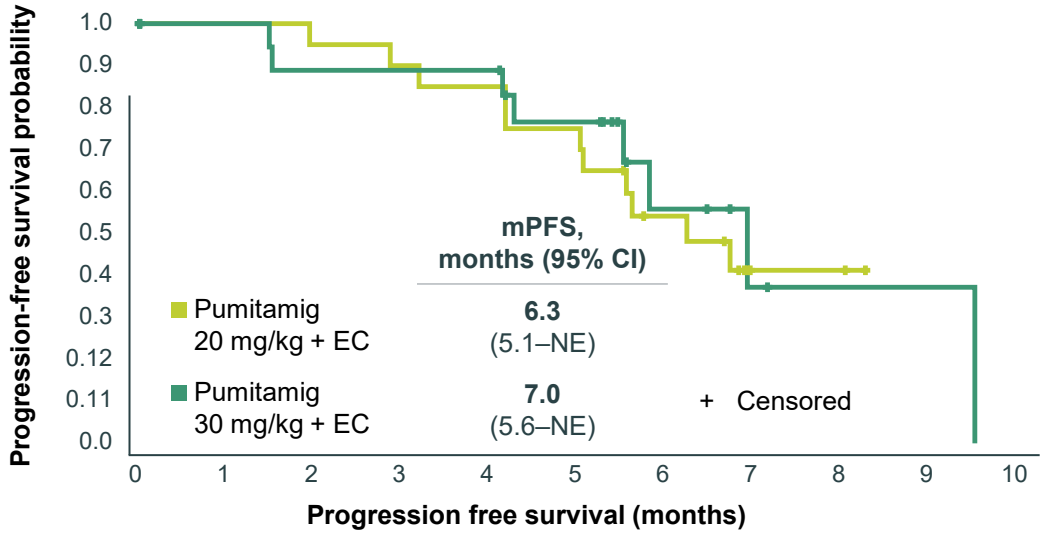
mDoR, months (95% CI):
4.9 (3.7–NE)

Pumitamig 30 mg/kg + EC

mDoR, months (95% CI):
5.4 (4.1–NE)



mPFS: **6.8** months (overall)



No. of patients at risk

Pumitamig 20 mg/kg + EC	22	20	19	18	17	15	9	2	2	0	0
Pumitamig 30 mg/kg + EC	21	18	16	16	16	12	5	2	1	1	0

Data cut-off: 07 Aug 2025; median follow-up 28.3 weeks (min, max 3.9,; 45.6) overall. Median treatment duration: 25.3 weeks (Q1 12.9, Q3 30.6).

BIONTECH

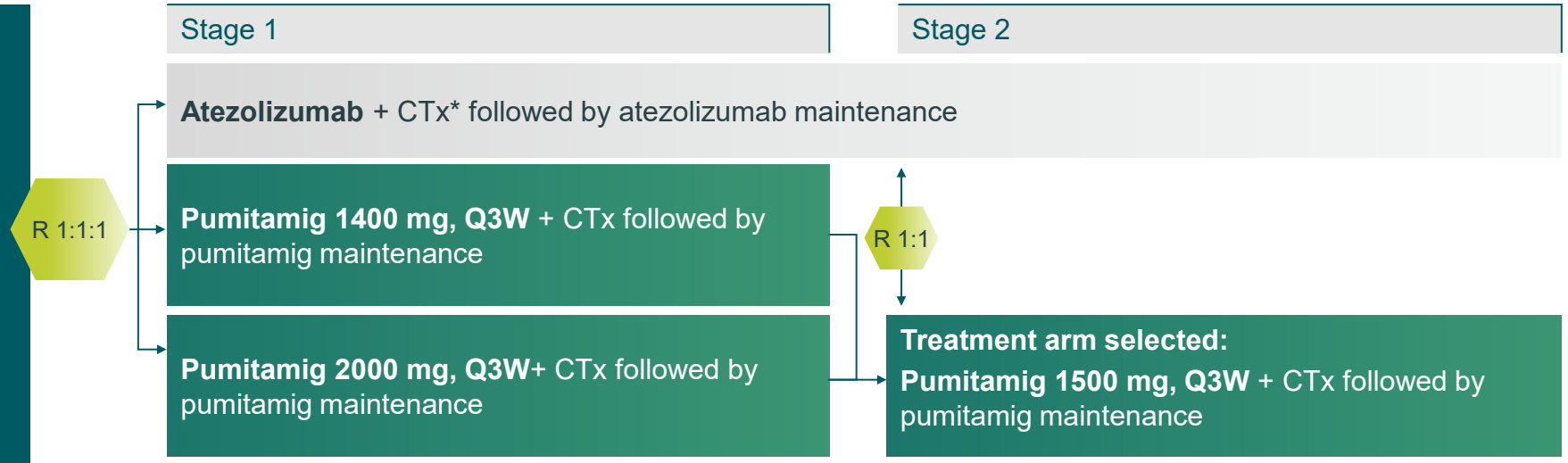
Global Phase 3 Trial to Establish Pumitamig[1] in ES-SCLC

ROSETTA LUNG-01

Phase 3 multi-site, double-blinded, randomized trial of pumitamig in combination with chemotherapy compared to atezolizumab with chemotherapy in previously untreated ES-SCLC

Key Inclusion Criteria

- Histologically or cytologically confirmed ES-SCLC
- No prior systemic therapy for ES-SCLC
- ECOG 0 or 1
- ≥ 1 measurable lesion (RECIST v1.1)



*CTx = carboplatin AUC 5 with a total dose of ≤750 mg IV on D1 + etoposide 100 mg/m IV on D1-3, Q3W for 4 cycles

Key Endpoints

Primary: OS
Secondary: PFS

Benchmark Data for 1L ES-SCLC

Regimen	ORR	mPFS	mOS	Stufy
Atezo + chemo	60%	5.2 mo	12.3 mo	IMpower133[2]

1. Partnered with Bristol Myers Squibb; 2. L. Horn et al., New England Journal of Medicine, 2018; NCT06712355.

BIONTECH

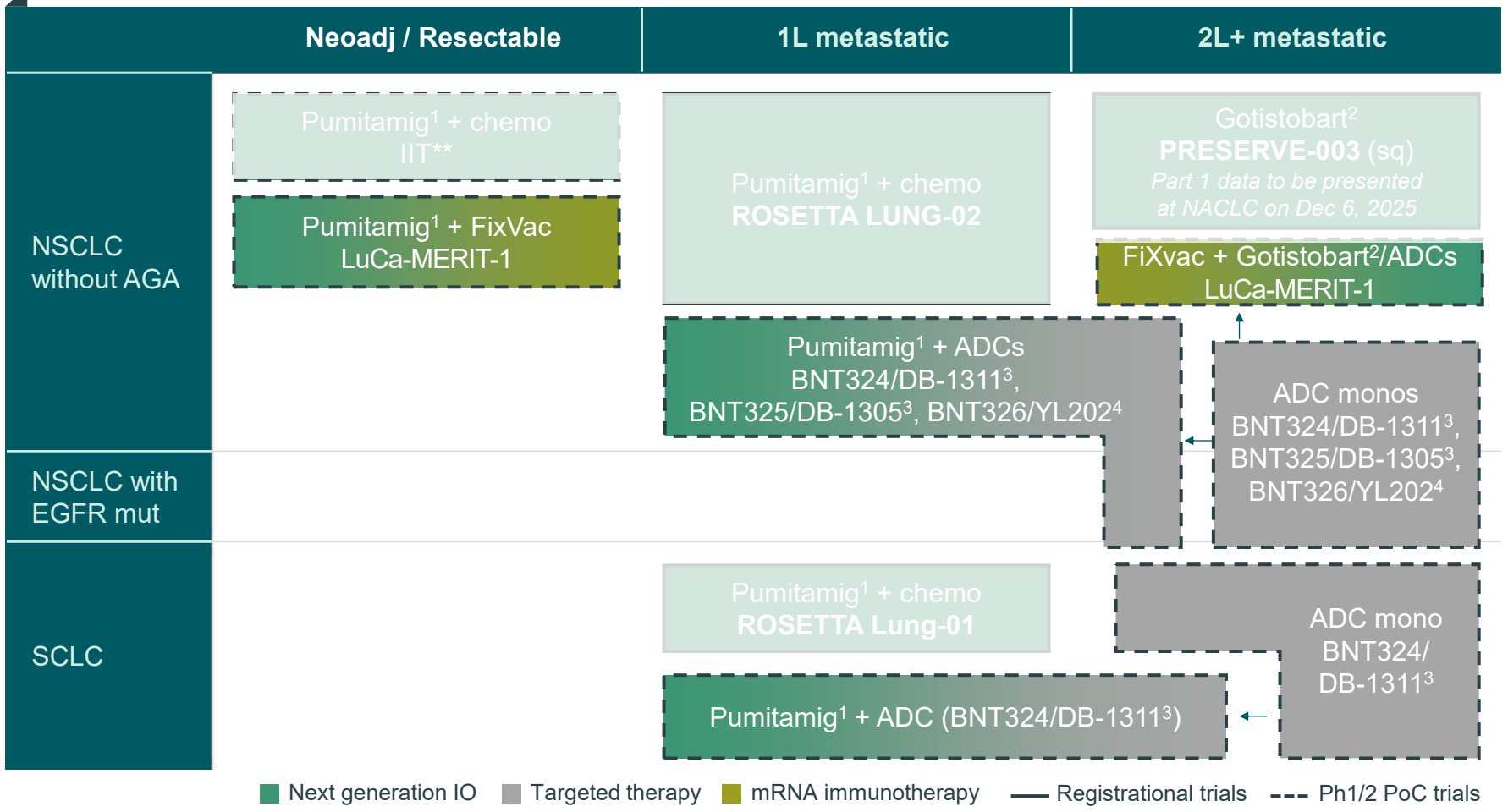
BioNTech's Currently Ongoing Trials* in Lung Cancer

Registrational trials in metastatic Lung Cancer with next-generation IO

- Pumitamig[1] aiming to improve over SoC in 1L NSCLC and ES-SCLC
- Gotistobart[2] to provide IO option for 2L NSCLC Sq (high unmet need)

PoC trials with ADC mono and novel combinations to inform future registrational trials

- ADC mono and FixVac data provided confidence to start combination PoC trials
- Multiple Pumitamig + ADC PoC trials ongoing for data-driven decision making and inform future registrational trials in the 1L setting

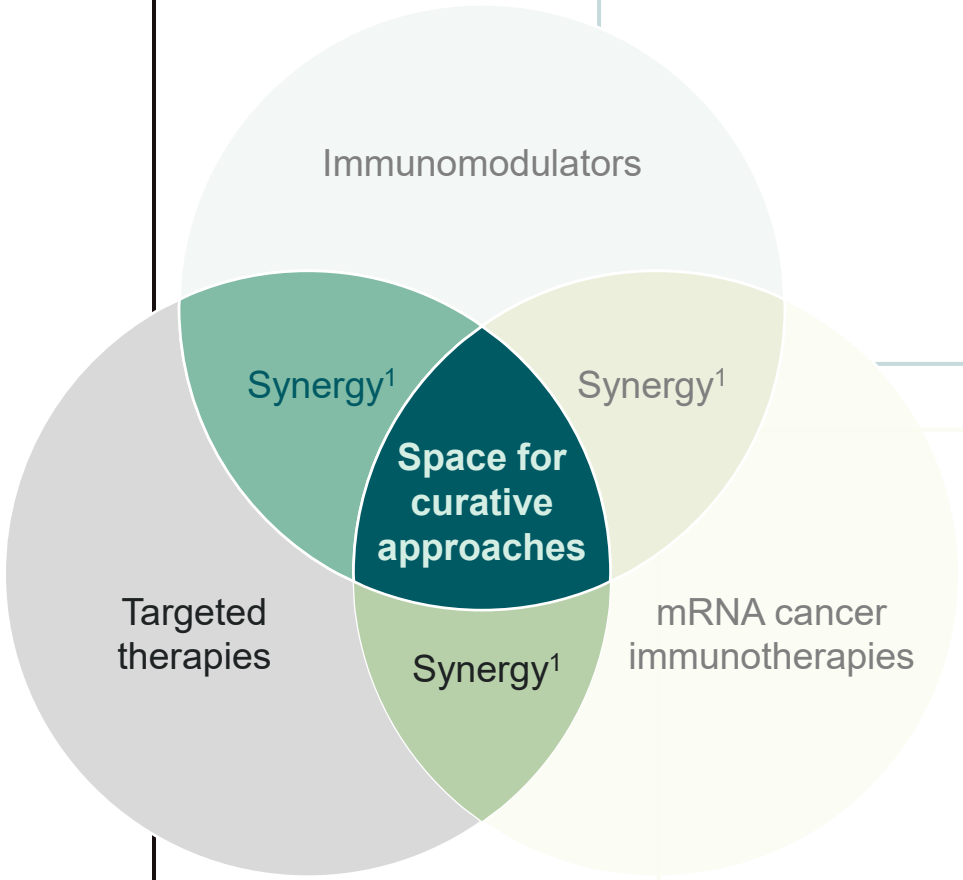


Partnered with: 1. Bristol Myers Squibb; 2. OncoC4; 3. DualityBio; 4. MediLink; *As of Nov 2025; **being conducted in China

Our Diverse Lung Cancer Pipeline

Targeted therapies

- BNT324/ DB-1311[2] — Anti-B7H3 ADC
- BNT326/ YL202[3] — Anti-HER3 ADC
- BNT325/ DB-1305[2] — Anti-TROP2 ADC



Immunomodulators

- Pumitamig[4] — Anti-PD-L1/ Anti-VEGF
- Gotistobart[5] — Anti-CTLA-4

mRNA cancer immunotherapy

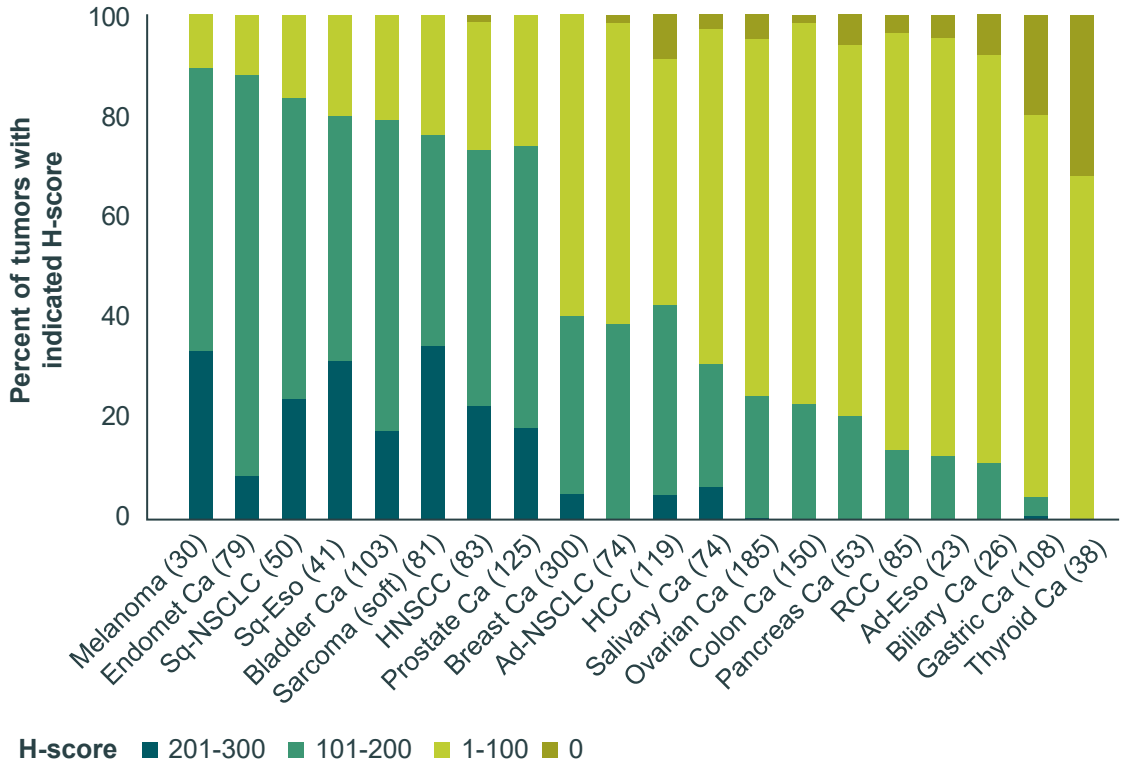
- FixVAC — Off-the-shelf mRNA → BNT116

1. Synergistic potential; Partnered with 2 DualityBio; 3. MediLink; 4. Bristol Myers Squibb; 5. OncoC4.

BIONTECH

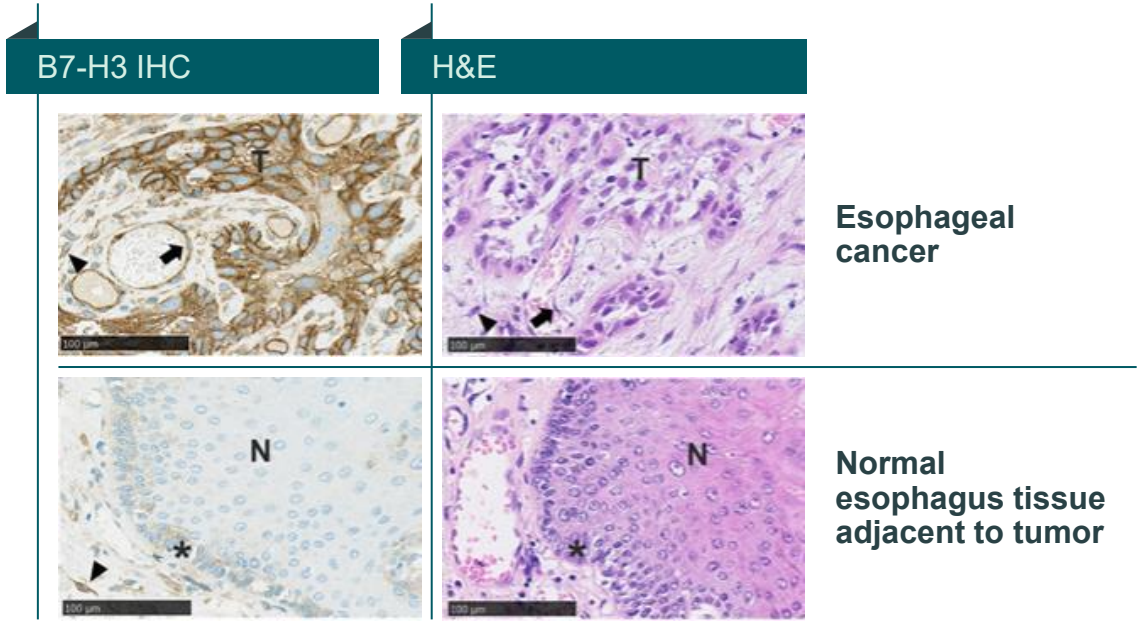
High B7-H3 Protein Expression Observed in Various Solid Tumors

B7-H3 IHC analysis in tumor microarrays



- H-score of B7-H3 expression on tumor cells in each sample was calculated.
- Number in parentheses indicates the number of samples.

B7-H3 IHC analysis in tumor vs. normal tissue



Arrow, vasculature/endothelium; arrowhead, fibrous stromal cells; asterisk, basal cells. Scale bar, 100 µm

- B7-H3 expression is predominately low in normal tissues, but overexpressed in various solid tumors
- B7H3 is also expressed in tumor associated vasculature/endothelium and stromal cells

Yamato et al., Mol Cancer Ther 2022

BIONTECH

BNT324/DB-1311[1] Monotherapy Development Focused on Fifteen Phase 2 Dose Optimization and Expansion Cohorts

Phase 1/2 dose escalation, optimization and expansion evaluating BNT324/DB-1311 in patients with advanced/metastatic solid tumors unselected for B7-H3 expression

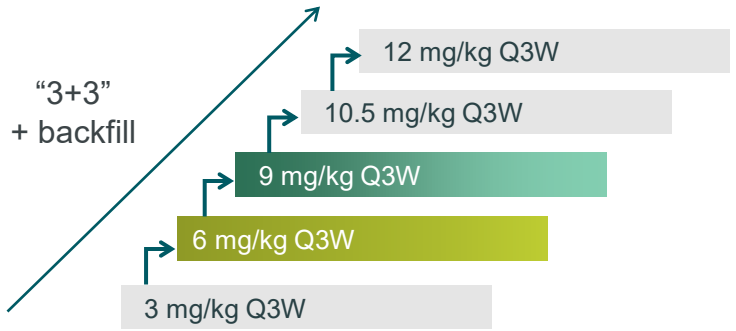
Key Inclusion Criteria

- Advanced or metastatic solid tumor that progressed on/after standard systemic treatments
- ≥1 measurable lesion per RECIST v1.1
- ECOG PS 0–1
- Asymptomatic brain metastases are allowed

Key Exclusion Criteria

- Prior treatment with B7-H3 therapy
- Prior treatment with TOP1 ADC

Phase 1: Dose escalation (complete)



BNT324/DB-1311 IV Q3W
Until disease progression/unacceptable toxicity

Phase 2: Dose optimization/expansion (ongoing). 6 or 9 mg/kg Q3W

Dose optimization

Cohort 1	**SCLC**
Cohort 2	**NSCLC**
Cohort 4	CRPC
Cohort 14	PROC
Cohort 9	HNSCC
Cohort 13	HNSCC

R → 9 mg/kg IV Q3W
R → 6 mg/kg IV Q3W

Dose expansion

Cohort 3	ESCC
Cohort 5	Melanoma
Cohort 6	HCC
Cohort 7	Cervical cancer
Cohort 8	Other solid tumors
Cohort 10	Rare tumors
Cohort 11	Post Lu-177 CRPC
Cohort 12	Taxane-naïve CRPC
Cohort 15	DDI Cohort

Key Endpoints

Primary: DLT/MTD (Phase 1), safety and ORR (Phase 2)
Secondary: DCR, DOR, PFS, OS, and B7-H3 expression

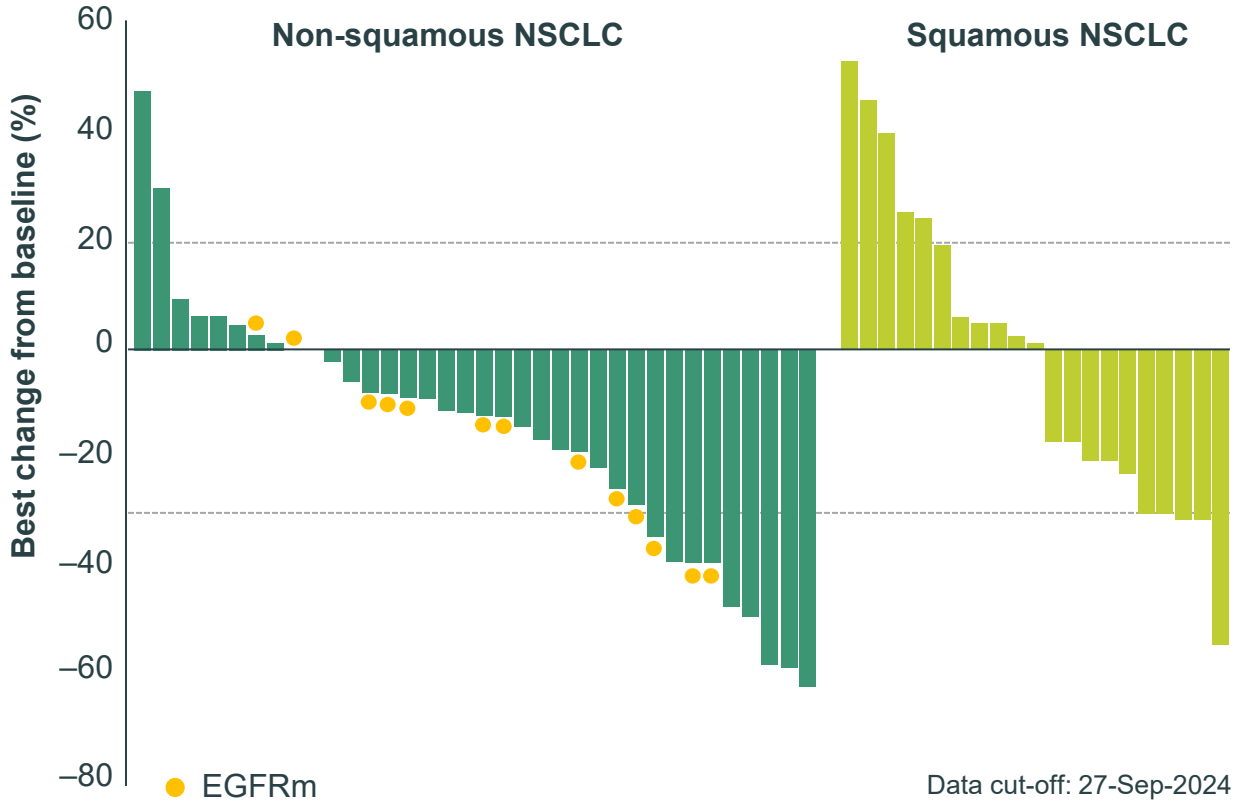
.An intermediate dose of 10.5 mg/kg was evaluated after 2 DLTs occurred with 12 mg/kg.
1. Partnered with DualityBio; Cheng Y et al. ESMO Asia 2024 #57O NCT05914116

Early Signs Of Encouraging Activity With BNT324/DB-1311[1] in NSCLC

Cheng Y et al. ESMO Asia 2024 57O.

	Non-squamous NSCLC (n=41)	Squamous NSCLC (n=25)
ORR, n (%) [95% CI]	9 (22.0) [10.6, 37.6]	4 (16.0) [4.5, 36.1]
Confirmed ORR, n (%)	5 (12.2)	0
Pending confirmation, n	3	4
DCR, n (%) [95% CI]	33 (80.5) [65.1, 91.2]	15 (60.0) [38.7, 78.9]
3-month PFS rate, %	74.5	50.5

EGFRm NSCLC (n=14) ORR: 3 (21.4%)



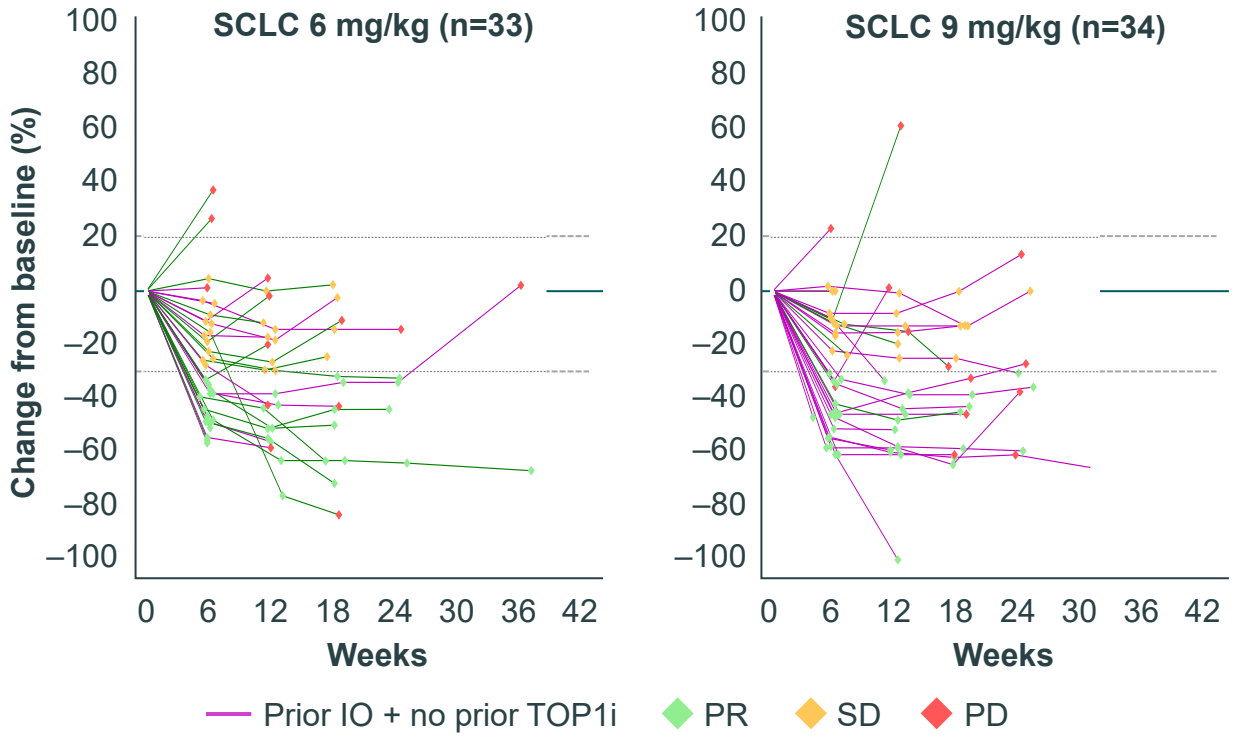
1. Partnered with DualityBio;

BIONTECH

Encouraging Antitumor Activity BNT324/DB-1311[1] in SCLC

Higher ORR with 9 mg/kg in patients who received prior IO but no prior TOP1i (79% of the patients)

	SCLC 6 mg/kg (n=33)	SCLC 9 mg/kg (n=34)
ORR, n (%) [95% CI]	18 (**54.5**) [36.4, 71.9]	20 (**58.8**) [40.7, 75.4]
Confirmed ORR, n (%)	9 (27.3)	12 (35.3)
Pending confirmation, n	6	4
DCR, n (%) [95% CI]	29 (**87.9**) [71.8, 96.6]	31 (**91.2**) [76.3, 98.1]
3-month PFS rate, %	**67.4**	**79.3**
Prior IO + no prior TOP1i	**n=15**	**n=27**
ORR, n (%)	7 (**46.7**)	19 (**70.4**)
Confirmed ORR, n (%)	3 (20.0)	11 (40.7)
Pending confirmation	3	4



Data cut-off: 27-Sep-2024

1, Partnered with DualityBio; Cheng Y et al. ESMO Asia 2024 57O.

BIONTECH

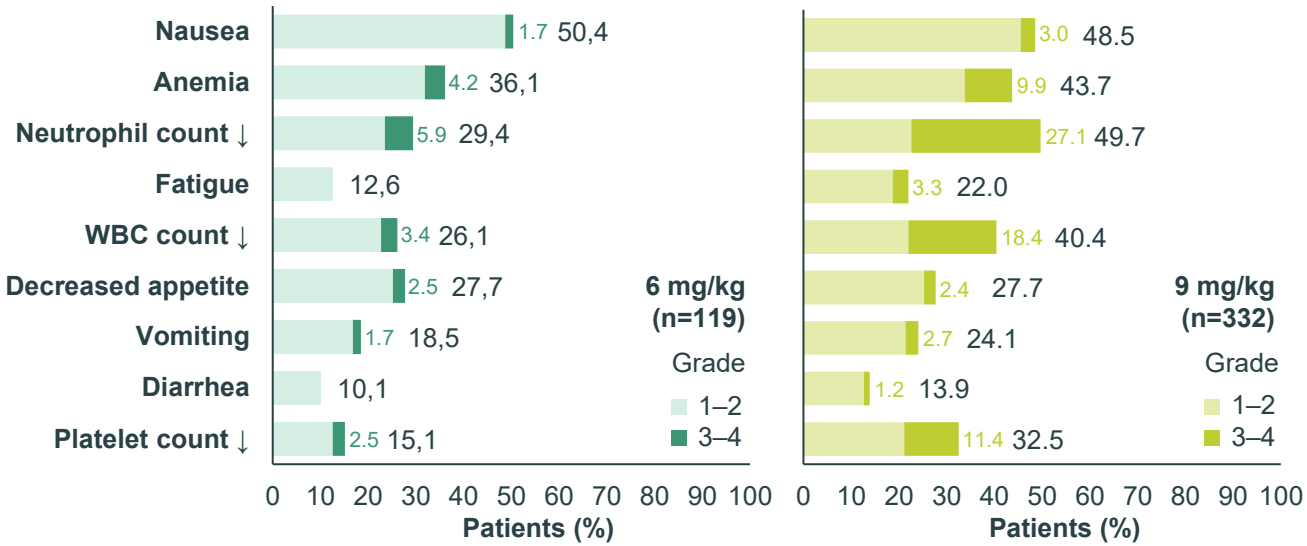
BNT324/DB-1311[1] Safety Profile

- More Grade ≥3 TRAEs with 9 mg/kg, but similarly low rate of TRAEs leading to discontinuation
- Gastrointestinal and hematological events, primarily Grade 1–2, were the most common TRAEs
- Hematological TRAEs occurred more frequently with 9 mg/kg than with 6 mg/kg

Overall Population

Parsonson A et al. ASCO 2025 5015

n (%)	Overall* (n=465)	6 mg/kg (n=119)	9 mg/kg (n=332)
Any TRAE	429 (92.3)	110 (92.4)	306 (92.2)
Grade ≥3 TRAE	220 (47.3)	34 (28.6)	178 (53.6)
TRAE leading to:			
Dose reduction	71 (15.3)	6 (5.0)	59 (17.8)
Interruption	100 (21.5)	16 (13.4)	81 (24.4)
Discontinuation	30 (6.5)	6 (5.0)	22 (6.6)
TRAE leading to death†	2 (0.4)	0	1 (0.3)



ILDs/pneumonitis reported in 5 patients receiving 6 mg/kg and 15 receiving 9 mg/kg, all Grade 1–2 except 2 Grade 3 events in two patients receiving 9 mg/kg.

Data cut-off: 04-Mar-2025

1. Partnered with DualityBio; *Includes 3 mg/kg (n=4), 10.5 mg/kg (n=4), and 12 mg/kg (n=6). The overall population includes patients with other tumors such as SCLC, NSCLC, ESCC, melanoma, HCC, cervical cancer, and HNSCC. †TRAEs leading to death: pneumonitis/respiratory failure in a patient receiving 10.5 mg/kg and encephalopathy in a patient receiving 9 mg/kg; Parsonson A et al. ASCO 2025 5015.

BIONTECH

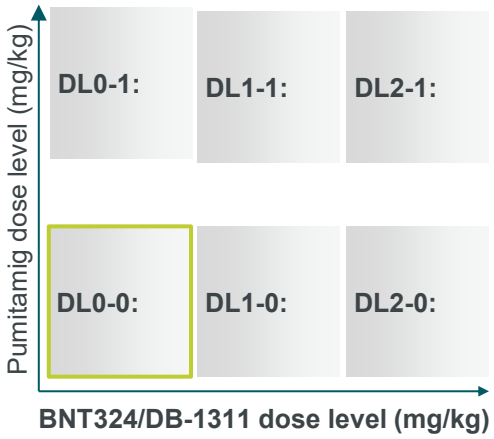
Evaluating BNT324/DB-1311[1] in Combination with Pumitamig[2] in Patients With Advanced Lung Cancer

Two-part study to evaluate efficacy and safety of a combination therapy with BNT324/DB-1311 and pumitamig in patients with advanced lung cancer

Key Inclusion Criteria

- Histologically or cytologically confirmed unresectable adv./met. SCLC or NSCLC
- Measurable disease (RECIST v1.1)
- ECOG PS 0–1
- Eligible regardless of PD-L1 status

Part 1: Dose escalation (BOIN Design)



Part 2: Dose optimization and signal-seeking

Cohort	Indication
Dose optimization cohorts	
DO1	1L nsq NSCLC AGA−
DO2	2L+ SCLC (post-chemo ± IO)
Signal-seeking cohorts	
3	2L+ nsq NSCLC AGA− (post-chemo ± IO)
4	1L sq NSCLC AGA−
5	2L+ sq NSCLC AGA− (post-chemo ± IO)
6	2L+ nsq NSCLC AGA+ (post-TKI)
7	1L ES-SCLC

DO1 → R 1:1 → RP2D, RP2D-1

DO2 → R 1:1 → RP2D, RP2D-1

Cohorts 3, 4, 5, 6, 7 → RP2D from Part 1

Key Endpoints

Primary: Safety (Part 1 and Part 2 Cohorts 1 and 2), ORR (Part 2, all cohorts)

Secondary: PFS, OS (Part 2 all cohorts), ORR (Part 1), safety (Part 2, Cohorts 3–7)

Partnered with: 1. Duality Bio; 2. Bristol Myers Squibb; NCT06892548

BIONTECH

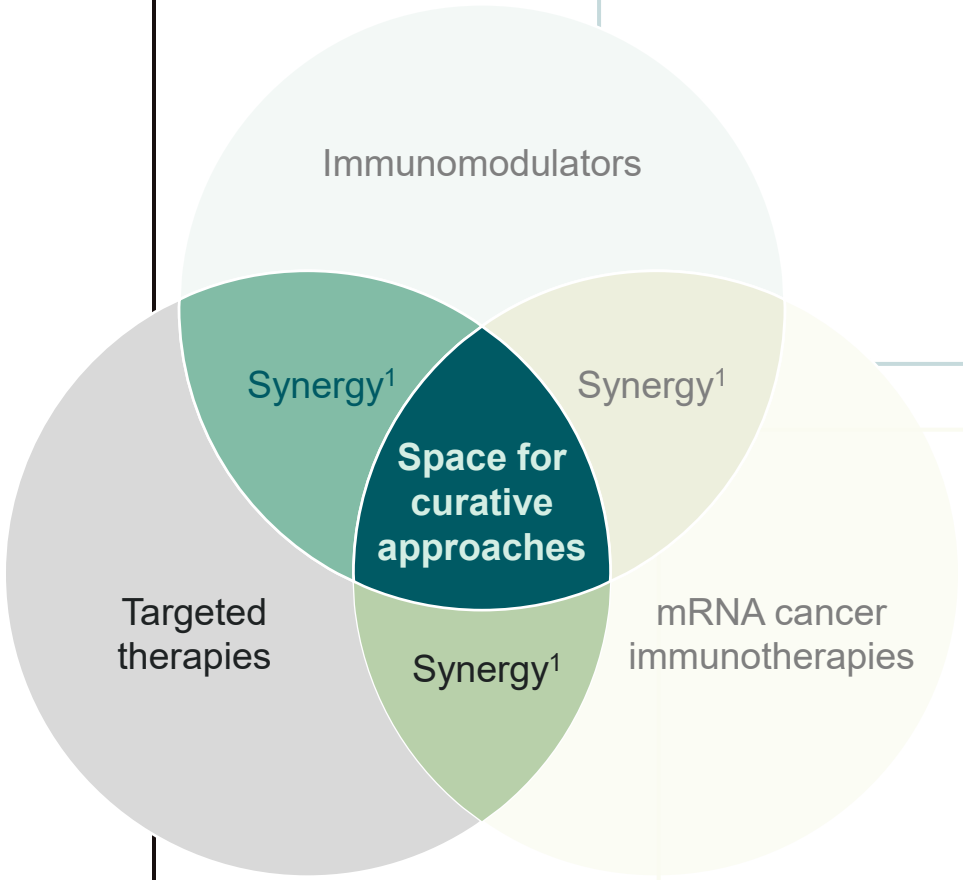
Our Diverse Lung Cancer Pipeline

Targeted therapies

BNT324/ DB-1311[2]
Anti-B7H3 ADC

BNT326/ YL202[3]
Anti-HER3 ADC

BNT325/ DB-1305[2]
Anti-TROP2 ADC



Immunomodulators

Pumitamig[4]
Anti-PD-L1/ Anti-VEGF

Gotistobart[5]
Anti-CTLA-4

mRNA cancer immunotherapy

FixVAC
Off-the-shelf mRNA

BNT116

1. Synergistic potential; Partnered with 2 DualityBio; 3. MediLink; 4. Bristol Myers Squibb; 5. OncoC4.

BIONTECH

Evaluating BNT326/YL202[1] in Patients with Advanced NSCLC and BC

Key Inclusion Criteria

Inclusion NSCLC

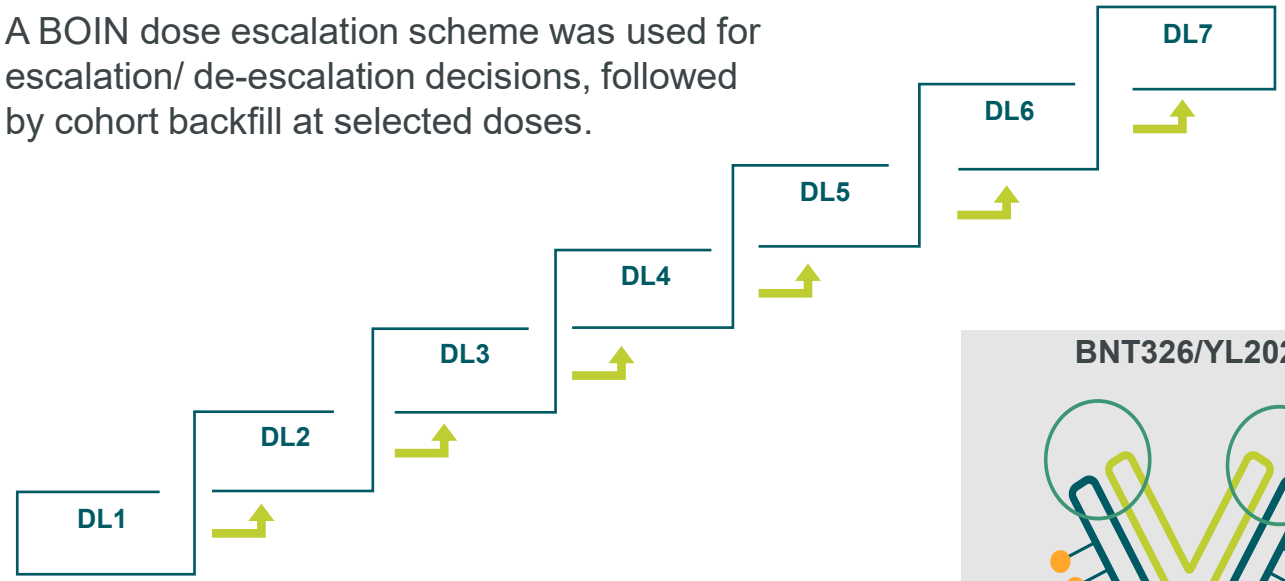
- Locally advanced/ metastatic disease
- EGFR-activating mutation (exon 19 deletion or L858R)
- Previous treatment with 3rd generation EGFR TKI, platinum-based CTx, and anti-PD-L1 antibody (US patients)
- ECOG PS of 0 to 2

Inclusion BC

- Unresectable, locally advanced or metastatic disease
- HR+ and HER2- (IHC 0, 1+, 2+/ISH–)
- Previous treatment with endocrine therapy combined with CDK4/6 inhibitor and 1–2 lines of CTx
- ECOG PS of 0 to 2

Dose escalation (n=80):

A BOIN dose escalation scheme was used for escalation/ de-escalation decisions, followed by cohort backfill at selected doses.



BNT326/YL202[1]

Target: HER3
Payload: topo I inhibitor
DAR = 8

Key Endpoints

Primary: Safety and tolerability, MTD
Secondary: Tumor activity

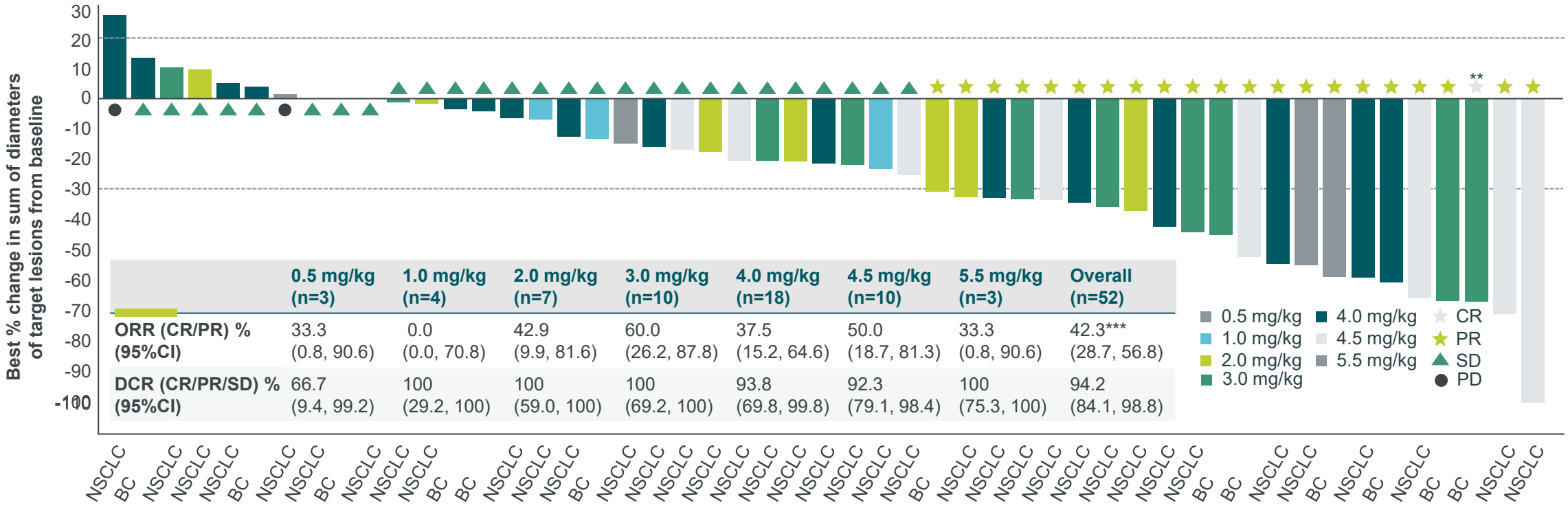
1. Partnered with MediLink.

BIONTECH

BNT326/YL202[1]: Encouraging Activity and Near-Complete Disease Control in Patients with Advanced Disease

FIH Phase 1 study: Clinical activity, best percent change from baseline in target lesion size (n=51*)

Cheng, Y. et al. ASCO 2024 #3034.



	0.5 mg/kg (n=3)	1.0 mg/kg (n=4)	2.0 mg/kg (n=7)	3.0 mg/kg (n=10)	4.0 mg/kg (n=18)	4.5 mg/kg (n=10)	5.5 mg/kg (n=3)	Overall (n=52)
ORR (CR/PR) % (95%CI)	33.3 (0.8, 90.6)	0.0 (0.0, 70.8)	42.9 (9.9, 81.6)	60.0 (26.2, 87.8)	37.5 (15.2, 64.6)	50.0 (18.7, 81.3)	33.3 (0.8, 90.6)	42.3*** (28.7, 56.8)
DCR (CR/PR/SD) % (95%CI)	66.7 (9.4, 99.2)	100 (29.2, 100)	100 (59.0, 100)	100 (69.2, 100)	93.8 (69.8, 99.8)	92.3 (79.1, 98.4)	100 (75.3, 100)	94.2 (84.1, 98.8)

Data Cut-Off: April 16, 2024

1. Partnered with MediLink. * One patient had non measurable target lesions at PD due to obstructive atelectasis induced by PD in non-target lesions and is therefore not presented in plot. ** CR occurred in patient with target lesion as lymph node that shrank to less than 10 mm. ***26.9% of patients had response confirmed on a subsequent scan; NCT05653752.

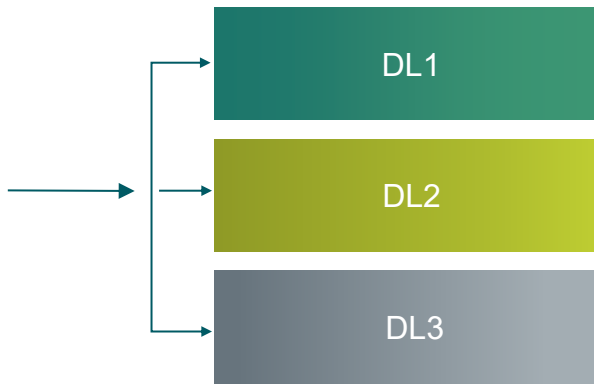
Broad Phase 2 Study to Evaluate BNT326/YL202[1] as a Monotherapy in Various Cancers

Phase 2 trial enrolling patients in China across NSCLC/BC/HNSCC and more

Key Inclusion Criteria

- Pretreated advanced or metastatic solid tumors
- ECOG PS 0-1
- Naïve to HER3-therapy

Phase 2 dose expansion cohorts



- 2L EGFRm NSCLC chemo naïve
- 3L+ EGFRm NSCLC post TKI & chemo
- SQ NSCLC
- NSQ NSCLC
- 2L HR+, HER2- BC post CDK4/6i
- 2L+ HNSCC

Key Endpoints

Primary: ORR & RP2D
Secondary: PFS, OS, safety

1. Partnered with MediLink, NCT06107686

BIONTECH

Evaluating BNT326/YL202[1] in Combination with Pumitamig[2] in Patients with Advanced Non-Small Cell Lung Cancer

600+ patients have been treated with BNT326/YL202; being also evaluated in combination with pumitamig in NSCLC across histologies, treatment lines

Key Inclusion Criteria

- Advanced squamous or non-squamous (all cohorts) NSCLC
- Measurable disease defined by RECIST 1.1
- ECOG PS ≤ 1

Part 1: Dose expansion

2L+, sq or non-sq NSCLC, AGA-neg/pos., any PD-L1

Optional: BNT326/YL202 (DL3) + pumitamig IV

BNT326/YL202 (DL2) + pumitamig IV

BNT326/YL202 (DL1) + pumitamig IV

Part 2a: Dose expansion

Cohort A: 2L+, sq or non-sq NSCLC, AGA-neg/pos., any PD-L1

R
- Arm 1: BNT326/YL202 (DL1) + pumitamig,
- Arm 2: BNT326/YL202 (DL2) + pumitamig

Cohort B: 1L, sq or non-sq NSCLC, AGA-neg, any PD-L1 (n = 40-80)

R
- Arm 1: BNT326/YL202 (DL1) + pumitamig
- Arm 2: BNT326/YL202 (DL2) + pumitamig

Part 2b: Dose optimization and contribution of components

Cohort C: 2L+, sq or non-sq NSCLC, AGA-negative or EGFR-activating mutation, any PD-L1., any PD-L1

R 1:1:1
- Arm 1: BNT326/YL202 + pumitamig, DL1
- Arm 2: BNT326/YL202 + pumitamig, DL2
- Arm 3 – Monotherapy: BNT326/YL202, DL1 or DL2

Cohort D1: 1L, sq or non-sq NSCLC, AGA-negative PD-L1 ≥50%

R 1:1:1
- Arm 1: BNT326/YL202 (DL2) + pumitamig
- Arm 2 - SOC: pembrolizumab
- Arm 3 – Monotherapy: pumitamig

Cohort D2: 1L+, sq or non-sq NSCLC, AGA-negative PD-L1 <50%

R 1:1
- Arm 1: BNT326/YL202 (DL2) + pumitamig
- Arm 2 - SOC: pembrolizumab + CTx

Key Endpoints

	Part 1	**Part 2a**	**Part 2b**
Primary:	Safety	ORR and safety	ORR
Secondary:			PFS, OS

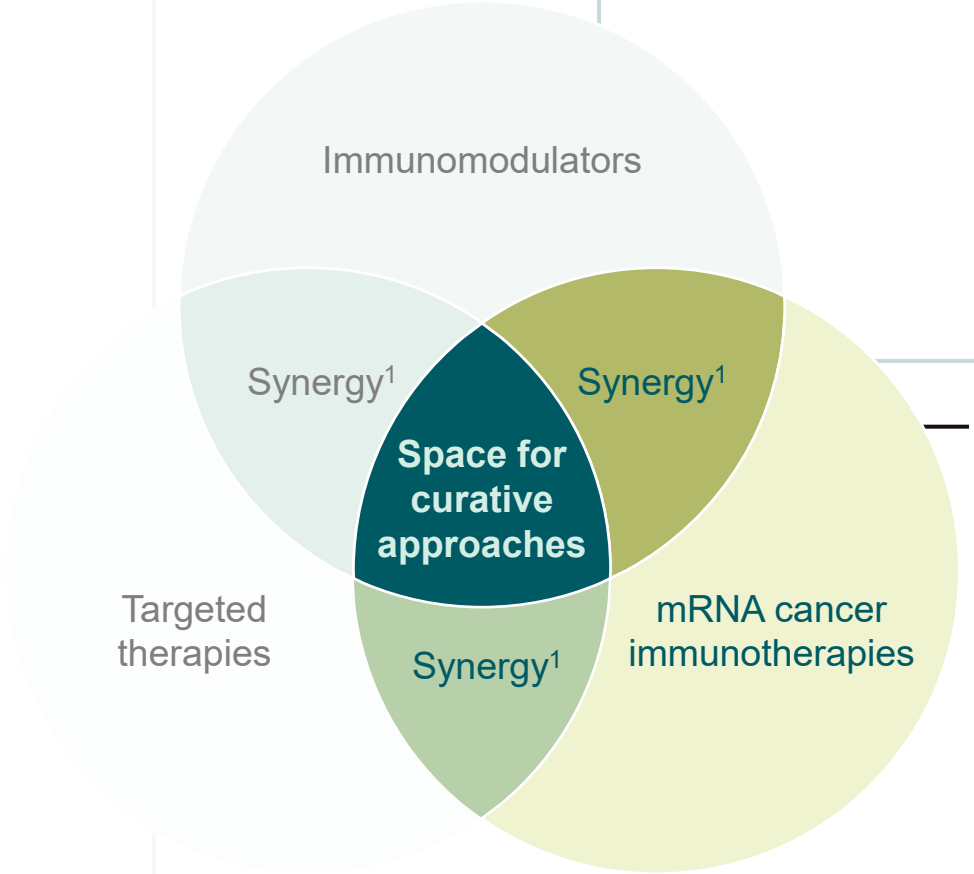
Partnered with: 1. MediLink; 2. Bristol Myers Squibb; (BNT326-02, NCT07111520)

BIONTECH

Our Diverse Lung Cancer Pipeline

Targeted therapies

- BNT324/ DB-1311[2] — Anti-B7H3 ADC
- BNT326/ YL202[3] — Anti-HER3 ADC
- BNT325/ DB-1305[2] — Anti-TROP2 ADC



Immunomodulators

- Pumitamig[4] — Anti-PD-L1/ Anti-VEGF
- Gotistobart[5] — Anti-CTLA-4

mRNA cancer immunotherapy

FixVAC Off-the-shelf mRNA → BNT116

1. Synergistic potential; Partnered with 2 DualityBio; 3. MediLink; 4. Bristol Myers Squibb; 5. OncoC4.

BIONTECH

BNT116[1]-Induced T-Cell Responses Have Been Observed in NSCLC

Vaccine induced CD4+ and CD8+ T-cell responses observed consistently

Öven BB, et. al. AACR 2024 CT051

Best vaccine response per patient, cell type and target, measured by IFNγ ELISpot post-IVS													BOR
Patient	CLDN6		KK-LC-1		MAGE-A3		MAGE-A4		MAGE-C1		PRAME		Inv.
	CD4+	CD8+	CD4+	CD8+	CD4+	CD8+	CD4+	CD8+	CD4+	CD8+	CD4+	CD8+	
03-016				■						■			SD
03-013	■	■	■	■	■		■	■	■	■	■		PR
03-018		■		■	■					■			PR

■ Induced T cell response (*ex vivo* ELISpot) ■ No response (*ex vivo* ELISpot)

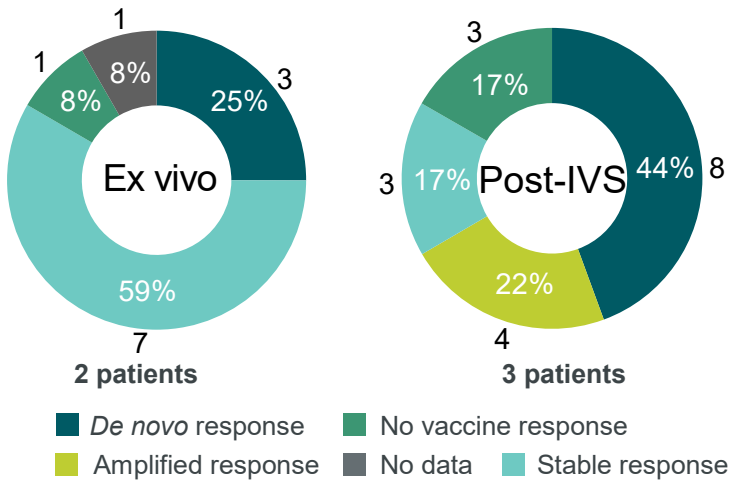
Summary of vaccine responses measured post-IVS by IFNγ ELISpot and response per RECISTv1.1

> 90% of NSCLC patients express ≥ 1 TAA

> 60% of NSCLC patients express ≥ 2 TAA

De novo and vaccine-expanded T-cell responses were observed across patients

Atmaca A, et. al. SITC 2024 P 1486



1. In collaboration with Regeneron; NCT05142189

BIONTECH

Broad Evaluation of FixVac mRNA Immunotherapy in Combination with ADCs and Immunomodulators in Lung Cancer

Key Inclusion Criteria

- Histologically confirmed NSCLC
- **Cohort 1–4, 7–9, 11:** unresectable Stage III or metastatic IV
- **Cohort 5, 11:** unresectable Stage III
- **Cohort 6:** resectable Stage II or III
- **Cohort 2, 4–6, 10, 11:** must tolerate anti-PD-1 therapy
- **Cohort 2, 3, 6, 7–9:** ECOG PS ≤1
- **Cohort 1, 4, 5, 10, 11:** ECOG PS 0-2

Key Endpoints

Primary: Safety
Secondary: ORR, DoR, DCR, PFS, OS

n= 280

Cohort 1, n=30	BNT116 monotherapy Optional: cemiplimab add-on from cycle 3 onwards (if eligible)
Cohort 2, n=20	BNT116 + cemiplimab PD-L1 TPS≥ 50%, after prior 1L/adj PD-1/PD-L1 inhibitor
Cohort 3, n=20	BNT116 + docetaxel After prior platinum-based therapy and PD-1 inhibitor (if eligible)
Cohort 4, n=20	BNT116 + cemiplimab (frail patients) Frail patients not eligible for 1L chemotherapy; PD-L1 TPS≥ 1%
Cohort 5, n=20	BNT116 + cemiplimab (after concurrent CRT) Unresectable Stage III NSCLC after chemoradiotherapy
Cohort 6, n=20	BNT116 + cemiplimab + carboplatin + paclitaxel (neoadjuvant) > surgery > BNT116 + cemiplimab (adjuvant) Resectable Stage II and III NSCLC eligible for neoadj. treatment
Cohort 7, n=30	BNT116 + gotistobart[3] After prior platinum-based chemotherapy and PD-1i (if eligible)
Cohort 8, n=30	BNT116 + BNT324/DB-1311[2] (B7H3 ADC) After prior platinum-based chemotherapy and PD-1i (if eligible)
Cohort 9, n=30	BNT116 + BNT326/YL202[4] (HER3 ADC) After prior platinum-based chemotherapy and PD-1i (if eligible)
Cohort 10, n=30	BNT116 + pumitamig[5] (frail patients) Frail patients not eligible for 1L chemotherapy
Cohort 11, n=30	BNT116 + pumitamig[5] (after concurrent CRT) Unresectable Stage III NSCLC after chemoradiotherapy

sitc 2023 — *Deme D et al.*

sitc2024 — *Atmaca A et al.*

AACR 2024 — *Öven BB et al.*

AACR Annual Meeting 2025 Chicago — *Dziadziuszko R et al.*

IASLC 2025 World Conference on Lung Cancer — *Atmaca A et al.*

1. In collaboration with Regeneron; Partnered with: 2. DualityBio; 3. OncoC4; 4. MediLink; 5. Bristol Myers Squibb; NCT05142189.

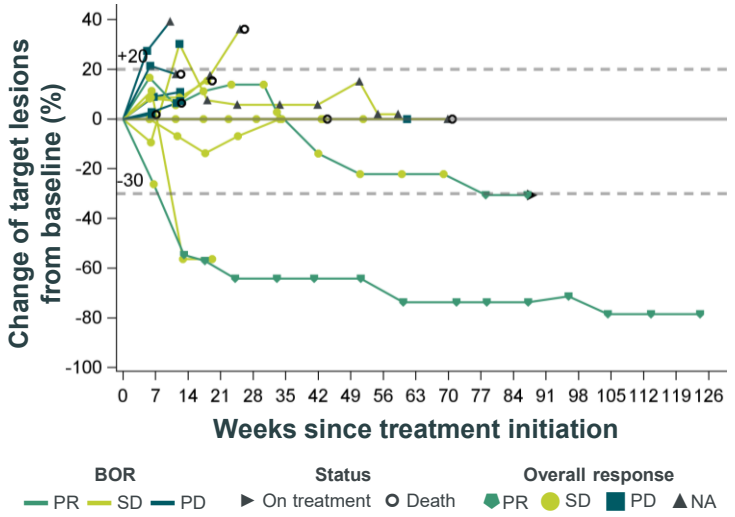
BIONTECH

BNT116 Has Shown Clinical Activity as Single Agent & in Combination with Chemo or Anti-PD-1 in Advanced NSCLC in Phase 1 Trial[1]

BNT116 monotherapy plus cemiplimab add-on from cycle 3

Deme et al. SITC 2023

Progression after PD-(L)1 therapy, platinum-based chemotherapy, and one other systemic therapy

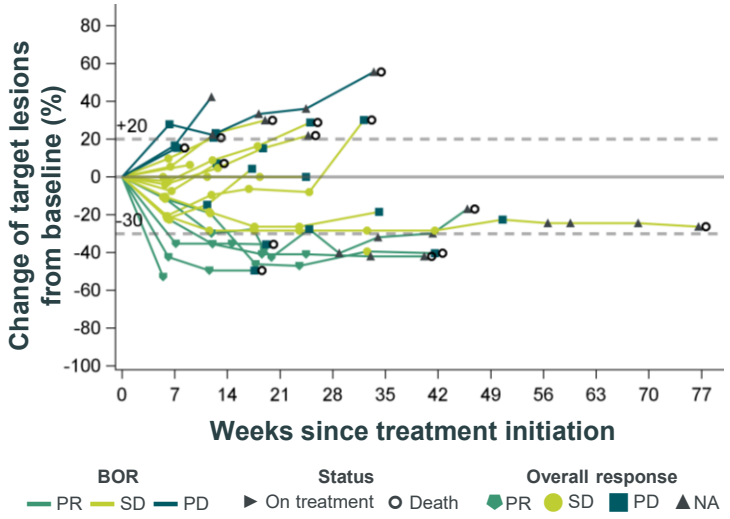


Combination therapy with BNT116 plus cemiplimab is active with DCR of 45% in heavily pre-treated lung cancer patients

BNT116 plus docetaxel

Öven et al. AACR 2024

Progression after PD-(L)1 therapy and platinum-based chemotherapy

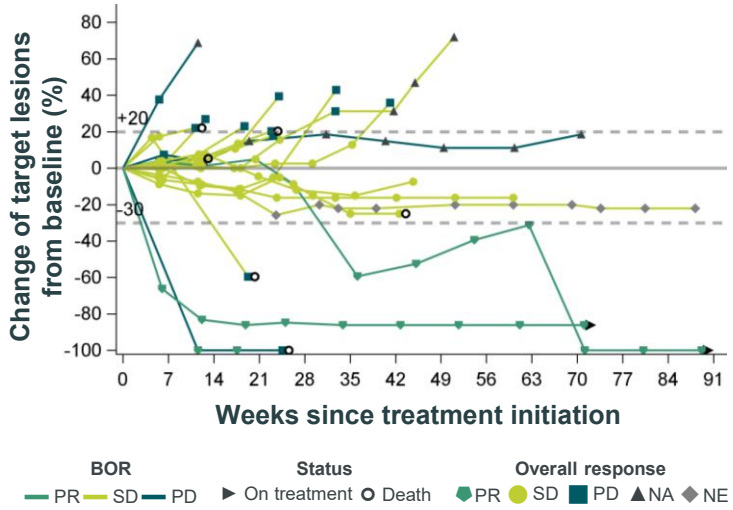


Combination therapy with BNT116 plus docetaxel is active with ORR of 30%, DCR of 85% and mPFS of 4.4 months

BNT116 plus cemiplimab

Atmaca et al. SITC 2024

NSCLC with PD-(L)1 TPS ≥50% that progressed after PD-(L)1 therapy as first-line or adjuvant therapy



Combination therapy with BNT116 plus cemiplimab is active with DCR of 80% and mPFS of 5.5 months

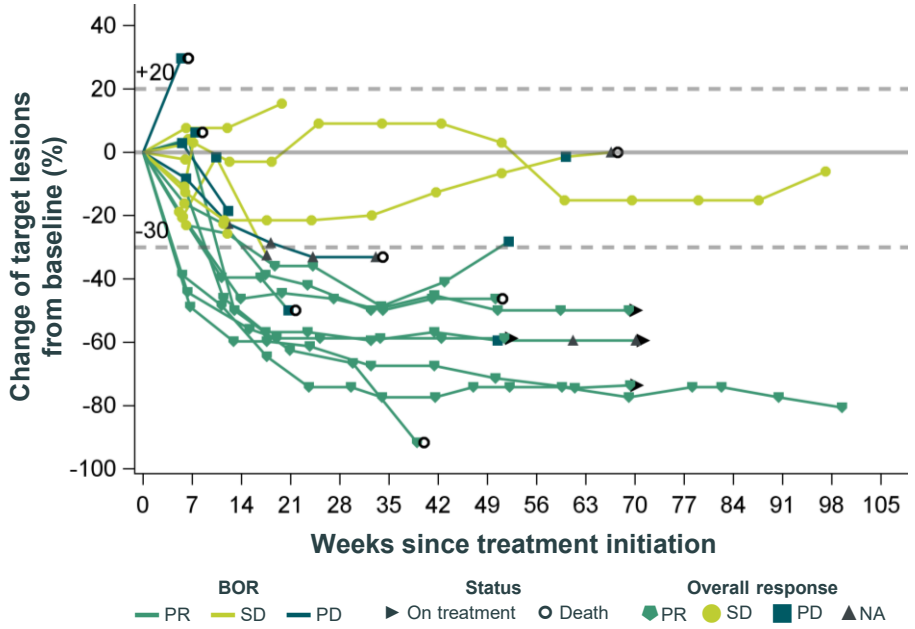
1. In collaboration with Regeneron; NCT05142189.

BIONTECH

BNT116 Has Shown Clinical Activity in Combination with Anti-PD-1 in Advanced NSCLC in Phase 1 Trial[1]

BNT116 plus cemiplimab in frail patients
Dziadziuszko et al. AACR 2025

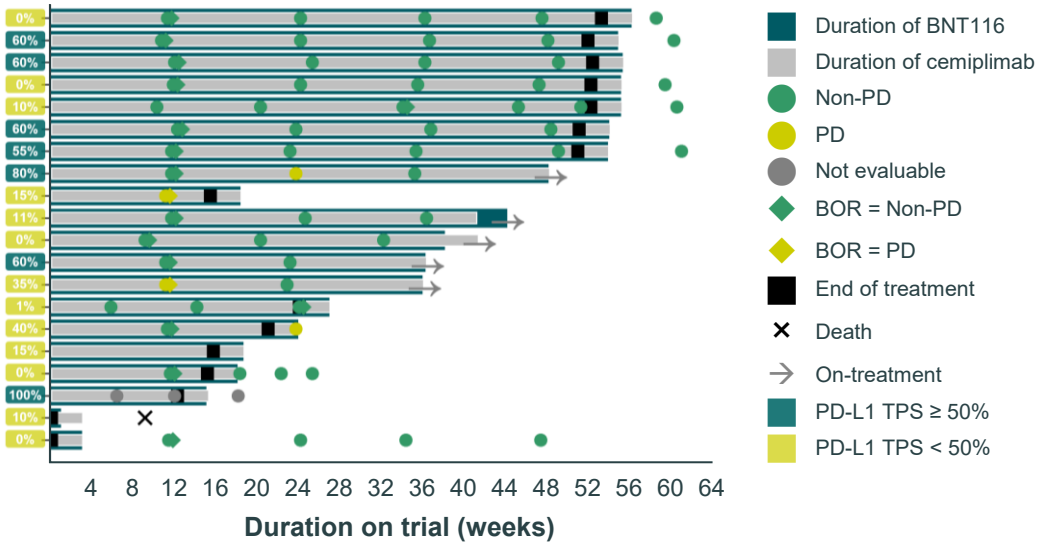
Frail patients unfit for 1L chemotherapy with TPS ≥1% advanced NSCLC



Combination therapy with BNT116 plus cemiplimab is active in frail patients with advanced NSCLC with ORR of 45%, DCR of 75% and mPFS of 9.9 months

BNT116 plus cemiplimab as consolidation treatment
Atmaca et al. WCLC 2025

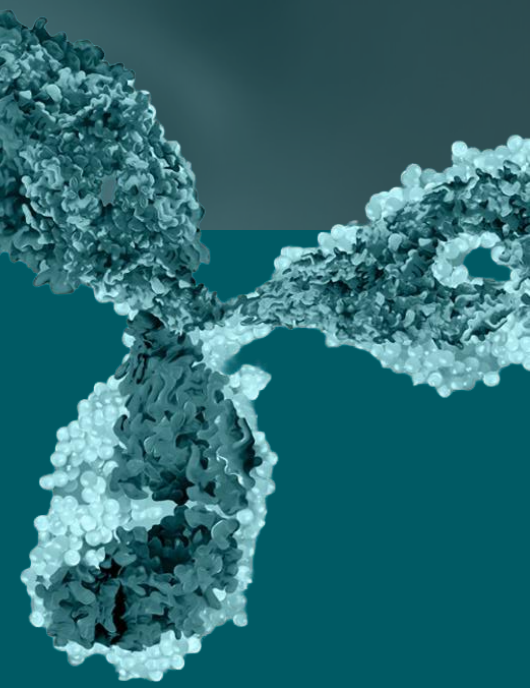
Advanced NSCLC patients after concurrent chemoradiotherapy



Combination therapy with BNT116 plus cemiplimab indicated encouraging clinical activity with 12-month OS rate of 95%

1. In collaboration with Regeneron; NCT05142189

Ongoing and Next Steps | Thoracic Cancer



Establishing pumitamig as a potential **frontline treatment for lung cancer**

ROSETTA Lung-01[1]

Pumitamig + chemotherapy
in 1L ES-SCLC

ROSETTA Lung-02[1]

Pumitamig + chemotherapy
in 1L NSCLC

Exploring novel combinations to identify **potential future standards-of-care**

PRESERVE-003[2]

Gotistobart[2]
in 2L+ sqNSCLC

Part 1 non-pivotal data to be presented at IASLC-NACLC on December 6, 2025

Providing new options for **IO experienced sqNSCLC**

Pumitamig[1]**/ FixVac + ADCs**

in metastatic disease

Pumitamig[1] **+ FixVac**

in early disease

Novel combination data to be presented in 2026

Partnered with: 1. Bristol Myers Squibb; 2. OncoC4.

BIONTECH

Coffee Break

15 minutes

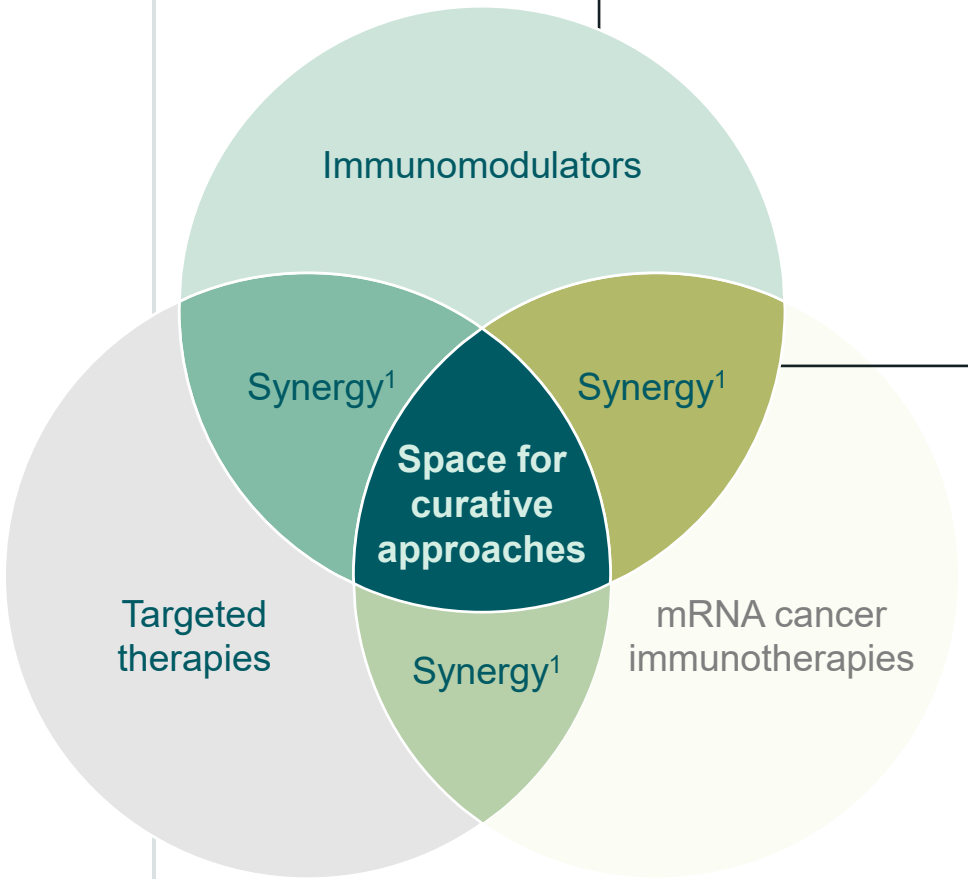
Breast Cancer

BIONTECH

Our Diverse Breast Cancer Pipeline

Targeted therapies

- Trastuzumab pamirtecan[2] — Anti-HER2 ADC
- BNT325/ DB-1305[2] — Anti-TROP2 ADC
- BNT326/ YL202[3] — Anti-HER3 ADC



Immunomodulators

- Pumitamig[4] — Anti-PD-L1/ Anti-VEGF

1. Synergistic potential; Partnered with 2. DualityBio; 3. MediLink; 4. Bristol Myers Squibb.

BIONTECH

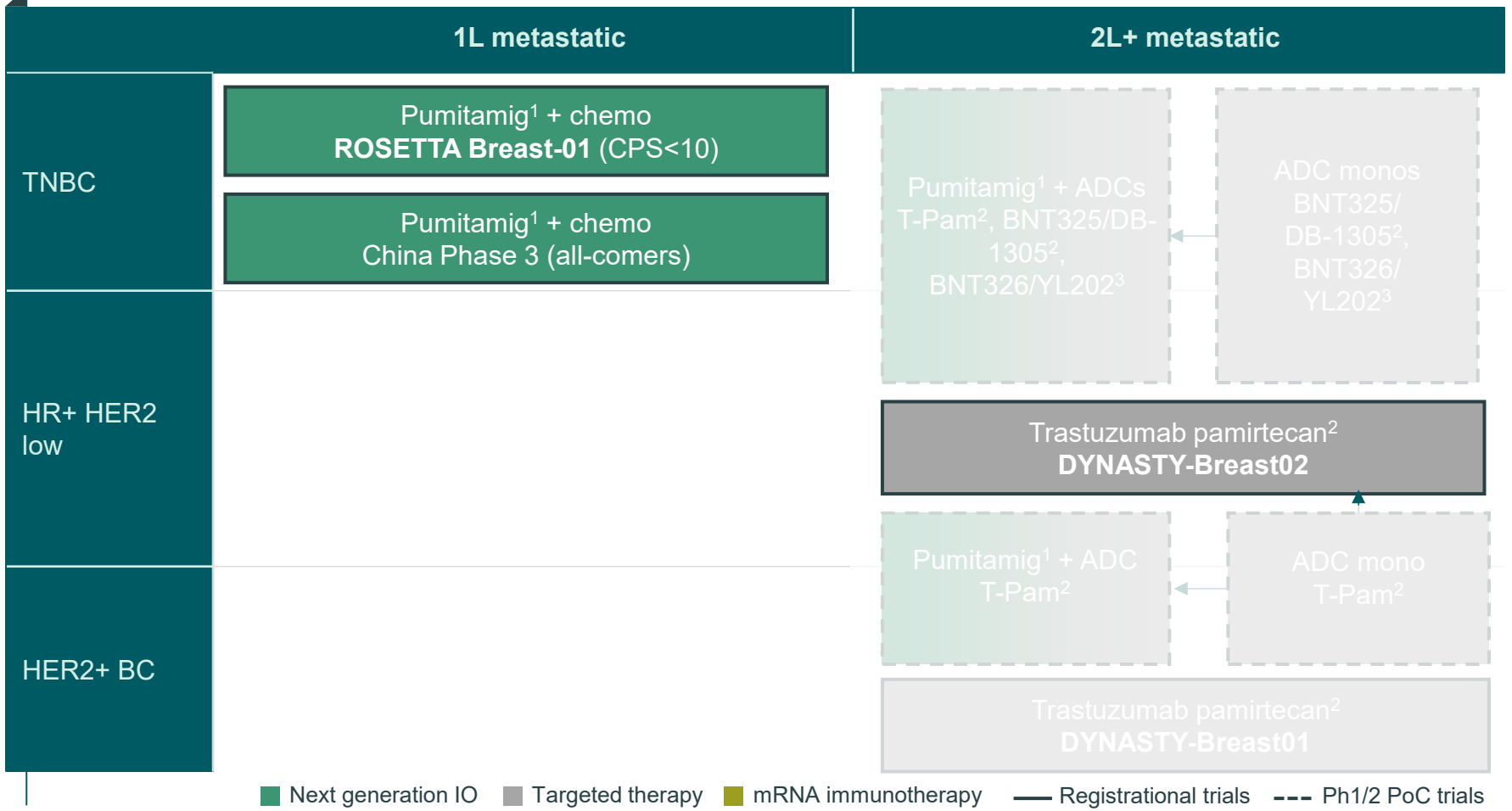
BioNTech's Currently Ongoing Trials* in Breast Cancer

Registrational trials in metastatic breast cancer

- Pumitamig[1] aiming to improve on SoC in 1L TNBC CPS<10, (historically insensitive to PD-(L)1)
- Trastuzumab pamirtecan mono Ph1/2 data informed pivotal trial in HER2 low BC enabling first potential BNT approval in BC

PoC trials with ADC mono and novel combinations to inform future registrational trials

- Emerging data from multiple BNT ADCs in breast cancer informed pumitamig + ADC PoC trials
- Parallelly exploring multiple combinations to inform the right combination for the right patient segment & accelerate registrational trial

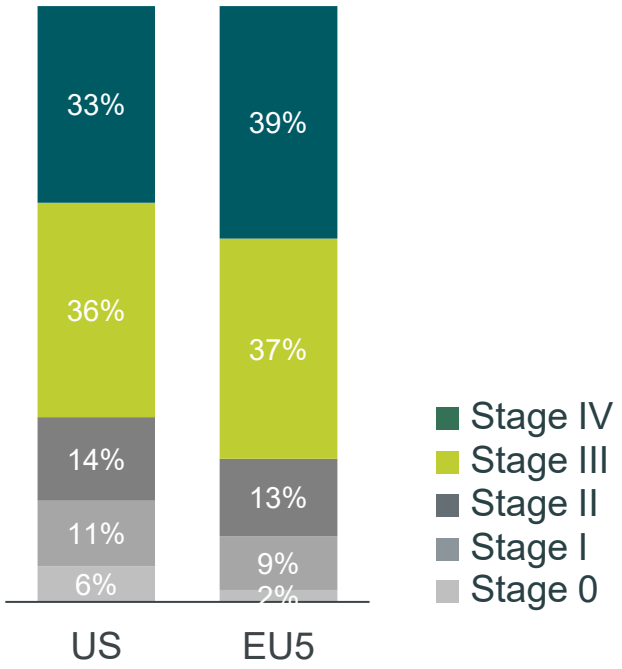


Partnered with: 1. Bristol Myers Squibb; 2. DualityBio; 3. MediLink *As of November 2025

TNBC Patients Face Poor Outcomes Due to Limited Therapeutic Options

2030 U.S., EU4, U.K. TNBC incidence[1] **~65k**

BC staging distribution[2]



Treatment outcomes vary based on PD-L1 levels in 1L TNBC

	PD-L1 CPS < 10 (~ 55%)[3,4]	PD-L1 CPS ≥ 10 (~ 45%)[3,4]
mOS	**Chemo: 15.0 mos** (KN-355) [4]	**Pembro + chemo: 23.0 mos** (KN-355) [4]
4-year OS	**Chemo: ~ 15 – 20%** (KN-355) [4]	**Pembro + chemo: ~ 25 – 30%** (KN-355) [4]
5-year survival Stage IV[2]	**10%**	

1. Incidence from SEER (US); Zentrum für Krebsregisterdaten (DE); Globocan (ES); Sante Publique (FR); AIOM (IT); Cancer Research UK 2. CancerMPact® 2024 Treatment Architecture EU5 and US 3. Danziger N, et al, Oncologist, 2023 Apr 6;28(4):319-326. 4. Cortes, J, et al. N. Engl. J. Med. 2022, 387, 217–226.

BIONTECH

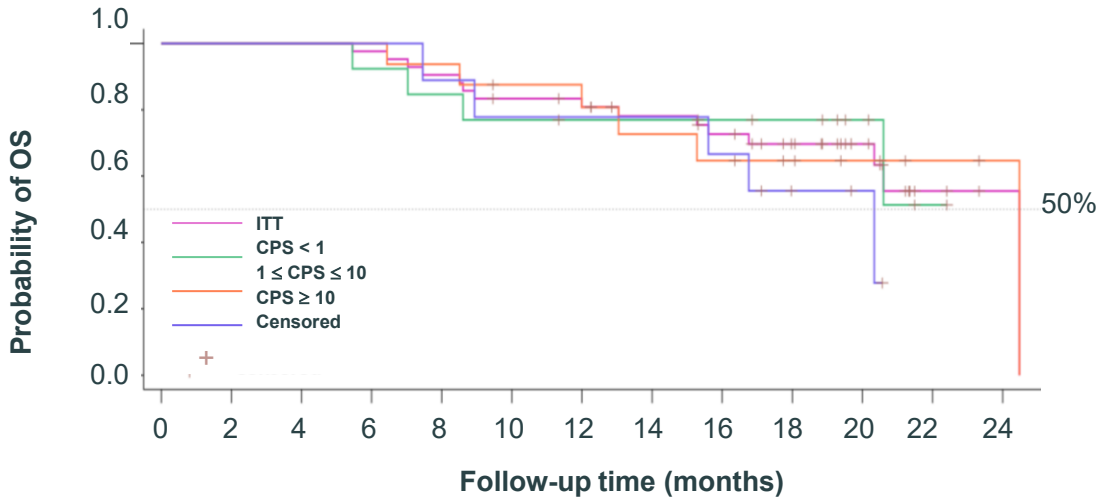
Pumitamig[1] in 1L Triple Negative Breast Cancer

Clinical Benefit Irrespective of PD-L1 Status | **Manageable Safety Profile** | **Novel Combinations Being Evaluated in Parallel**

Patient Population	ITT2	PD-L1 CPS<1	PD-L1 1≤CPS<10	PD-L1 CPS≥10
N	42	13	16	9
cORR (%)	**73.8**	**76.9**	**56.3**	**100.0**
DCR (%)	95.2	100.0	93.8	100.0
mPFS (months)	13.5	18.1	14.0	10.8
18-mo OS rate %	**69.7**	**76.9**	**64.6**	**55.6**
Congress	SABCS 2024			

Jiong Wu et al. SABCS 2024 PS3-08

Phase 1/2 Study*: Interim overall survival (pumitamig + nab-paclitaxel)



Benchmark data[2] 1L TNBC

Regimen	ORR	mPFS	mOS	Study
Chemo (CPS <10)	35%	5.6 mo	15.2 mo	KN-355[3]
Pembro + Chemo (CPS ≥ 10)	53%	9.7 mo	23.0 mo	

1. Partnered with Bristol Myers Squibb; 2. This benchmarking is not based on head-to-head trials between BioNTech's investigational candidates and other products or product candidates. Furthermore, definitive conclusions cannot be drawn from cross-trial comparisons or anticipated data, as they may be confounded by various factors, and should be interpreted with caution; 3. Cortes, J, et al., New England Journal of Medicine, 2022; *NCT05918133

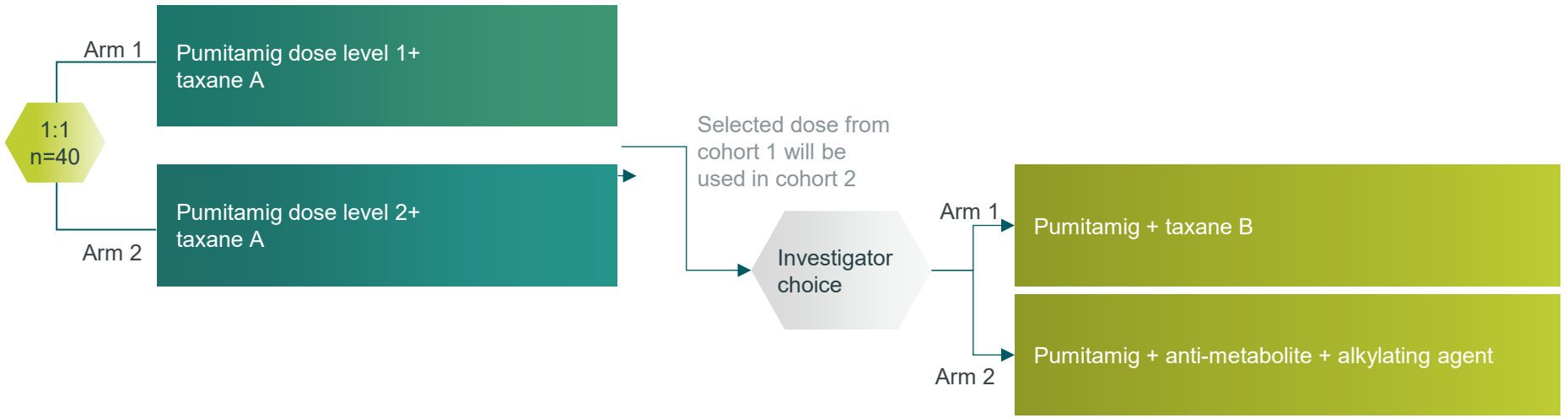
BIONTECH

Pumitamig[1] Global Phase 2 in Combination with Chemotherapy for 1L/2L Triple Negative Breast Cancer

Trial enrolling heterogenous population across 1L/2L, IO naïve and experienced

Key Inclusion Criteria

- Histologically confirmed, Ia/ mTNBC
- 1L or 2L
- If recurrent, stage I-III BC, at least 6 months has elapsed between completion of treatment with curative intent
- ECOG PS 0,1



Key Endpoints

Primary: ORR per RECIST v1.1 and safety according to NCI-CTCAE v5.0

Data expected at SABCS 2025

1. Partnered with Bristol Myers Squibb 2. Cortes, J, et al. N. Engl. J. Med. 2022; BNT327-02: NCT06449222.

BIONTECH

Phase 3 Study of Pumitamig[1] in Combination with Chemotherapy in PD-L1 negative TNBC

ROSETTA BREAST-01

Phase 3, multi-site, randomized, double-blind trial of pumitamig in combination with chemotherapy versus placebo with chemotherapy in previously untreated locally recurrent inoperable or metastatic PD-L1 negative TNBC

Key Inclusion Criteria

- Locally recurrent inoperable or metastatic TNBC
- Ineligible for PD-(L)1 + chemo per their tumor PD-L1 expression status
- No prior systemic therapy for TNBC in the advanced setting

n=558
R 1:1

Pumitamig + chemotherapy of physician's choice

Placebo + chemotherapy of physician's choice

Key Endpoints

Primary: PFS (BICR) and OS

Benchmark Comparator Data for 1L TNBC (CPS <10)

Regimen	ORR	mPFS	mOS	Benchmark study
Chemotherapy	35%	5.6 mo	15.2 mo	KEYNOTE-355[2]

1. Partnered with Bristol Myers Squibb; 2. Cortes, J, et al. N. Engl. J. Med. 2022; NCT07173751.

BIONTECH

Our Diverse Breast Cancer Pipeline

Targeted therapies

Trastuzumab pamirtecan[2]

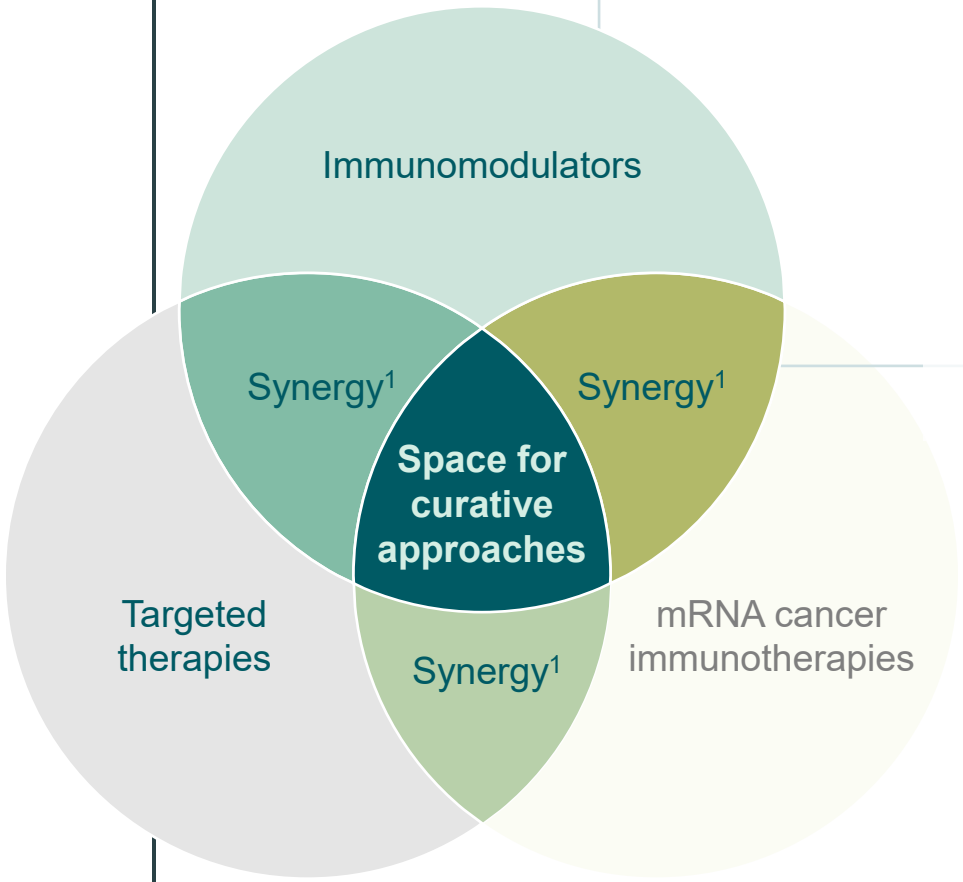
Anti-HER2 ADC

BNT325/ DB-1305[2]

Anti-TROP2 ADC

BNT326/ YL202[3]

Anti-HER3 ADC



Immunomodulators

Pumitamig[4]

Anti-PD-L1/ Anti-VEGF

1. Synergistic potential; Partnered with 2. DualityBio; 3. MediLink; 4. Bristol Myers Squibb.

BIONTECH

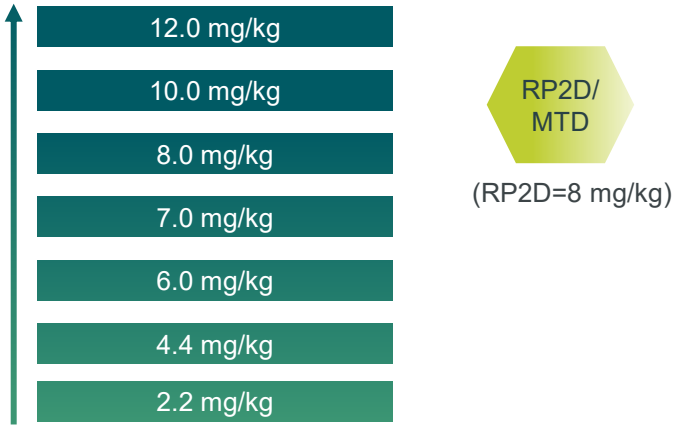
Evaluating T-Pam[1] in Patients With Advanced HER2-Expressing Solid Tumors

Key Inclusion Criteria

- Pretreated advanced or metastatic solid tumors
- HER2-positive or HER2-expressing cancers
- Previous systemic therapies
- ECOG PS 0-1

Part 1: **Dose escalation** (n=88 patients)

HER2 IHC 3+, IHC 2+, IHC 1+ or ISH+, or HER2 amplification and mutation by NGS)



Part 1: **Dose escalation** (n=88 patients)

Trastuzumab-treated HER2+ (IHC3+, IHC2+/ISH positive) gastric or GEJ adenocarcinoma, esophageal carcinoma and CRC

- Both HER2 overexpression and HER2 low (IHC3+,2+,1+ or ISH positive) endometrial carcinoma
- HR+/HER2 Low (IHC2+ /ISH negative, or IHC1+) breast cancer
- HER2+ (IHC3+, IHC2+/ISH positive) breast cancer
- NSCLC with activating HER2 mutation
- HER2+ or HR+/HER2-low breast cancer with treatment failure of trastuzumab deruxtecan (HER2+ BC; HR+/HER2-low BC)

Key Endpoints

Safety, tolerability, pharmacokinetic, preliminary anti-tumor activity at the selected MTD/RP2D

1. Partnered with DualityBio; NCT05150691..

BIONTECH

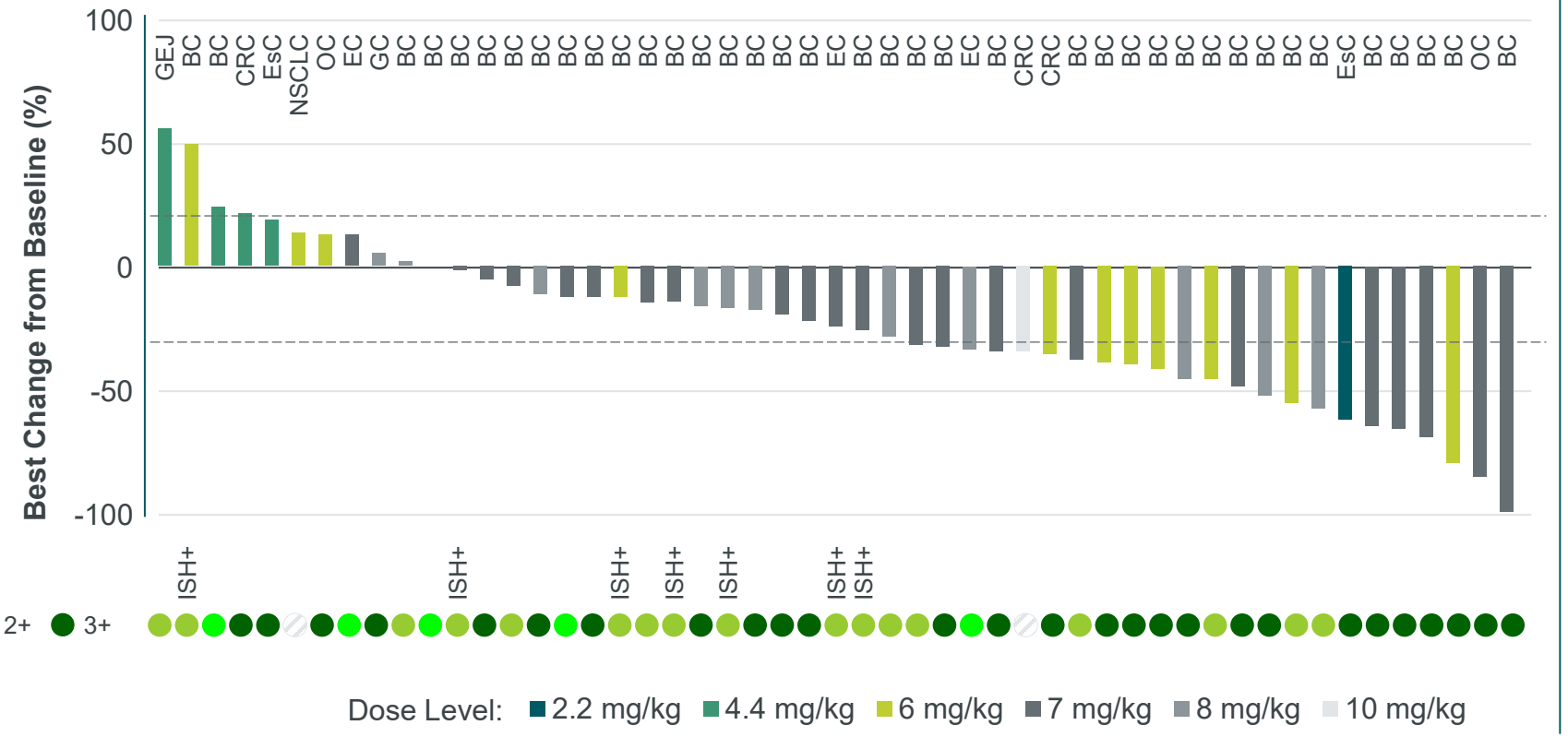
Trastuzumab-Pamirtecan[1] Demonstrates Encouraging Antitumor Activity in HER2-Expressing Patients

Phase 1/2a*: Clinical Efficacy

Moore K. et al. ASCO 2023 #3023.

Anti-tumor activity in heavily pretreated HER2-expressing patients

	ORR, %	DCR, %
All patients (n=52)	44.2	88.5
HER2+ breast cancer (n=26)	50.0	96.2
HER2 low breast cancer (n=13)	38.5	84.6



1. Partnered with DualityBio; *NCT05150691.

BIONTECH

Phase 3 Trial Design T-Pam[1] in Chemotherapy-Naïve Patients with HR+ HER2-Low Breast Cancer

Key Inclusion Criteria

- Adult participants, aged 18 years and older
- Documented advanced or metastatic HR+/HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer
- Progressed on at least 2 lines of prior ET or within 6 months of first line ET + CDK4/6 inhibitor in the metastatic setting
- No prior chemotherapy for advanced or metastatic breast cancer*
- ECOG performance status 0 or 1

n=532
R 1:1

Experimental arm:
Trastuzumab-pamirtecan
8 mg/kg IV, Q3W

Investigator's choice single agent chemotherapy
(paclitaxel or nab-paclitaxel or capecitabine)

Historical efficacy chemotherapy in BC patients:[2]
ORR = 11-36%;
mPFS = 3-8 months;
mOS = 9-16 months

Randomized patients are treated until:

- RECIST 1.1 defined disease progression or
- unacceptable toxicity or
- withdrawal of consent or
- any other criterion for discontinuation is met

Key Endpoints

Primary: PFS
Secondary: OS, ORR, safety

1. Partnered with DualityBio; 2. Twelves C. et al. Clinical Breast Cancer. 202;. NCT06018337;
* Subjects who have received chemotherapy in the neo-adj. or adj. setting are eligible, as long as they have had a disease-free interval (defined as completion of systemic chemotherapy to diagnosis of adv. or met disease) of >12 months.

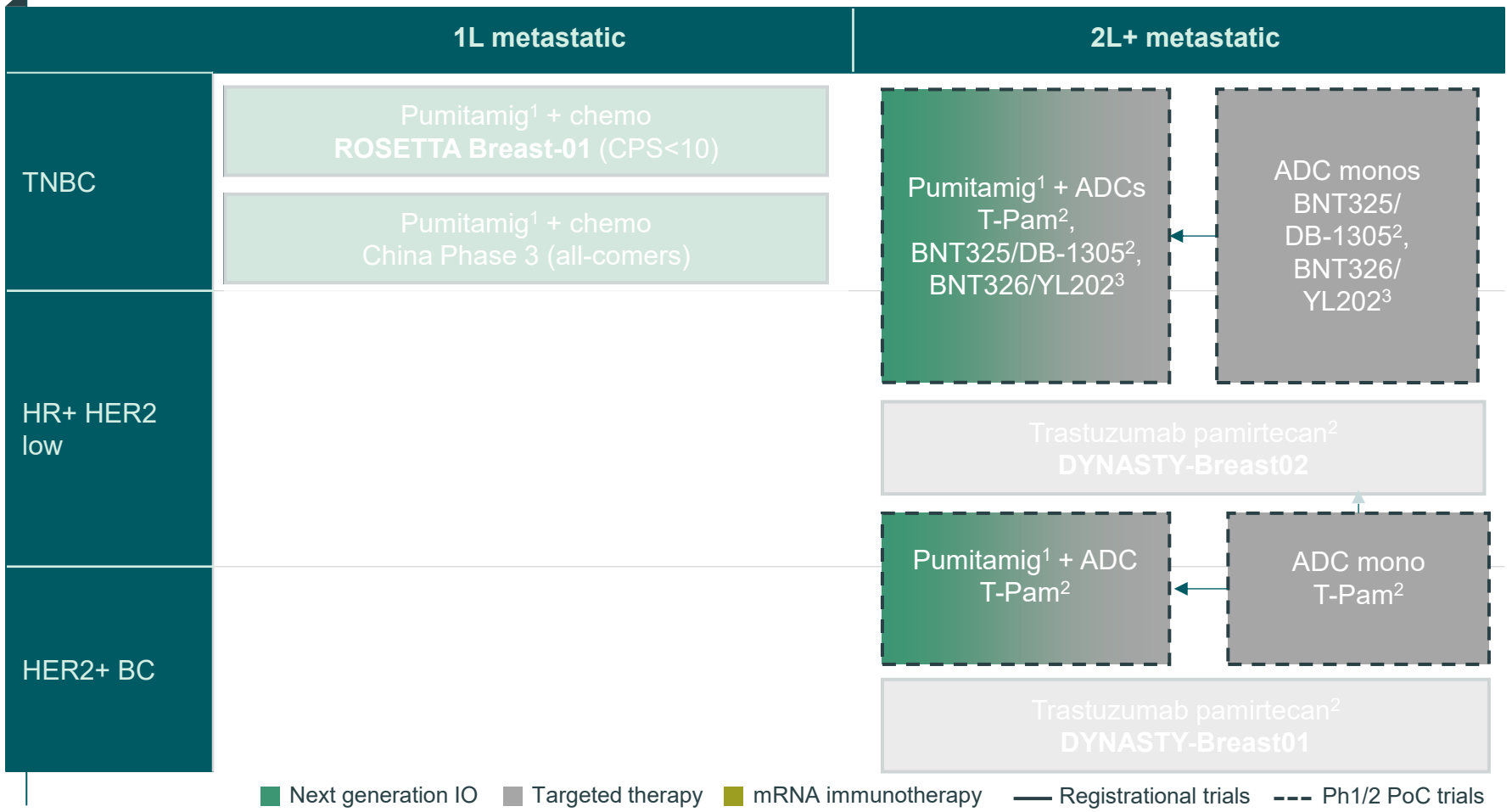
BioNTech's Currently Ongoing Trials* in Breast Cancer

Registrational trials in metastatic breast cancer

- Pumitamig[1] aiming to improve on SoC in 1L TNBC CPS<10, (historically insensitive to PD-(L)1)
- Trastuzumab pamirtecan mono Ph1/2 data informed pivotal trial in HER2 low BC enabling first potential BNT approval in BC

PoC trials with ADC mono and novel combinations to inform future registrational trials

- Emerging data from multiple BNT ADCs in breast cancer informed pumitamig + ADC PoC trials
- Parallelly exploring multiple combinations to inform the right combination for the right patient segment & accelerate registrational trial



Partnered with: 1. Bristol Myers Squibb; 2. DualityBio; 3. MediLink *As of November 2025

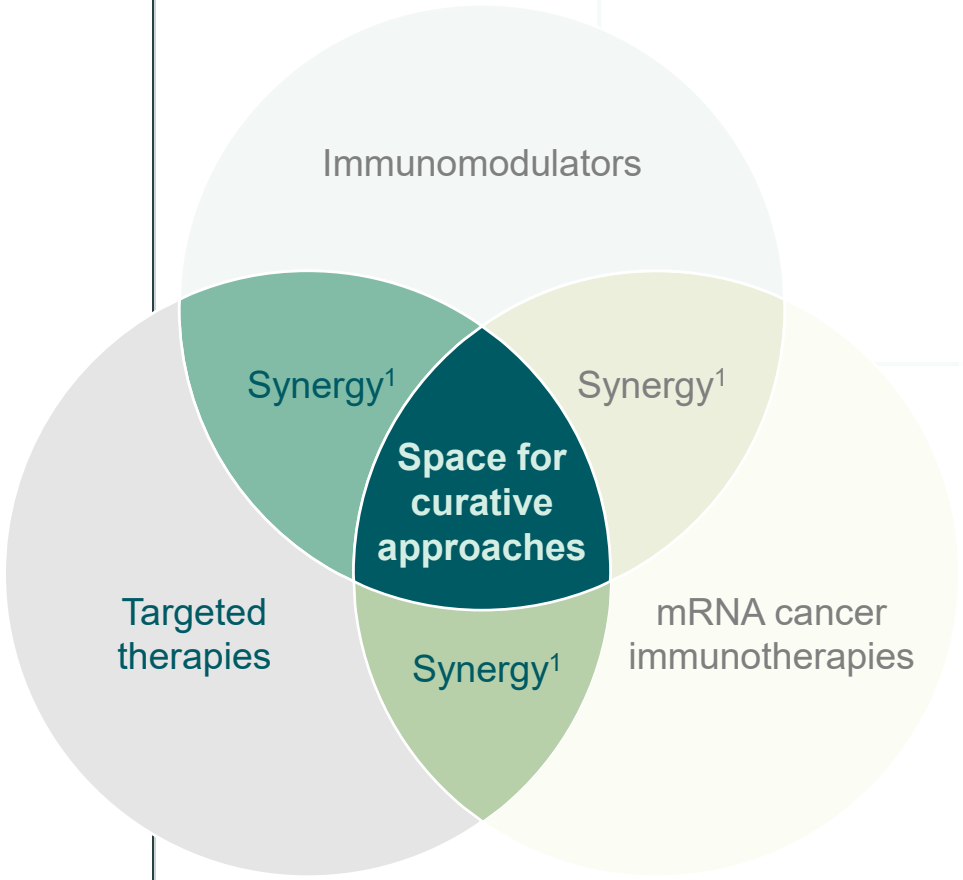
Our Diverse Breast Cancer Pipeline

Targeted therapies

Trastuzumab pamirtecan[2]
Anti-HER2 ADC

BNT325/ DB-1305[2]
Anti-TROP2 ADC

BNT326/ YL202[3]
Anti-HER3 ADC



Immunomodulators

Pumitamig[4]
Anti-PD-L1/ Anti-VEGF

1. Synergistic potential; Partnered with 2. DualityBio; 3. MediLink.

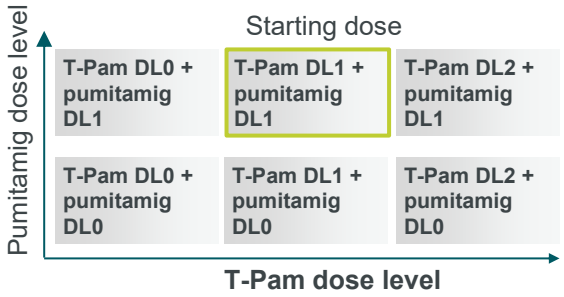
T-Pam: Phase 1/2 Study of T-Pam[1] in Combination with Pumitamig[2] in Advanced Breast Cancer

Phase 1/2 trial to evaluate efficacy, safety and pharmacokinetics of T-Pam in combination with pumitamig in participants with advanced breast cancer

Key Inclusion Criteria

- HR+ HER2-low (IHC 1+ or IHC 2+/ISH–) BC
- At least one line of prior ET +/– targeted therapy
- One to three lines of prior CTx

Part 1: Dose escalation



Key Inclusion Criteria

Dose optimization cohort
Cohort 1
- HR+, HER2-low or HER2-ultralow BC
- At least one prior line of ET +/– targeted therapy
- No prior CTx for the treatment of locally advanced, unresectable or metastatic disease

Part 2: Dose optimization cohorts

R 2:2:1:1

- Arm 1 → **RP2D: T-Pam + pumitamig**
- Arm 2 → **RP2D or lower dose: T-Pam + pumitamig**
- Arm 3 → **Monotherapy: T-Pam**
- Arm 4 → **Monotherapy: pumitamig**

Exploratory cohorts

Cohort 2
- HR– or HR+, HER2-positive BC
- At least one prior line of taxane-based CTx in combination with HER2-targeted therapies

Cohort 3
- HR+, HER2-null BC after ET
- 1-3 prior lines of CTx

Cohort 4
- TNBC
- At least one prior line of therapy which may include CTx with or without an anti-PD(L)1 inhibitor

Part 2: Exploratory cohorts

→ **T-Pam + pumitamig**

Key Endpoints

	Part 1	**Part 2**
Primary:	Safety	ORR
Secondary:	ORR	DOR, DCR, PFS

Partnered with: 1. DualityBio; 2. Bristol Myers Squibb; NCT06827236.

BIONTECH

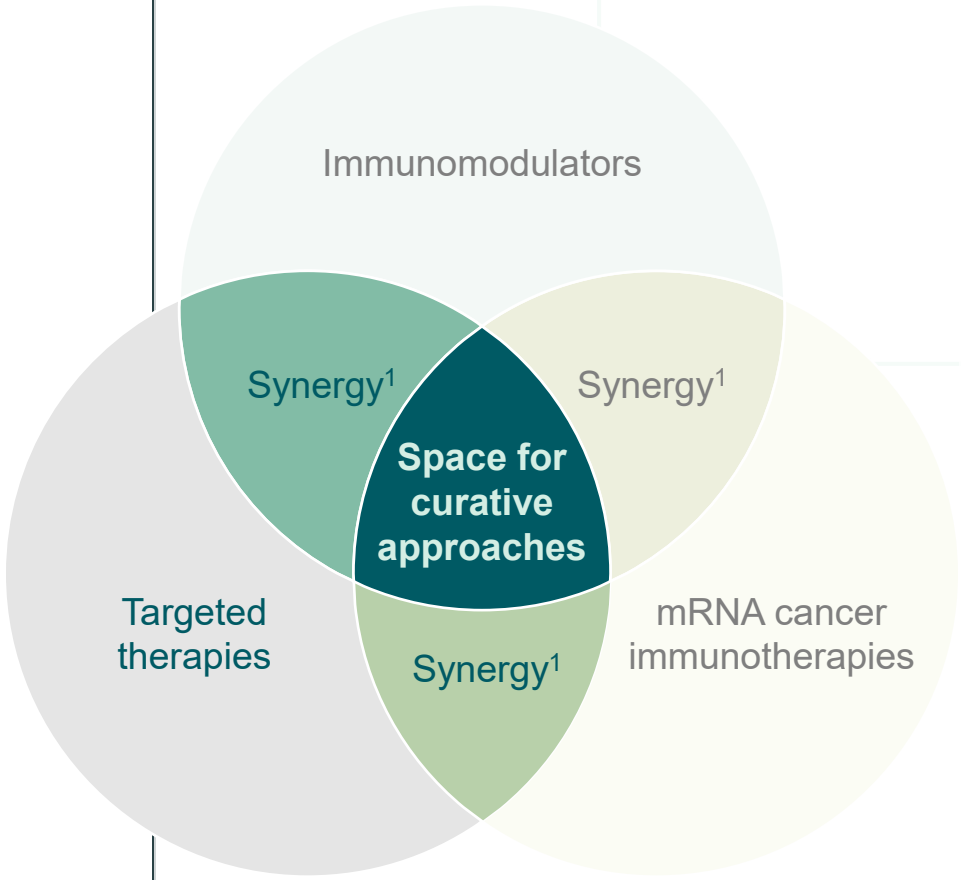
Our Diverse Breast Cancer Pipeline

Targeted therapies

Trastuzumab pamirtecan[2]
Anti-HER2 ADC

BNT325/ DB-1305[2]
Anti-TROP2 ADC

BNT326/ YL202[3]
Anti-HER3 ADC



Immunomodulators

Pumitamig[4]
Anti-PD-L1/ Anti-VEGF

1. Synergistic potential; Partnered with 2. DualityBio; 3. MediLink.

Phase 2 Trials Evaluating BNT326/YL202[1] as a Monotherapy in Patients with Advanced Breast Cancer

Phase 2 trial to evaluate BNT326/YL202 in patients with advanced/metastatic breast cancer

Global Phase 1/2 randomized, open-label, adaptive, two-part trial to evaluate BNT326/YL202 as monotherapy and in combination with pumitamig in across solid, including breast cancer

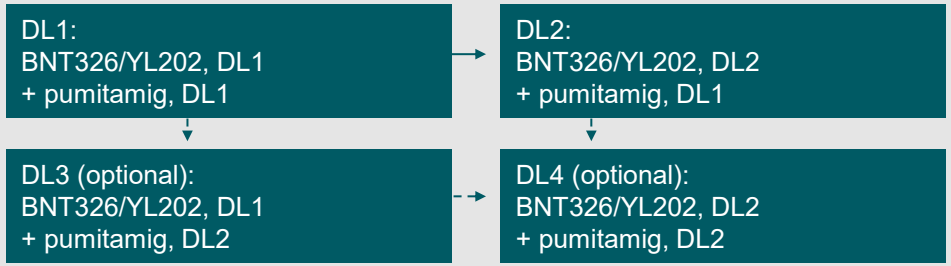
Cohorts
Cohort A: TNBC HER2 IHC score of 0, 1+, 2+/ISH-, estrogen receptor (ER) and progresterone receptor (PR) expression <1%
Cohort B: HR+ and HER2-null and HER2-low expression) HR+ and HER2-null expression (HER2 no expression, HER2 ultralow expression [0 < IHC < 1+]) and HER2-low expression (IHC score of 1+, 2+/ISH-)
Cohort C: HER2-low/null BC post ADC treatment HER2-low/null BC patients who have failed prior HER2-ADC or TROP2-ADC treatment

Part 1: Safety & dose expansion (Monotherapy)
Cohort 1A: 2L+ Cutaneous melanoma
Cohort 1B: 2L+ NSCLC
Cohort 1C: 2L+ EGFRm NSCLC
Cohort 1D: Rare melanoma (acral/uveal/mucosal)
Cohort 1E: Other advanced solid tumors

Part 2: Combination therapy

Cohort 2A: 2L+ Cutaneous melanoma

Cohort 2B: HER2-negative breast cancer



Ongoing and Next Steps | Breast Cancer

Establishing pumitamig[1] as a potential **frontline treatment for TNBC**

ROSETTA Breast-01[1]

Pumitamig + chemotherapy in 1L TNBC CPS < 10

China Phase 3

Pumitamig + chemotherapy in 1L TNBC

Data expected in 2026

Evaluating novel pumitamig[1] + ADC combinations to **bring checkpoint inhibition to additional breast cancer subtypes and treatment settings**

Pumitamig[1] + ADCs

Novel combination data expected in 2026

Establishing trastuzumab pamirtecan[2] as a **backbone for HER2-expressing breast cancers**

DYNASTY Breast-02[2]

Trastuzumab pamirtecan in chemo naïve HR+, HER-2 low BC

Data expected in 2026

Partnered with: 1. Bristol Myers Squibb; 2. DualityBio.

BIONTECH

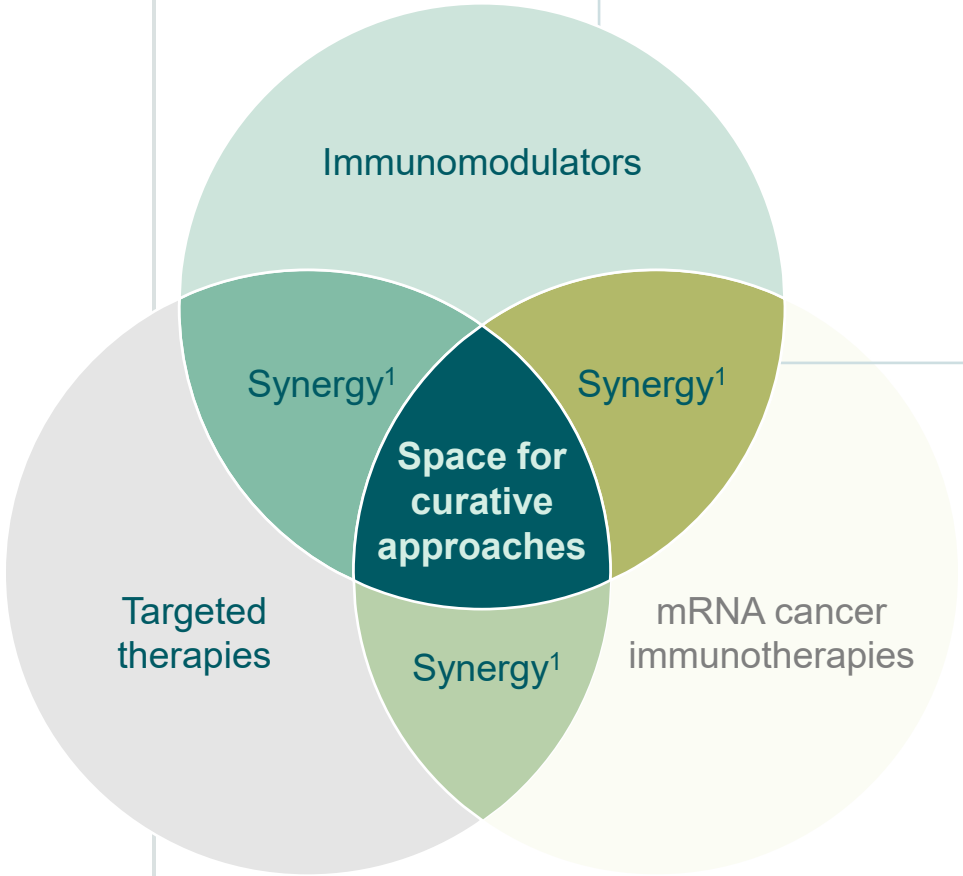
Gynecologic Cancers

BIONTECH

Our Diverse Gyn Cancer Pipeline

Targeted therapies

- BNT324/ DB-1311[2] — Anti-B7H3 ADC
- BNT325/ DB-1305[2] — Anti-TROP2 ADC
- Trastuzumab pamirtecan[2] — Anti-HER2 ADC
- BNT326/ YL202[3] — Anti-HER3 ADC



Immunomodulators

- Pumitamig[4] — Anti-PD-L1/ Anti-VEGF

1. Synergistic potential; Partnered with 2. DualityBio; 3. MediLink; 4. Bristol Myers Squibb.

BIONTECH

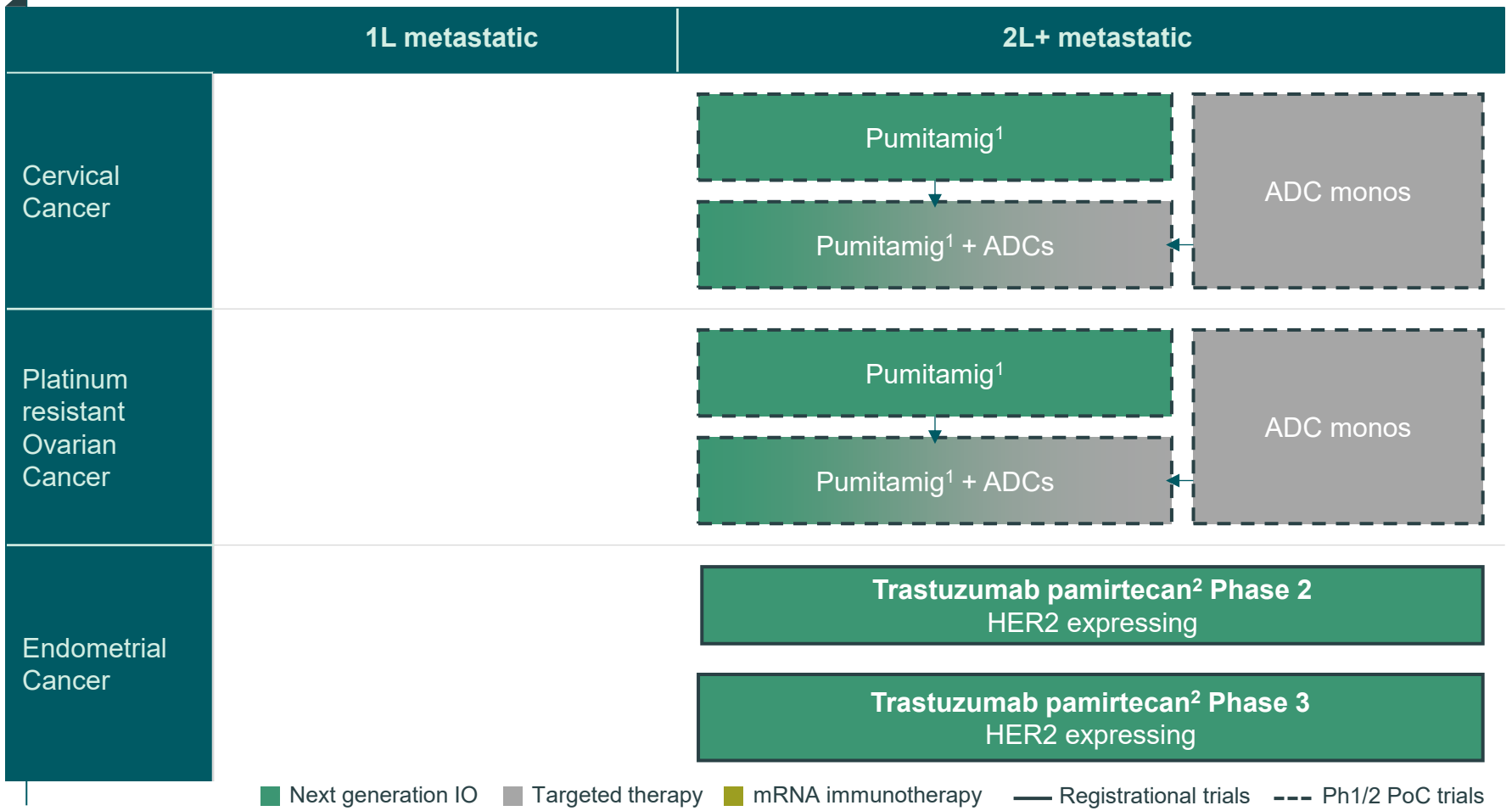
BioNTech's Currently Ongoing Trials* in Gynecologic Cancers

Registrational trials in gyn cancers

- Registrational trial with trastuzumab pamirtecan[2] in endometrial cancer

PoC trials with novel combinations to inform future registrational trials

- Pumitamig[1] demonstrated encouraging efficacy as monotherapy in gyn cancers
- Emerging ADC data informed the start of PoC trials for pumitamig[1] + ADC combinations
- Combination data will inform future registrational trials



Partnered with: 1. Bristol Myers Squibb; 2. DualityBio *As of November 2025

T-Pam[1] Clinical Activity Across HER2-Expression Levels in Endometrial Cancer

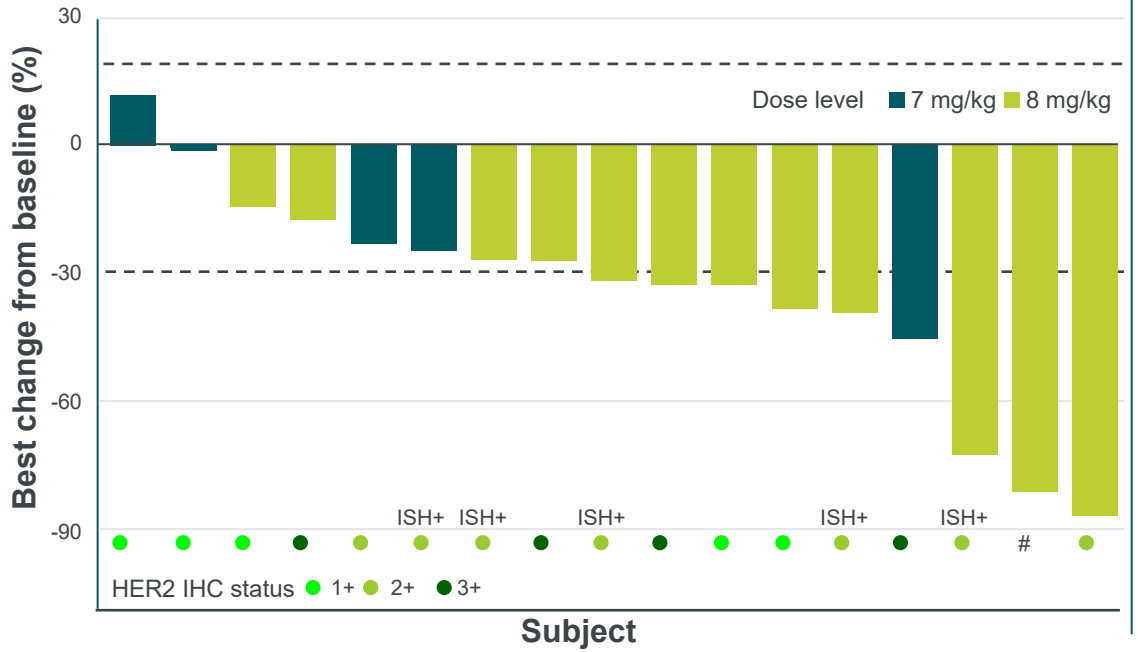
Phase 1/2 FIH study: Clinical Efficacy

Moore K. et al. Presented at ESGO 2023. Abstract # 430

- HER2 tumor expression of IHC 1, 2 and 3+: 31%, 41% and 25%, respectively. Clinical response observed across HER2-expression levels, including IHC 1+.
- Patients received median 2 lines of prior treatment. ~60% of patients had prior IO, ~38% prior anti-HER2 antibody.

	Dose Escalation		Dose Expansion	
Response[a]	**7 mg/kg** (n=4)[b]	**8 mg/kg** (n=4)[b]	**8 mg/kg** (n=9)[b]	**Total** (n=17)[b]
Unconfirmed ORR, n (%)	**2 (50)**	**4 (100)**	**4 (44)**	**10 (59)**
Confirmed ORR, n (%)	1 (25)	3 (75)	0	4 (24)
Pending confirmation ORR, n (%)	1 (25)	1 (25)	4 (44)	6 (35)
Unconfirmed DCR, n (%)	**4 (100)**	**4 (100)**	**8 (89)**	**16 (94)**

[a] By investigator. [b] Response-evaluable subjects, which includes subjects with ≥1 postbaseline overall response.



Data cut-off: May 8, 2023

Benchmark Data for 2L+ Endometrial Cancer

Regimen	ORR	mPFS	mOS	Study
Single-agent chemo	15%	3.8 mo	11.4 mo	KEYNOTE-775[2]

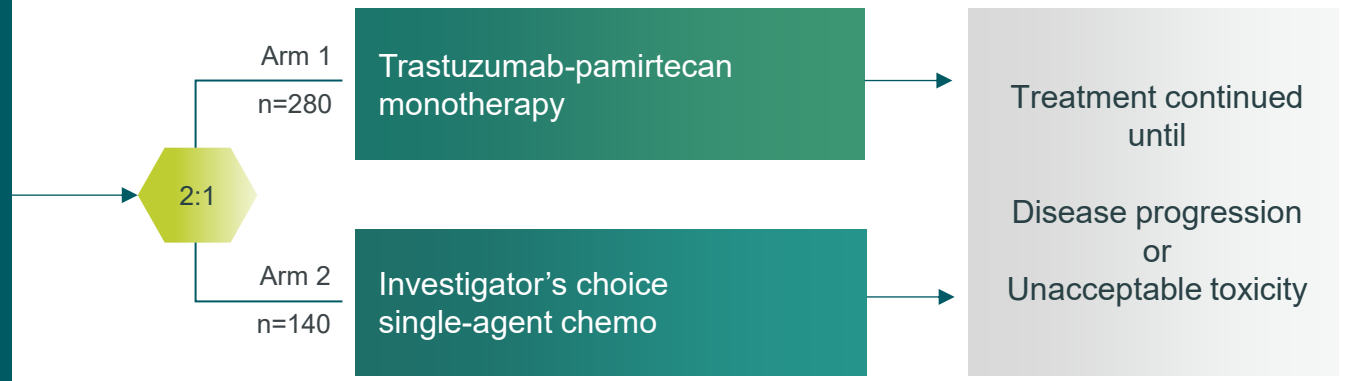
1. Partnered with DualityBio; 2. Makker V. et al. NEJM 2022 (ITT population), NCT05150691

BIONTECH

Phase 3 Trial of T-Pam[1] vs Chemotherapy in 2L+ HER2-Expressing Endometrial Cancer

Key Inclusion Criteria

- Recurrent, metastatic endometrial cancer (including HER2 1+, 2+, or 3+ score on IHC by central testing)
- At least 1 prior line of platinum-based therapy (in any setting) and prior ICI (in any setting), up to three lines of prior therapy (excluding endocrine therapies)
- Measurable disease per RECIST v1.1
- ECOG PS 0 or 1



Key Endpoints

Primary: PFS

Benchmark Data for 2L+ Endometrial Cancer

Regimen	ORR	mPFS	mOS	Study
Single-agent chemo	15%	3.8 mo	11.4 mo	KEYNOTE-775[2]

1. Partnered with DualityBio; 2. Makker V. et al. NEJM 2022.; NCT06340568

Evaluating BNT325/DB-1305[1] as a Monotherapy in Platinum Resistant Ovarian Cancer

A multicohort, first-in-human Phase 1/2 trial evaluating BNT325/DB-1305[1] in patients with advanced/metastatic solid tumors unselected for TROP2 expression

Key Inclusion Criteria

- ≥18 years of age
- ≥1 measurable lesion per RECIST v1.1
- ECOG PS 0–1
- Adequate organ function
- Asymptomatic brain metastases are allowed

Key Inclusion Criteria

- Ovarian cancer, primary peritoneal cancer, or fallopian tube cancer (high-grade serous histology)
- 1–4 prior lines of systemic therapy
- PROC disease

Phase 1: Dose escalation

n=18 →

2 mg/kg
up to 5 mg/kg
IV, Q3W

Exposure-response (E-R) relationships for efficacy and safety were performed to support dose identification

Phase 2a: Dose optimization
Cohort 3 in 2L–5L PROC

Dose optimization started with 4 mg/kg and was changed per SMC guidance to 3.5 mg/kg after 10 patients had received 4 mg/kg

n=20 R 1 →
- 4 mg/kg Q3W
- 3 mg/kg Q3W

n=20 R 2 →
- 3.5 mg/kg Q3W
- 3 mg/kg Q3W

- 58 patients with ovarian cancer received ≥1 dose of DB-1305/BNT325
- 3 mg/kg (n=30) dose identified for further expansion

Key Endpoints

Primary: ORR, safety
Secondary: DCR, DOR, PFS, OS

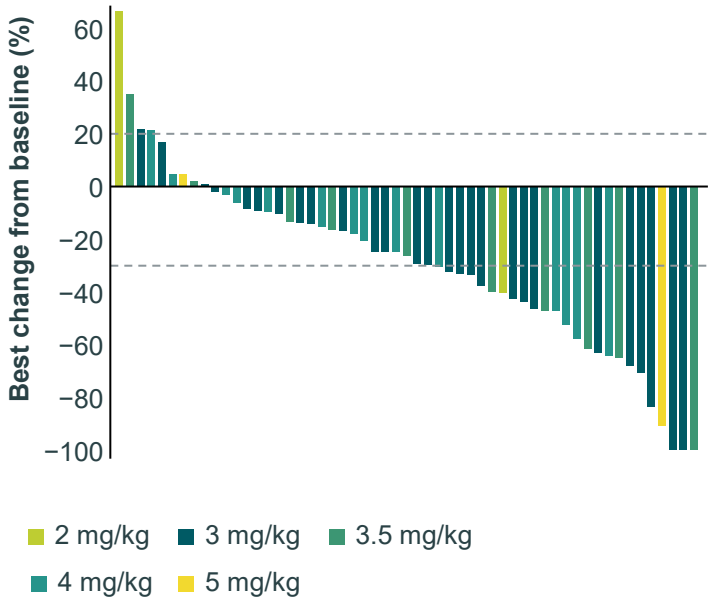
1. Partnered with DualityBio.

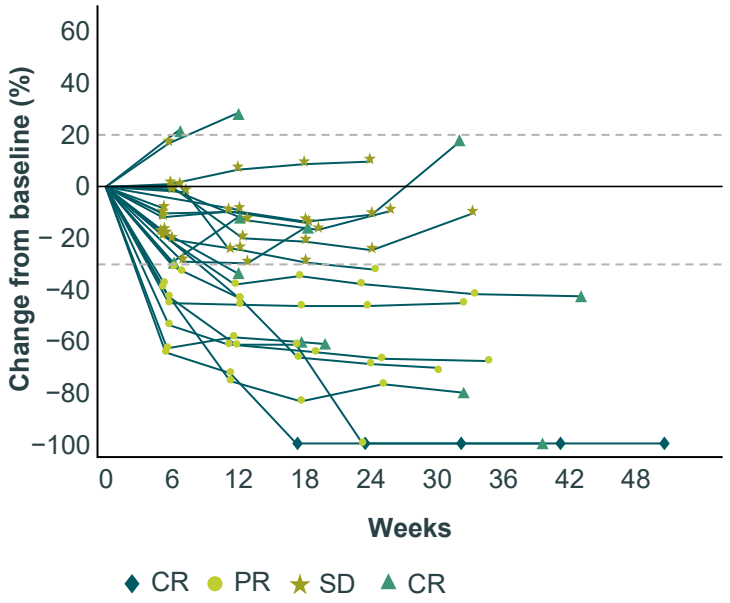
BIONTECH

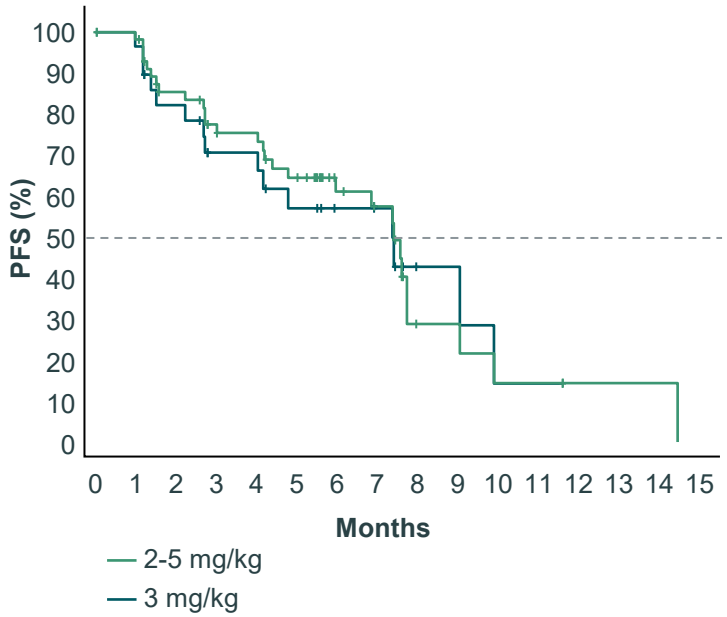
BNT325/DB-1305[1] Shows Durable Antitumor Activity in Previously Treated Ovarian Cancer

Encouraging antitumor activity in previously treated ovarian cancer

Responders* (n)	8
mDOR (months)	**7.3**







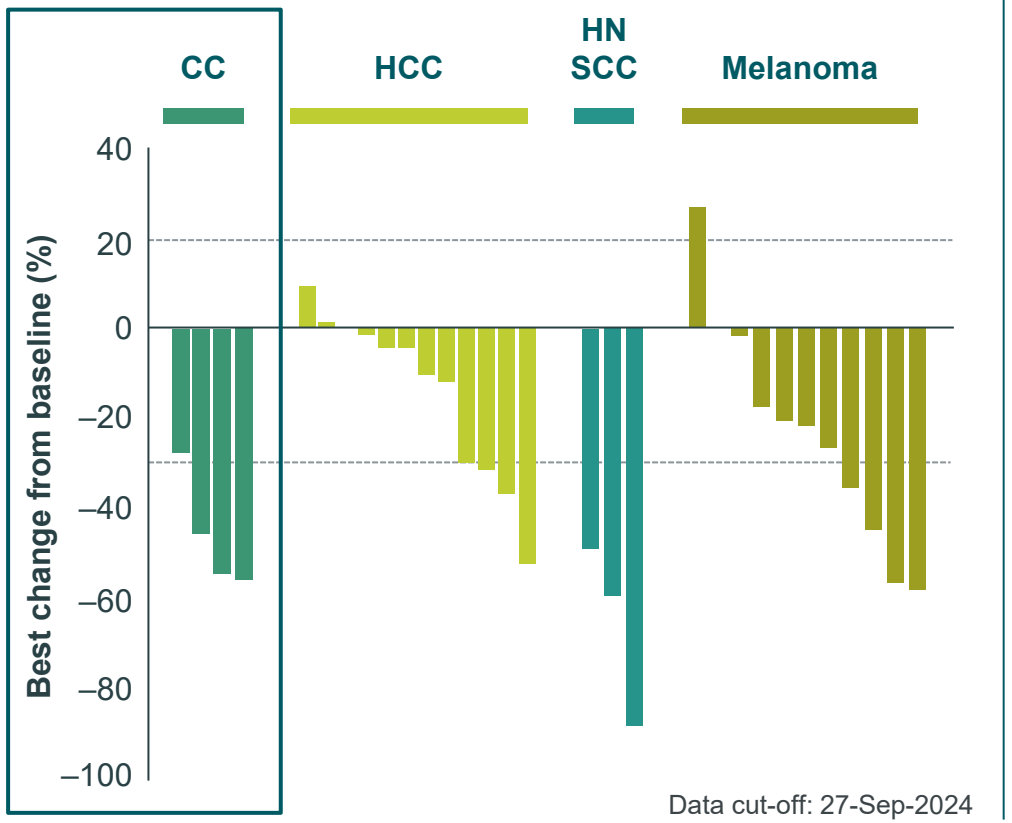
Overall mPFS of 7.4 months

Data cut-off: 15-Dec-2024

1. Partnered with DualityBio; *BOR not included for 3 patients (3 mg/kg). In 2 mg/kg (n=2): 1 PR and 1 PD and in 5 mg/kg (n=2): 1 CR and 1 SD; *DOR in patients with confirmed response. Rubinstein et al SGO 2025

BNT324/DB-1311[1] Shows Emerging Activity in Melanoma, HCC, Cervical Cancer and HNSCC

	CC	HCC	HNSCC	Melanoma
Treated, n	7	12	7	12
Evaluable for efficacy, n	4	12	3	11
ORR, n (%) [95% CI]	3 (**75.0**) [19.4, 99.4]	3 (**25.0**) [5.5, 57.2]	3 (**100**) [29.2, 100]	4 (**36.4**) [10.9, 69.2]
Confirmed ORR, n (%)	3 (75.0)	2 (16.7)	2 (66.7)	2 (18.2)
Pending confirmation, n	0	1	1	2
DCR, n (%) [95% CI]	4 (**100**) [39.8, 100]	11 (**91.7**) [61.5, 99.8]	3 (**100**) [29.2, 100]	9 (**81.8**) [48.2, 97.7]



1. Partnered with DualityBio; All patients received either 6 mg/kg or 9 mg/kg except for 1 patient with SCCHN who received 10.5 mg/kg. The difference between the number of patients treated and those evaluable for efficacy is due to patients still on treatment without a first post-baseline scan. Cheng Y et al. ESMO Asia 2024 57O.

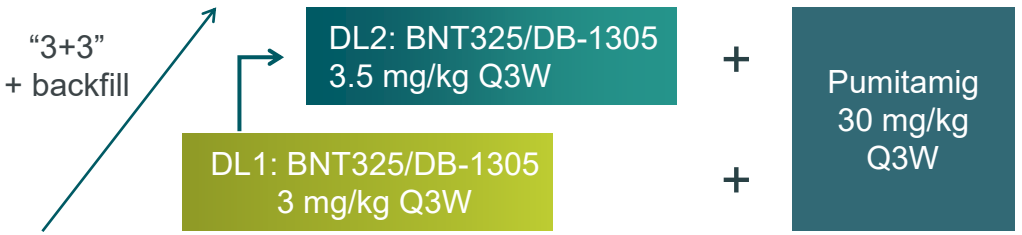
Pumitamig[1] in Combination with Novel ADCs in High Unmet Need Indications

Ongoing, first-in-human Phase 1/2 trial evaluating BNT325/DB-1305[2] and pumitamig in patients with advanced/metastatic solid tumors: DB-1305-O-1001 study

Key Inclusion Criteria

- ≥18 years of age
- ≥1 measurable lesion per RECIST v1.1
- ECOG PS 0–1
- Adequate organ function
- Asymptomatic brain metastases allowed

Part 1: Dose escalation



Part 2: Dose expansion (n=30)

Cohort	Indication
PM1	1-2L NSCLC AGA−
PM2	2L nsq NSCLC AGA+
PM3	1L Cervical cancer
PM4	2-4L PROC
PM5	1L TNBC

Key Endpoints

Primary: DLT, safety, ORR

Partnered with: 1. Bristol Myers Squibb; 2.Duality; NCT05438329

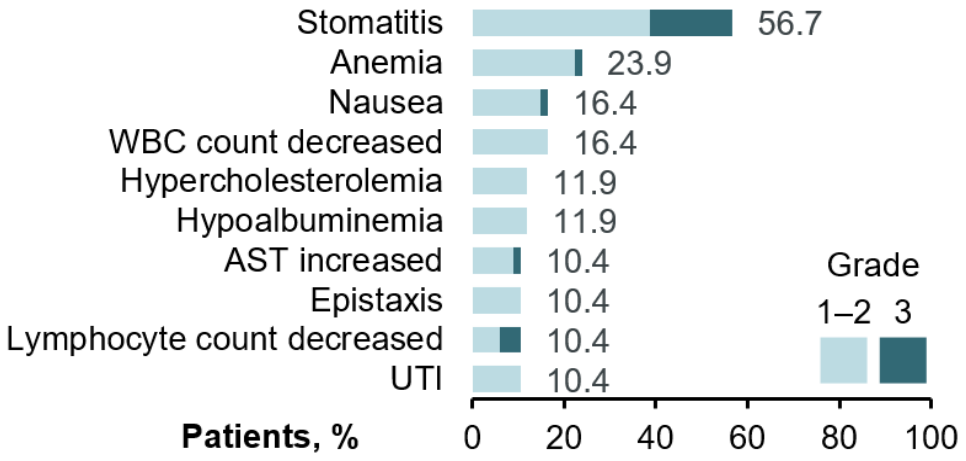
BIONTECH

Preliminary Data Combining Pumitamig[1] with ADC Showed a Manageable Safety Profile with Few Overlapping Toxicities and Signs of Clinical Activity

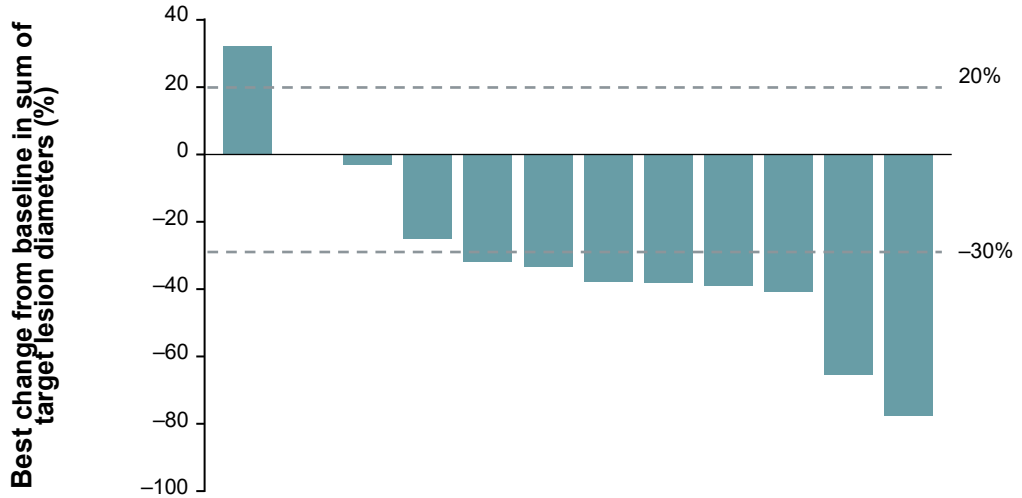
Phase 1/2: Pumitamig[1] combined with TROP2 ADC BNT325/DB-1305[2] in 2L–4L PROC

Erika Hamilton et al. AACR 2025 P648

TRAEs occurring in ≥10% of patients receiving BNT325/DB-1305 + pumitamig[1] Q3W (N=67)



Waterfall plot for PROC from dose expansion cohort in 2-4L PROC (N=13)



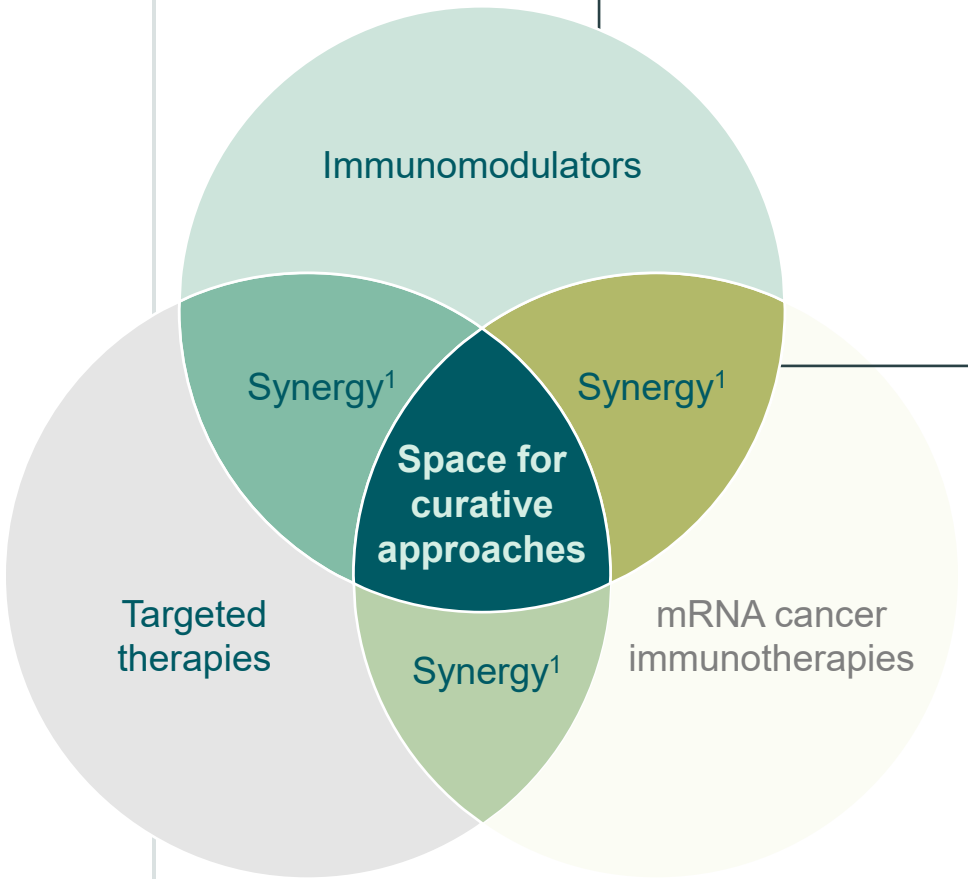
1. Partnered with: 1. Bristol Myers Squibb; 2.Duality; NCT05438329.

BIONTECH

Our Diverse Gyn Cancer Pipeline

Targeted therapies

- BNT324/ DB-1311[2] — Anti-B7H3 ADC
- BNT325/ DB-1305[2] — Anti-TROP2 ADC
- Trastuzumab pamirtecan[2] — Anti-HER2 ADC
- BNT326/ YL202[3] — Anti-HER3 ADC



Immunomodulators

- Pumitamig[4] — Anti-PD-L1/ Anti-VEGF

1. Synergistic potential; Partnered with 2. DualityBio; 3. MediLink; 4. Bristol Myers Squibb.

BIONTECH

Evaluating Pumitamig[1] Monotherapy in Patients with Advanced CC and PROC

Key Inclusion Criteria

- Advanced or metastatic CC (≤ 2 prior treatment lines) and PROC (≤ 1 prior treatment line after platinum resistance)
- Age 18-75 years
- ECOG PS 0-1
- Adequate organ function
- Exclude evidence of significant bleeding and coagulation disorder or other significant bleeding risk

20mg/kg Q2W
n=73

30mg/kg Q2W
n=1

20mg/kg Q3W
n=7

45mg/kg Q3W
n=6

CC cohort
n=48

PROC cohort
n=39

Treatment continued until

a) Disease progression

b) Intolerable toxicity

Key Endpoints

Primary: ORR per RECIST1.1
Secondary: DCR, PFS, safety

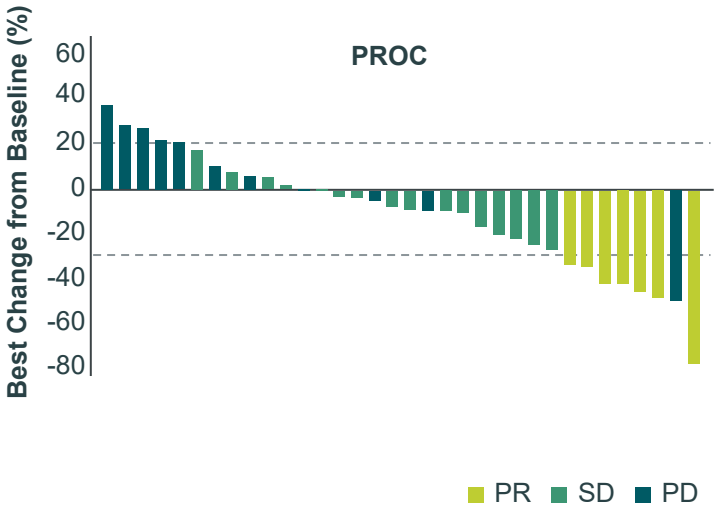
1. Partnered with Bristol Myers Squibb; NCT05918445

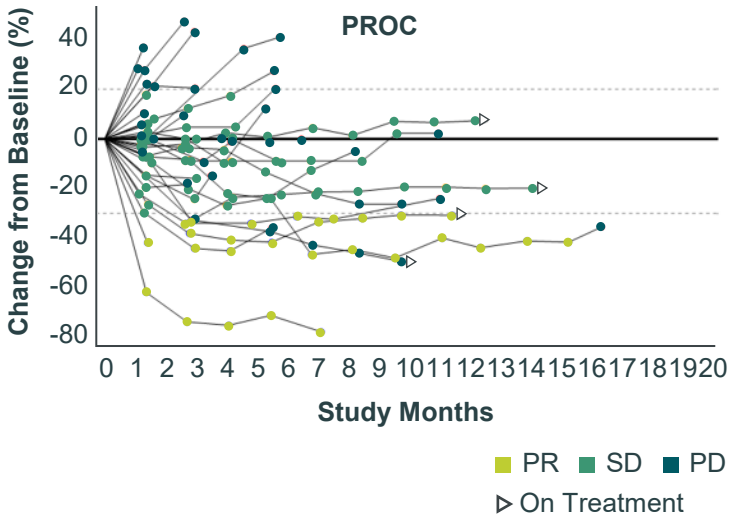
BIONTECH

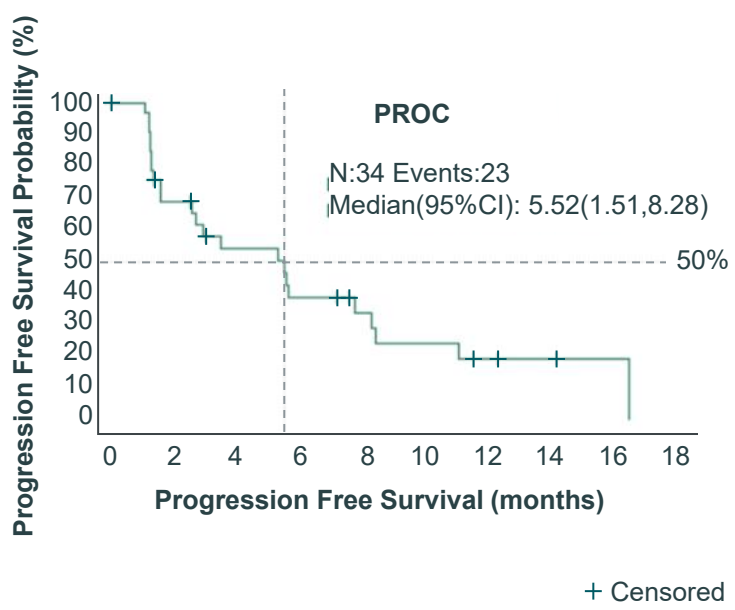
Pumitamig[1] as Monotherapy Showed Encouraging Efficacy Signals in Patients with PROC

Phase 1/2 trial: Efficacy signals PROC

Wu, L. et al. ASCO 2024 #5524







PROC: N=34 | 7 PR | 16 SD | ORR of 20.6% and DCR of 67.7%

mPFS was **5.5 months**

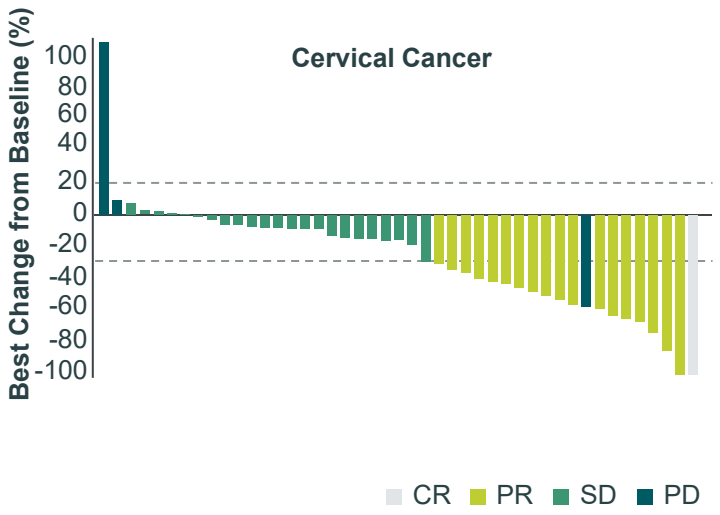
1. Partnered with Bristol Myers Squibb; NCT05918445

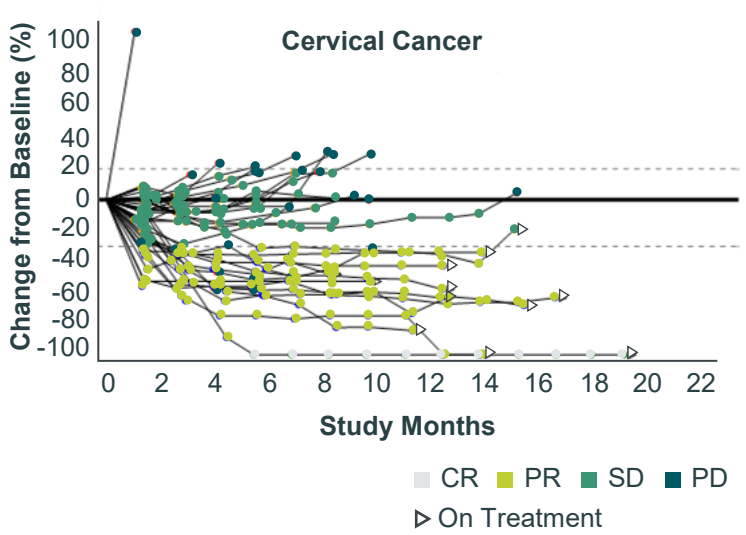
BIONTECH

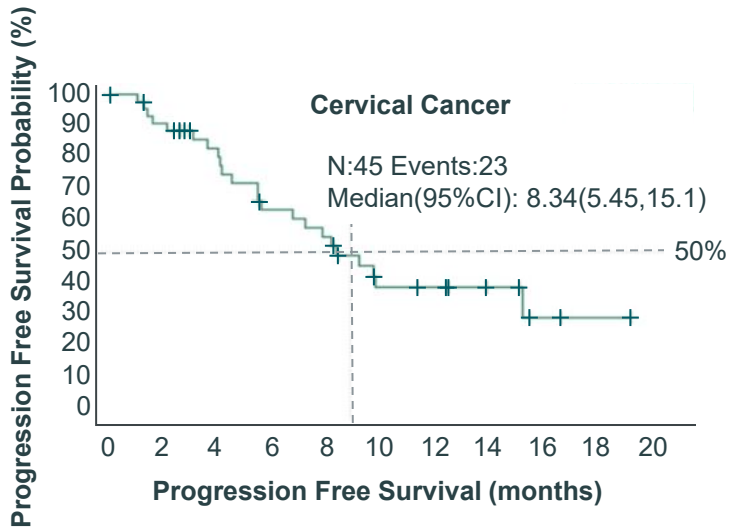
Pumitamig[1] as Monotherapy Showed Encouraging Efficacy Signals in Patients with CC

Phase 1/2 trial: Efficacy signals CC

Wu, L. et al. ASCO 2024 #5524







CC: N=45 | 1 CR | 18 PR | 23 SD | ORR was 42.2% and DCR 93.3% | ORR in patients with PD-L1-positive tumors was 52.4%

mPFS was **8.3 months**

Progression Free Survival (months)

1. Partnered with Bristol Myers Squibb; *NCT05918445

BIONTECH

Ongoing and Next Steps | Gynecological Cancer

Establishing trastuzumab pamirtecan[2] in **HER2-expressing endometrial cancer**

Single arm registrational Phase 2

Trastuzumab pamirtecan[2] in 2L+ HER2-expressing EC

BLA submission planned for 2026

Data to be presented in 2026

Confirmatory Phase 3

Trastuzumab pamirtecan[2] in 2L+ HER2-expressing EC

Evaluating ADC monotherapy and novel pumitamig[1] + ADC combinations in **ovarian and cervical cancers**

Pumitamig[1] + ADCs

Novel combination data to be presented in 2026

Partnered with: 1. Bristol Myers Squibb; 2. DualityBio.

BIONTECH

Gastrointestinal Cancers

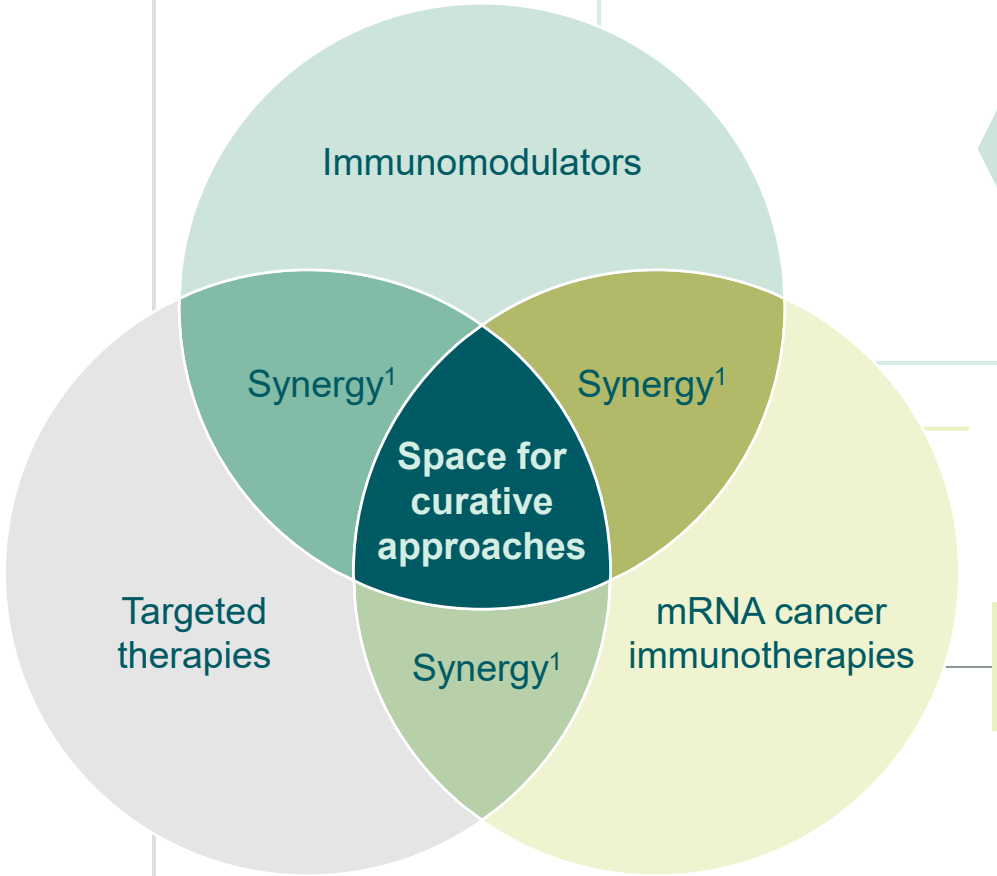
BIONTECH

Our Diverse GI Cancer Pipeline

Targeted therapies

BNT324 /DB-1311[2]
Anti-B7H3 ADC

BNT326 /YL202[3]
Anti-HER3 ADC



Immunomodulators

Pumitamig[4]
Anti-PD-L1/ Anti-VEGF

BNT314 /GEN1059[5]
Anti-EpCAM/ Anti-4-1BB

mRNA cancer immunotherapy

iNeST
Fully individualized immunotherapy

→ Autogene cevumeran[6]

1. Synergistic potential; Partnered with 2. DualityBio; 3. MediLink; 4. Bristol Myers Squibb; 5. Genmab; 6. Genentech, a member of the Roche Group.

BIONTECH

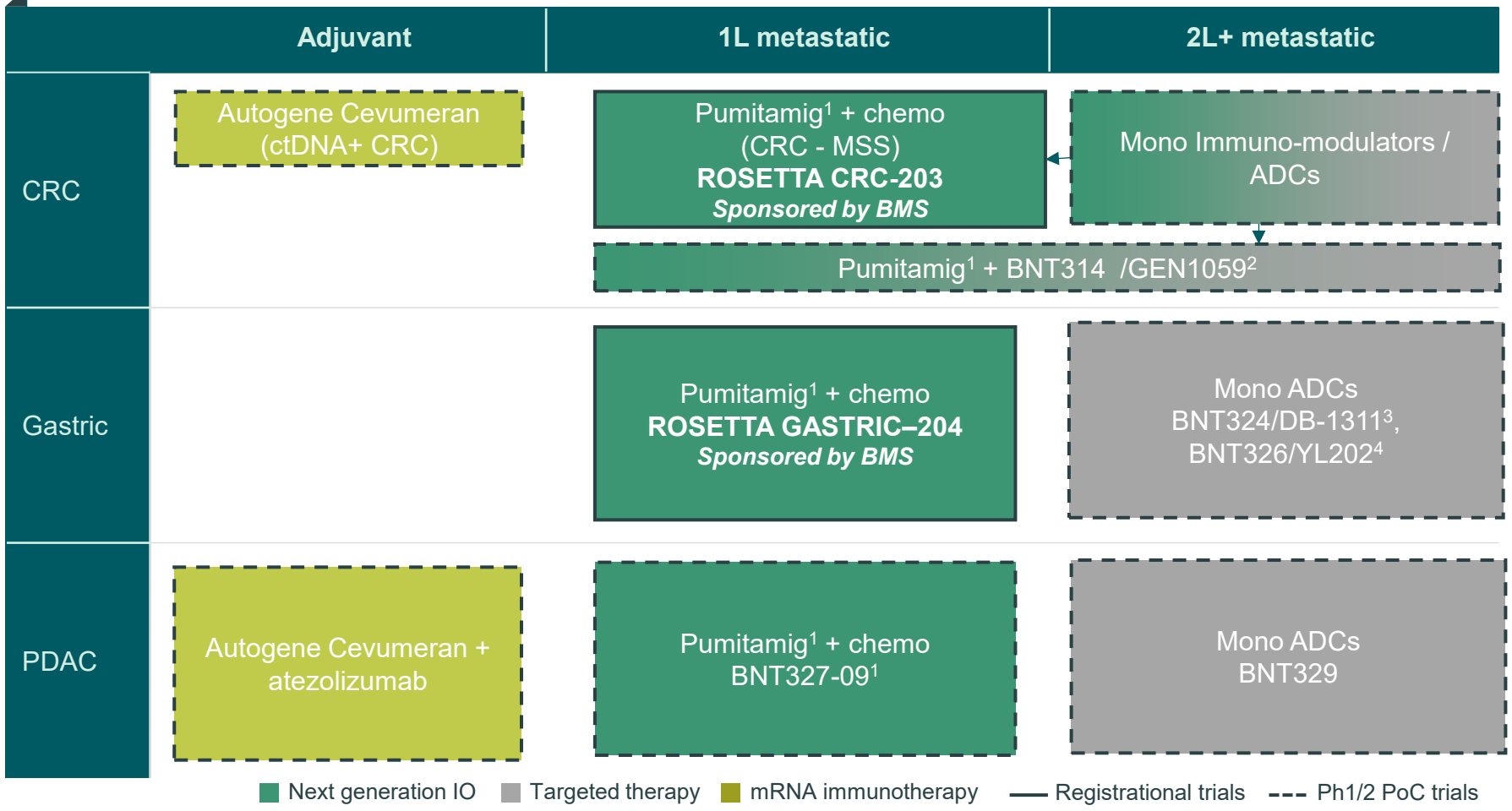
BioNTech's Currently Ongoing Trials* in GI Cancers

Registrational trials in metastatic GI cancers

- Pumitamig[1] aiming to provide IO option in CRC-MSS
- Pumitamig[1] aiming to improve upon SoC in Gastric Cancer

PoC trials with novel combinations to inform future registrational trials

- Mono data being generated in 2L+ settings with ADCs and immunomodulators
- In parallel, combination trials will start to generate indication specific data
- mRNA cancer immunotherapies being evaluated in randomized clinical trials in the adjuvant setting

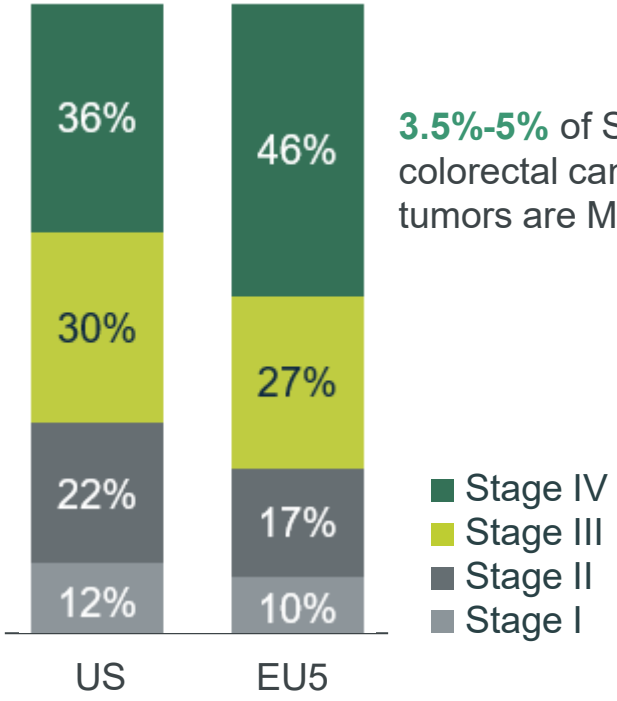


Partnered with: 1. Bristol Myers Squibb; 2. Genmab; 3. DualitiyBio; 4. MediLink.*As of November 2025

MSS CRC: Significant Global Incidence with Unmet Need for New Therapies

2030 U.S., EU4, U.K. CRC incidence[1] **~470k**

CRC staging distribution[2]



3.5%-5% of Stage IV colorectal cancer tumors are MSI-H[2]

Patients with metastatic MSS-CRC have few treatment options and require new therapeutic strategies

	dMMR / MSI-H	pMMR / MSS
mOS	**Pembro: 77.5mo** (KEYNOTE-177)[3]	**Bevacizumab / Cetuximab + chemotherapy: ~30mo**[4, 5]
5-year OS	**Pembro: ~55%** (KEYNOTE-177)[3]	**Bevacizumab / Cetuximab + chemotherapy: ~15-25%**[4, 5]

1. Globocan – Cancer Tomorrow. 2. CancerMPact® 2024 Treatment Architecture EU5 and US. 3. André, Ann Oncol., 2024. 4. Cremolini, Lancet, 2015. 5. Venook, JAMA, 2017

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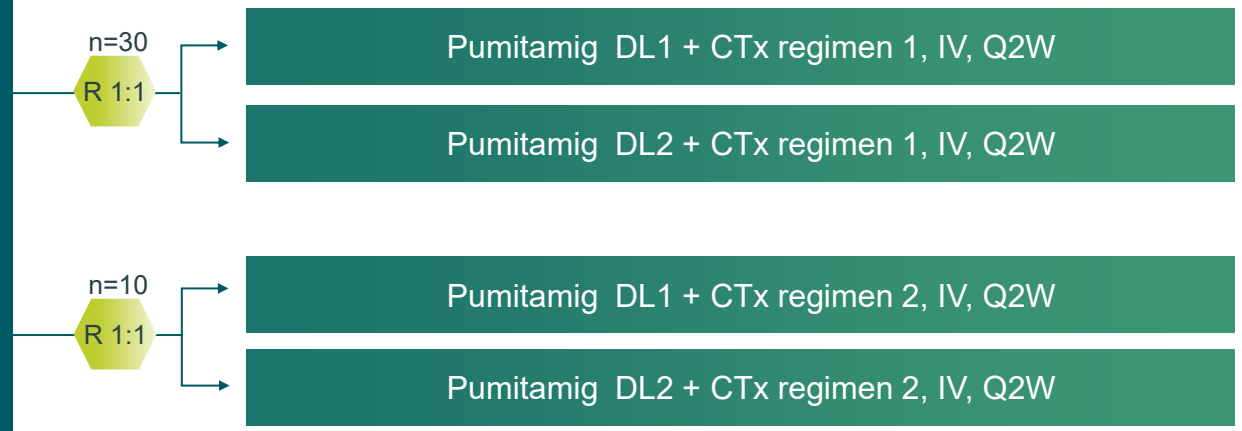
Phase 2 Signal Seeking Trial of Pumitamig[1] in Combination with Chemotherapy in Colorectal Cancer

Phase 2, multicenter, open label trial to evaluate efficacy and safety of pumitamig in combination with chemotherapy in 1L MSS or MSI-L/pMMR metastatic CRC

Key Inclusion Criteria

- Histologically or cytologically confirmed metastatic colorectal cancer
- No dMMR or MSI-H
- No prior systemic anti-tumor therapy for CRC
- Measurable lesions per RECISTS v1.1
- ECOG PS 0 or 1



Key Endpoints

Primary: ORR, safety
Secondary: DOR, DCR, PFS, OS

1. Partnered with Bristol Myers Squibb; NCT07133750

Phase 2/3 Study with Pumitamig[1] in Combination with Chemotherapy in Patients with CRC

ROSETTA CRC-203

Phase 2/3, randomized study to evaluate safety and efficacy of pumitamig in combination with CTx vs. Bevacizumab in combination with CTx in participants with previously untreated, unresectable, or metastatic CRC

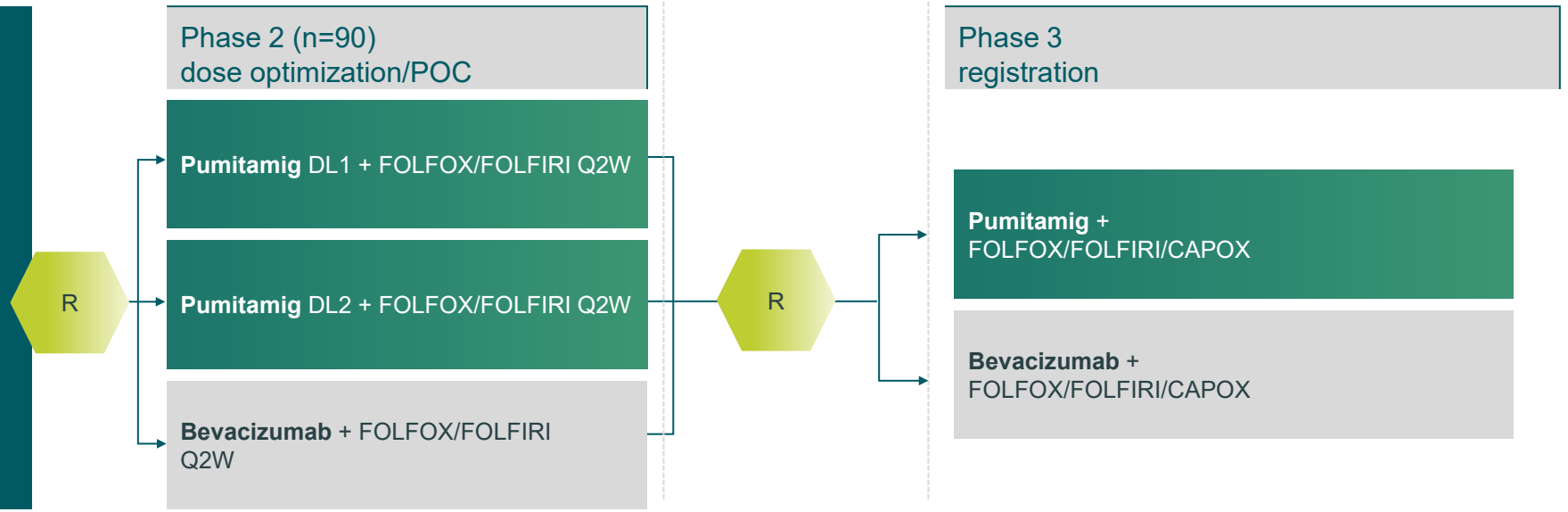
Key Inclusion Criteria

- Unresectable metastatic MSS CRC
- No prior systemic therapy
- No actionable mutation (e.g. MSI-H, BRAF V600E mut)

Stratification Factors

Phase 2
- RAS mut, sidedness and chemotherapy
- Limit Iri to 10 pts per arm to generate safety data

Phase 3
- Chemo, sidedness and liver metastasis



Key Endpoints

Primary:

Phase 2
ORR

Phase 3
PFS

Benchmark Data for 1L MSS CRC

Regimen	ORR	mPFS	mOS	Benchmark study
Bevacizumab + FOLFIRI	65%	9.7 mo	25.8 mo	TRIBE
Bevacizumab + FOLFOX	47%	9.4 mo	21.0 mo	NO16966

1. Partnered with Bristol Myers Squibb; NCT07221357

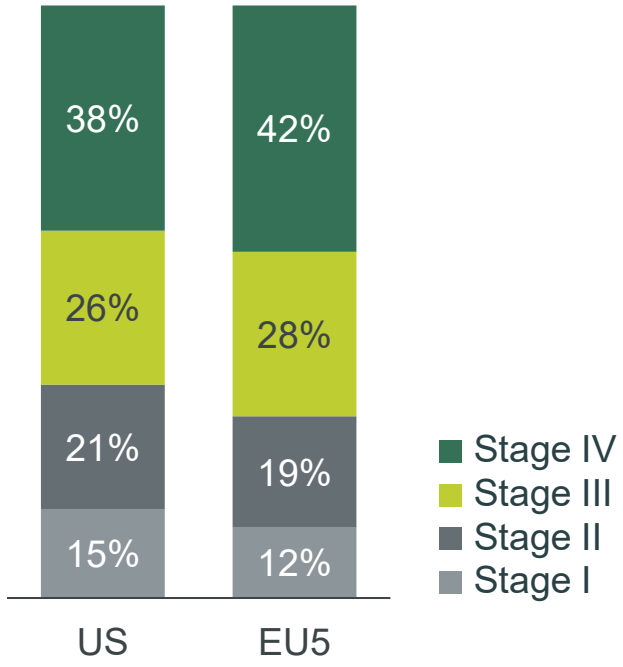
BIONTECH

Gastric Cancer: Poor Outcomes and Restricted Therapies in Biomarker Negative Patients

2030 U.S., EU4, U.K. gastric cancer incidence[1]

~75k

Staging distribution[2]



High unmet need for metastatic gastric cancer patients as long-term survival outcomes are very poor and treatment options remain limited to chemotherapy in biomarker negative patients

	HER2 positive (~15-20%)	HER2 negative (~80-85%)
PD-L1, CPS ≥ 1 (~80%)	**Pembro[1] + trastuzumb[2] + chemo** **mOS: 20.1 mo** **2-year OS: 41%** (KEYNOTE-811)[3]	**Nivolumab + chemotherapy** **mOS: 13.8mo** (CheckMate-649)[4]
PD-L1, CPS < 1 (~20%)	**Trastuzumab[2] + chemo** **mOS: 20.4 mo** (KEYNOTE-811)[3]	**Chemotherapy** **mOS 12.5mo** (CheckMate-649)[4]

1.1. Globocan – Cancer Tomorrow; 2. CancerMPact® 2024 Treatment Architecture EU5 and US; 3. Janjigian, NEJM 2024; 4. Janjigian, JCO 2024

BIONTECH

Phase 2/3 Study with Pumitamig[1] in Combination with Chemotherapy in 1L Gastric Cancer

ROSETTA GASTRIC-204

Phase 2/3 study of pumitamig in combination with chemotherapy to evaluate safety and efficacy in 1L Gastric Cancer

Key Inclusion Criteria

- Advanced or metastatic GC/GEJ/EAC
- No prior systemic therapy
- PD-L1 CPS ≥ 1
- HER2 negative

R

Phase 2 dose optimization/POC

- **Pumitamig** DL1 + FOLFOX
- **Pumitamig** DL2 + FOLFOX
- Nivolumab + FOLFOX

R

Phase 3 registration

- **Pumitamig +** FOLFOX or CAPOX
- Nivolumab + FOLFOX or CAPOX

Key Endpoints

Primary:

Phase 2	**Phase 3**
ORR	PFS, OS

Benchmark Comparator Data for HER2-negative gastric cancer (PD-L1 CPS ≥ 1)

Benchmark regimen	ORR	mPFS	mOS	Benchmark study
Nivolumab + chemo	60%	7.5 mo	13.8 mo	CheckMate-649

1. Partnered with Bristol Myers Squibb; NCT07221149

BIONTECH

Evaluating BNT314/GEN1059[1] in Combination with Pumitamig[2] in Patients with Metastatic Colorectal Cancer

Phase 1/2 trial across 482 patients to evaluate combination BNT314/GEN1059 and pumitamig and chemotherapy in patients with advanced metastatic CRC

Key Inclusion Criteria

- Unresectable histologically confirmed adenocarcinoma of the colon or rectum.
- Confirmed non-microsatellite instability-high (non-MSI-H)/pMMR mCRC.
- Measurable disease defined by RECIST v1.1.
- Have ECOG 0 - 1.

Part A: Safety run-in

3L+ MSS/pMMR mCRC
BNT314/GEN1059 + Pumitamig*

- DL5: BNT314/GEN1059 + pumitamig
- A-DL4: BNT314/GEN1059 + pumitamig
- A-DL3: BNT314/GEN1059 pumitamig
- A-DL2: BNT314/GEN1059 + pumitamig
- A-DL1: BNT314/GEN1059 + pumitamig

Part B: Dose optimization

2L MSS/pMMR mCRC

R
- **B1-DL1:** BNT314/GEN1059 + pumitamig + chemotherapy
- **B2-DL2:** BNT314/GEN1059 + pumitamig + chemotherapy

1L MSS/pMMR mCRC

R
- **B3-DL1:** BNT314/GEN1059 + pumitamig + chemotherapy
- **B4-DL2:** BNT314/GEN1059 + pumitamig + chemotherapy

Part C: Phase 2

2L MSS/pMMR mCRC

R
- C-TA1: BNT314/GEN1059 + pumitamig + chemotherapy
- C-TA2 (SOC): Bevacizumab + chemotherapy
- C-TA3: Pumitamig + chemotherapy

Key Endpoints

	Part A	Part B	Part C
Primary:	Safety	Safety, ORR	PFS
Secondary:	ORR, DOR, DCR	DOR, DCR	ORR, OS, safety

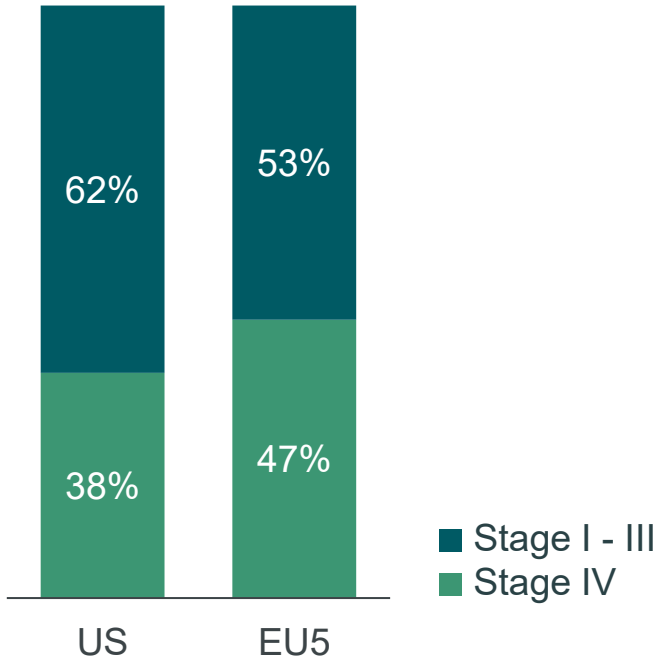
Partnered with: 1. Genmab; 2. Bristol Myers Squibb. 3. Bennouna J. et al. Lancet Oncol. 2013.

BIONTECH

Pancreatic Cancer Patients Have Poor Long-Term Survival Rates and Limited Treatment Options

2030 U.S., EU4, U.K. pancreatic cancer incidence[1] **~153k**

Staging distribution[2]



High unmet need for pancreatic cancer patients as long-term survival outcomes are very poor and treatment options remain limited to chemotherapy

	Stage I-III + Stage IV resectable	Stage IV metastatic
mOS	**Chemo: 53.5 mo** (PRODIGE-24)[3]	**GnP: 8~9 mo** (MPACT)[4] **FOLFIRINOX: ~11 mo** (PRODIGE-IV)[5]
24 mos OS	**70%** (PRODIGE-24)[3]	**GnP: 10%** (MPACT)[4] **FOLFIRINOX: 10%** (PRODIGE-IV)[5]
5-year survival	**43%** (PRODIGE-24)[3]	**3%**[6]

1.1. Globocan – Cancer Tomorrow; 2. CancerMPact® 2024 Treatment Architecture EU5 and US; 3. Conroy et al., JAMA Oncol, 2022; 4. Von Hoff et al., N Engl J Med, 2013; 5. Conroy et al., N Engl J Med, 2011; 6. CancerMPact® 2024 Treatment Architecture EU5 and US.

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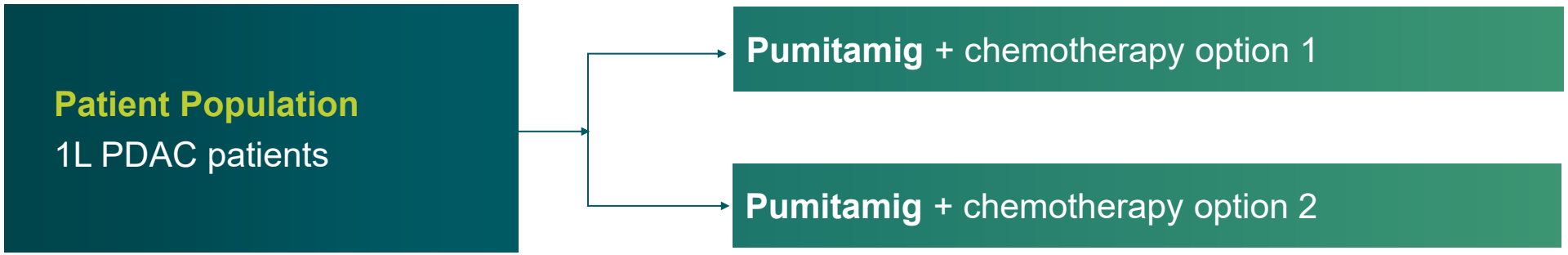
Phase 2 Trial with Pumitamig[1] in Combination with Chemotherapy in Patients with PDAC

ROSETTA PDAC-109



Key Endpoints

Primary: ORR, safety

Benchmark Data for 1L PDAC

Benchmark regimen	ORR	mPFS	mOS	Benchmark study
mFOLFIRINOX	32%	6.4 mo	11.1 mo	MPACT[2]
GnP	23%	5.5 mo	8.7 mo	PRODIGE-IV[3]

1. Partnered with Brsitol Myers Squibb; 2. Von Hoff et al., N Engl J Med, 2013; 3. Conroy et al., N Engl J Med, 2011;

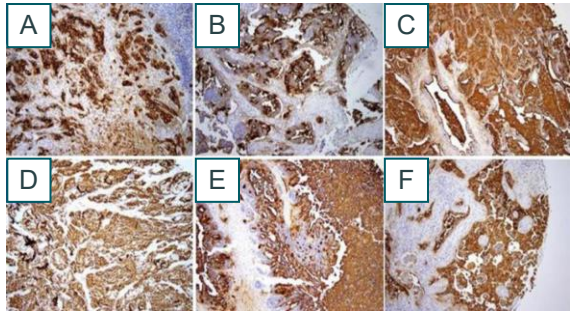
BIONTECH

Exploring CA19-9-ADC BNT329 To Build Presence in GI Cancers

CA19-9 as an ADC target[1-3]

- CA19-9 is highly expressed in PDAC and other GI cancers[4]

Tumor Site	CA 19-9+ / total (%)
Pancreas	29/31 (94%)
Bile Duct	10/11 (91%)
Transitional (bladder)	22/29 (76%)
Distal esophogus/stomach	21/30 (70%)
Colon	36/51 (71%)
Ovary	22/37 (59%)
Endometrium	27/44 (61%)



- A Pancreatic ductal adenocarcinoma
- B Colon carcinoma
- C Lung adenocarcinoma
- D Urinary bladder, mucinous adenocarcinoma
- E Colon metastatic to ovary
- F Breast carcinoma, lymph node

First-in-Human trial with BNT329

Key Inclusion Criteria

- No patient pre-selection based on CA19-9 expression
- All comer tumor indications known to express CA 19-9 (PDAC, Gastric, Endometrial, Colorectal cancer)

Dose Level 7
Dose Level 6
Dose Level 5
Dose Level 4
Dose Level 3
Dose Level 2
Dose Level 1

- Cohort A
  2L+ PDAC
- Cohort B
  2L+ Basket (Gastric, CRC)

Adapted from Loy et al. 1993

1. Passerini R, et al. Am J Clin Pathol 2012;138(2):281–7; 2. Data on file; 3. Lee et al. World J Gastrointest Surg. 2020 Dec 2712(12): 468-490; 4. Loy et al. Am J Clin Pathol.1993;99:726-728

BIONTECH

Ongoing and Next Steps | Gastrointestinal Cancer

Establishing pumitamig[1] in **gastrointestinal cancers**

ROSETTA CRC[1]

Pumitamig[1] + chemotherapy in 1L MSS-CRC

ROSETTA Gastric-204[1]

Pumitamig[1] + chemotherapy in 1L HER2-, PD-L1+ gastric

Signal-seeking Phase 2

Pumitamig[1] + chemotherapy in 1L PDAC

Evaluating novel pumitamig[1] + immunomodulator and **ADC monotherapy in late-stage disease**

Pumitamig[1] + immunomodulator

ADCs

Partnered with: 1. Bristol Myers Squibb.

BIONTECH

Genitourinary Cancers

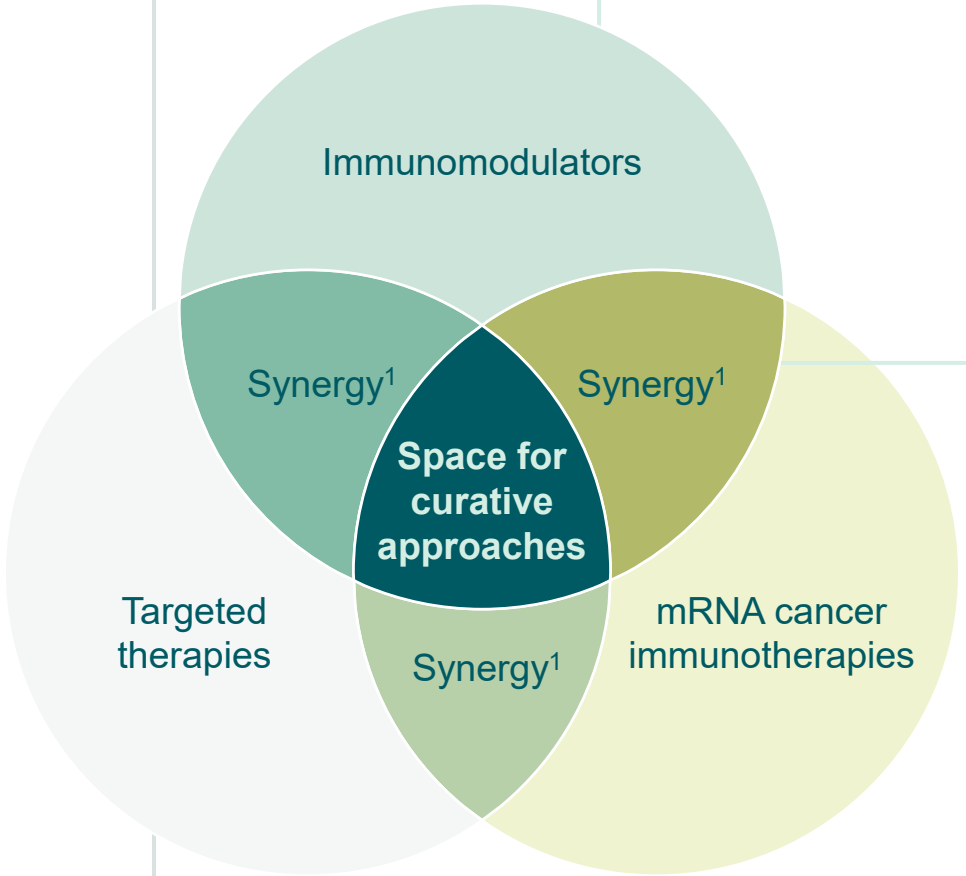
BIONTECH

Our Diverse GU Cancer Pipeline

Targeted therapies

BNT324 /DB-1311[2]

Anti-B7H3 ADC



Immunomodulators

Pumitamig[3]

Anti-PD-L1/ Anti-VEGF

Gotistobart[4]

Anti-CTLA-4

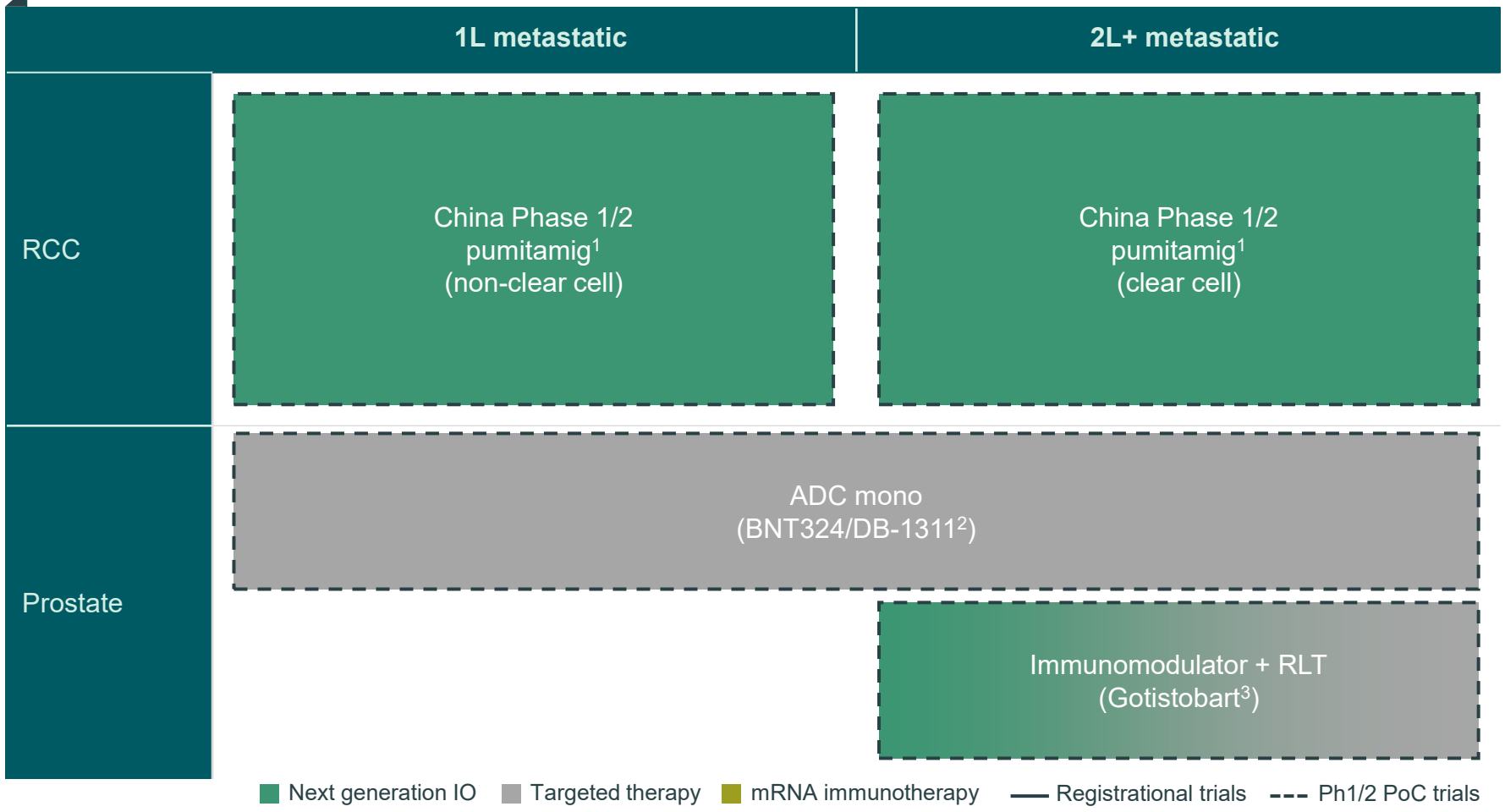
1. Synergistic potential; Partnered with: 2. DualityBio; 3. Bristol Myers Squibb; 4. OncoC4.

BIONTECH

BioNTech's Current Development in GU Cancer

PoC trials in GU cancers to inform future registrational studies

- RCC: Pumitamig[1] demonstrated encouraging efficacy as monotherapy in RCC
- Prostate: Encouraging data for BNT324/DB-1311[2] and gotistobart[3] in late line mCRPC
- Ongoing trials will inform future registrational trials



Partnered with: 1. Bristol Myers Squibb; 2. DualityBio; 3. OncoC4.

Evaluating Pumitamig[1] Monotherapy in Patients with 2L Clear Cell RCC and 1L Non-Clear Cell RCC

Phase 1/2 multiple cohort monotherapy trial to evaluate safety and efficacy of pumitamig in patients with advanced solid tumors, including RCC

Key Inclusion Criteria

- Locally advanced inoperable or metastatic RCC with or without sarcomatoid component
  - ccRCC: progress on prior 1L VEGF TKI +/- IO
  - nccRCC: no prior systemic therapy
- Malignant tumor confirmed by histology or cytology
- Adequate organ function
- ≥ 1 measurable lesion not been previously treated (RECIST 1.1)
- ECOG 0-1

n = 53

Pumitamig, iv,
Q2W or Q3W

Treatment continued
until disease progression
or intolerable toxicity

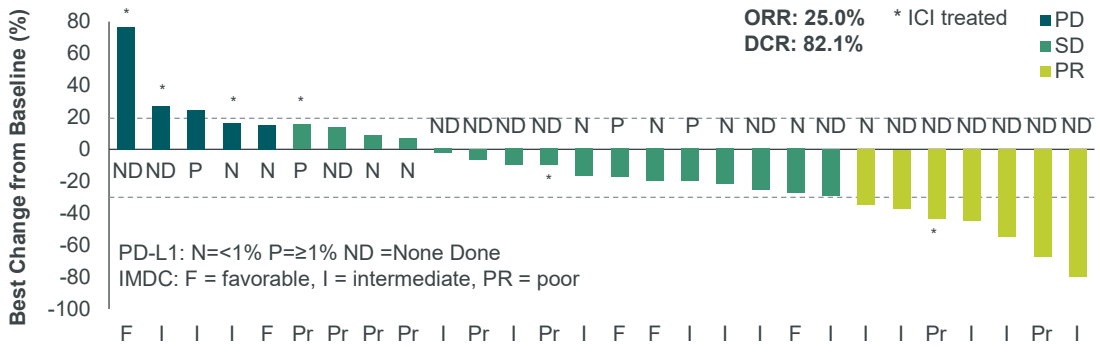
Key Endpoints

Primary: ORR
Secondary: DCR , DOR, PFS, safety

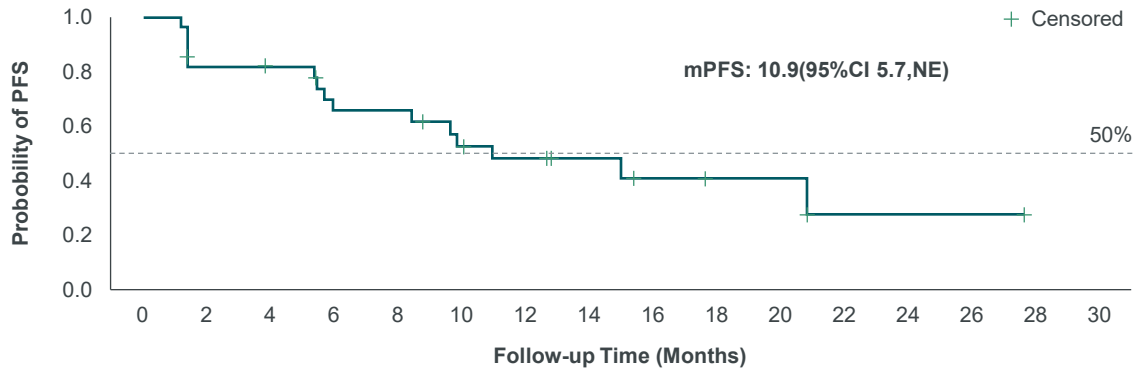
1. Partnered with Bristol Myers Squibb; NCT05918445

Pumitamig[1] Showed Encouraging Anti-Tumor Activity in Patients with 2L+ Clear Cell RCC

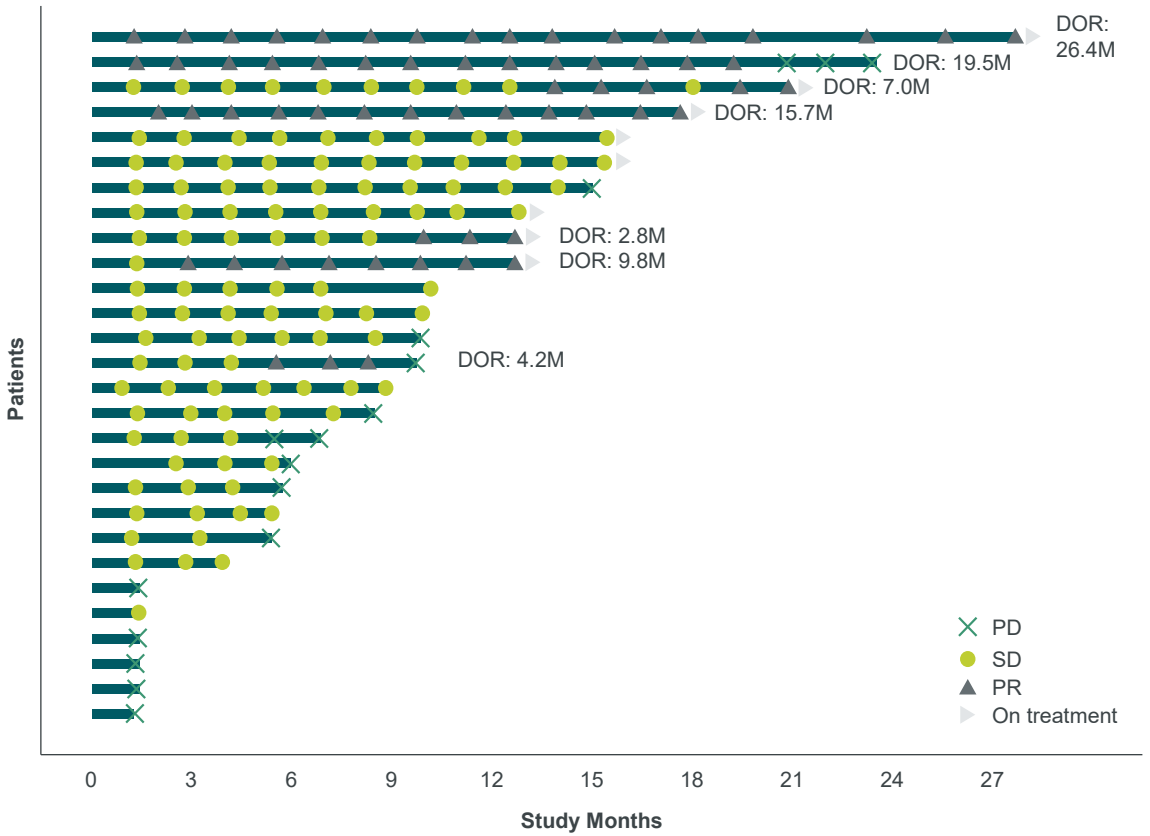
ORR: 25.0%; DCR: 82.1% (n=28)



mPFS: 10.9 months



mDOR: 19.6 months



1. Partnered with Bristol Myers Squibb; Xinan Sheng al. ESMO 2024 1692P

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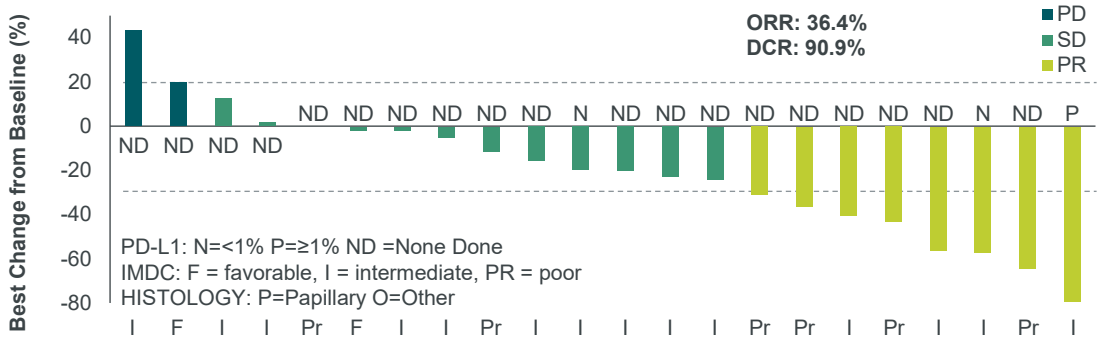
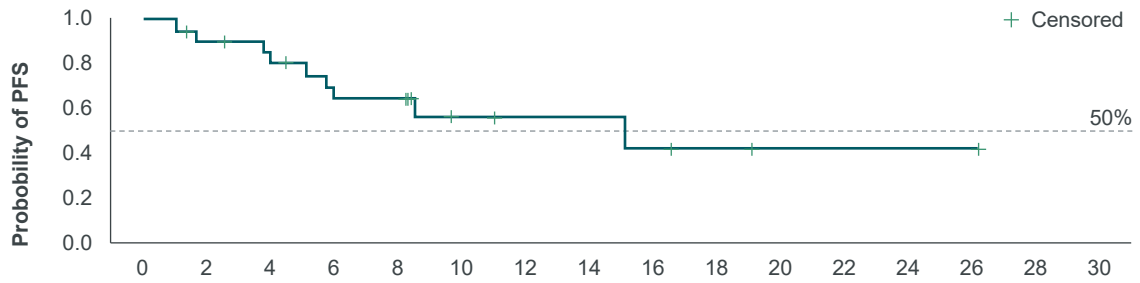
Pumitamig[1] Showed Encouraging Anti-Tumor Activity in Patients with 1L nccRCC Across Subtypes

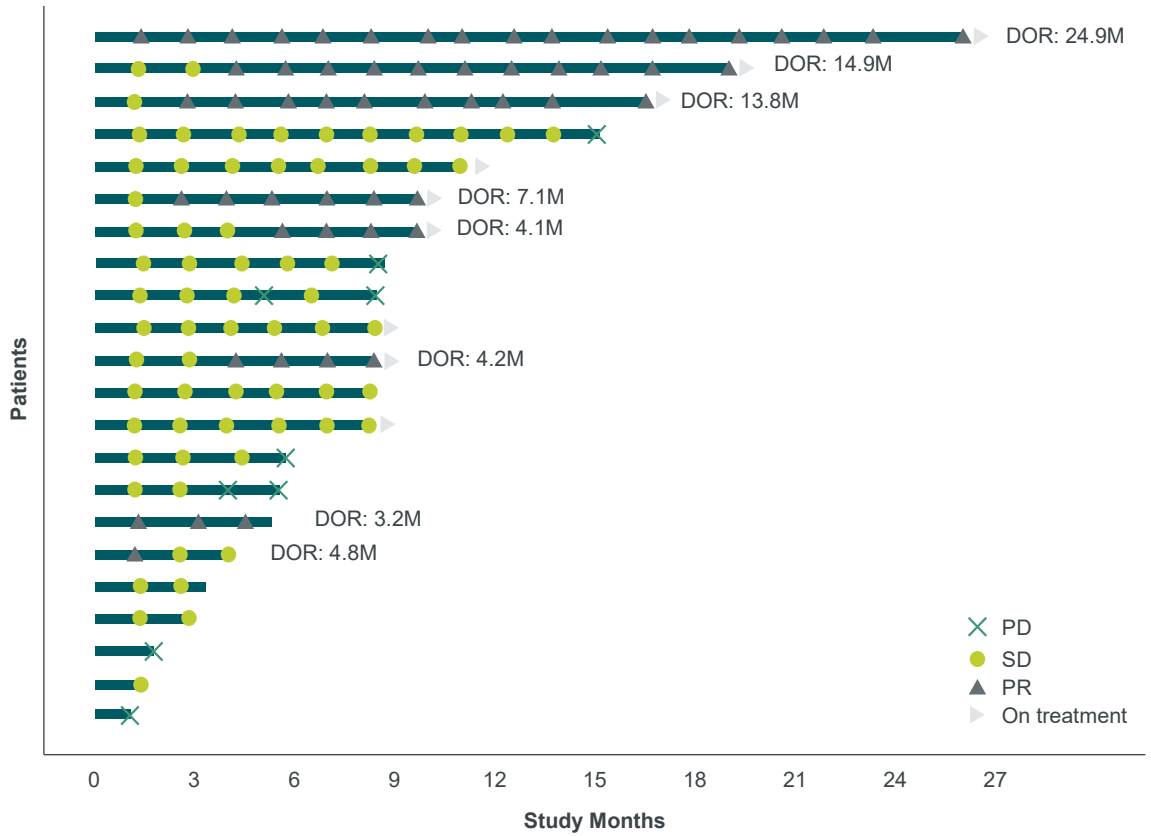
ORR: 36.4%; DCR: 90.9% (n=22)



mPFS: 15.1 months



DOR of up to 24.9 months



1. Partnered with Bristol Myers Squibb; Xinan Sheng, et. al. ESMO 2024 1692P.

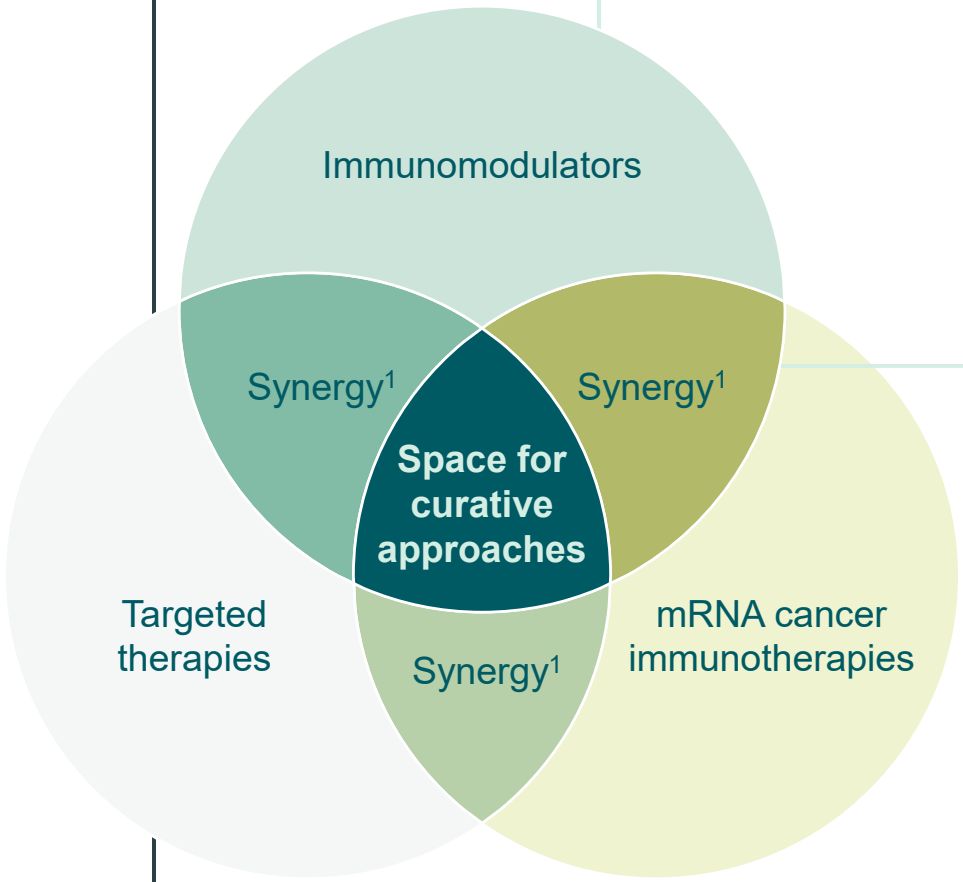
BIONTECH

Our Diverse GU Cancer Pipeline

Targeted therapies

BNT324 /DB-1311[2]

Anti-B7H3 ADC



Immunomodulators

Pumitamig[3]

Anti-PD-L1/ Anti-VEGF

Gotistobart[4]

Anti-CTLA-4

1. Synergistic potential; Partnered with: 2. DualityBio; 3. Bristol Myers Squibb; 4. OncoC4.

BIONTECH

Broad Exploration of BNT324/DB-1311[1]

Phase 1/2, multicenter trial of BNT324/DB-1311 enrolling 465 patients with advanced/metastatic solid tumors unselected for B7H3 expression, including in Prostate Cancer

Key Inclusion Criteria

- ≥1 measurable lesion per RECIST v1.1 (bone-only disease allowed)
- ECOG PS 0–1
- Adequate organ function
- Progressive mCRPC (serum testosterone <50 ng/dL and PD as defined by PCWG3 criteria)

Key Exclusion Criteria

- Prior B7H3 targeted therapy
- Prior TOP1 ADC

Study part/cohort	Additional inclusion criteria	Dose
Phase 1 Dose escalation/backfill		3 mg/kg up to 12 mg/kg IV Q3W
Phase 2:		
Cohort 4 (Dose optimization)	• Prior docetaxel; docetaxel rechallenge allowed • Prior NHT	R — 9 mg/kg IV Q3W (n=20) 6 mg/kg IV Q3W (n=22)
Cohort 11 (Post Lu-177)	• 1–2 lines of systemic chemotherapy, including docetaxel • Prior NHT • Prior Lu-177 radioligand therapy	• 6 mg/kg IV Q3W
Cohort 12 (Taxane-naïve)	• Taxane-naïve; prior (neo)adjuvant use >12 months earlier allowed • Prior NHT	• 6 mg/kg IV Q3W

Key Endpoints

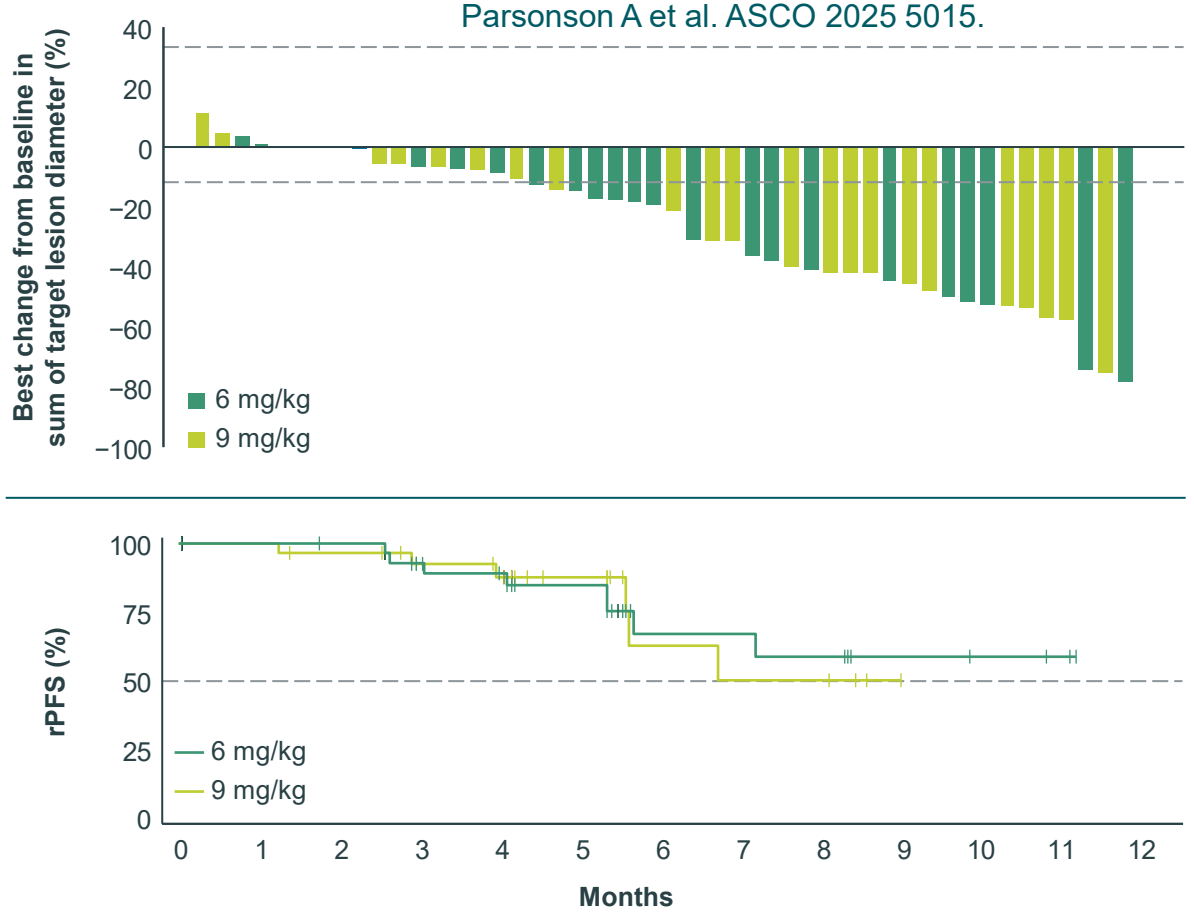
Primary: ORR, safety
Secondary: DCR, DOR, rPFS

1. Partnered with DualityBio; BNT324/DB-1311 treatment continued until disease progression/ unacceptable toxicity (treatment beyond progression was allowed); NCT05914116

Encouraging Efficacy with BNT324/DB-1311[1] in Late-Line mCRPC

	Overall (n=73)	6 mg/kg (n=38)	9 mg/kg (n=33)
Response evaluable, n	52	24	28
ORR, (%) [95% CI]	**42.3** [28.7, 56.8]	**41.7** [22.1, 63.4]	**42.9** [24.5, 62.8]
cORR, (%) [95% CI]	**30.8** [18.7, 45.1]	**29.2** [12.6, 51.1]	**32.1** [15.9, 52.4]
Pending confirmation, n	5	3	2
DCR, (%) [95% CI]	**90.4** [79.0, 96.8]	**91.7** [73.0, 99.0]	**89.3** [71.8, 97.7]
mDOR,* months [95% CI]	**ne** [4.0, ne]	**ne** [4.2, ne]	**ne** [4.0, ne]
Evaluable for rPFS, n	68	33	33
Median rPFS			
Months [95% CI]	**ne** [5.7, ne]	**ne** [5.7, ne]	**ne** [5.6, ne]
rPFS events, n (%)	14 (20.6)	8 (24.2)	6 (18.2)
rPFS rate, %			
6-month	**67.7**	**67.1**	**62.7**
9-month	58.0	58.7	ne

Parsonson A et al. ASCO 2025 5015.



Data cut-off: March 04, 2025

1. Partnered with DualityBio:

Ongoing and Next Steps | Genitourinary Cancer

Exploring pumitamig **in GU cancers**	**China Phase 1/2** Pumitamig[1] in 2L+ ccRCC and 1L nccRCC
Evaluating ADCs and novel combinations in GU cancers	**ADCs**

Partnered with: 1. Bristol Myers Squibb.

BIONTECH

5 Innovating Early-Stage Cancer Treatment with mRNA Cancer Immunotherapies

Prof. Özlem Türeci, M.D.
Chief Medical Officer and Co-founder

BIONTECH

SARS-CoV-2 mRNA Vaccines Sensitize Tumors to CPI

COVID-19 mRNA vaccines are associated with improved survival in patients with NSCLC or metastatic melanoma receiving immunotherapy in study with over 800 patients

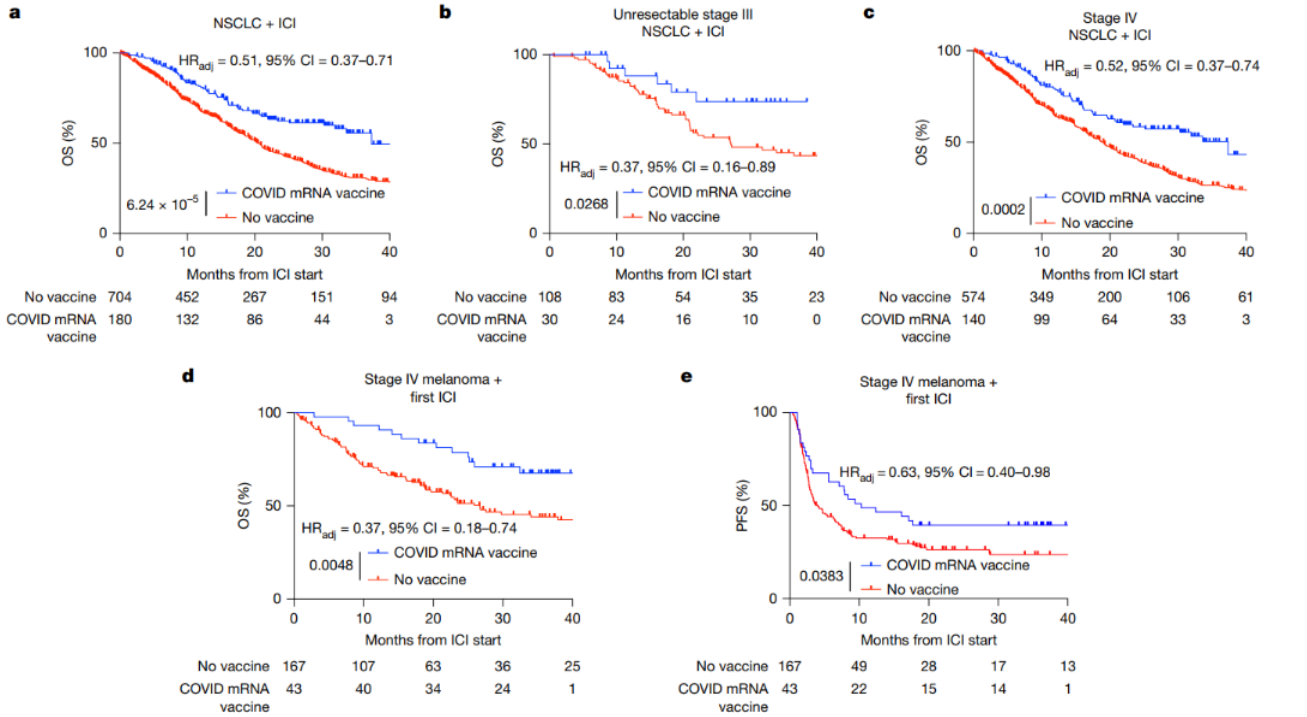
- ~25% of these patients received mRNA COVID-19 vaccines within 100 days of initiating immunotherapy
- Demonstrates potential of mRNA vaccines to stimulate innate immunity

Article

SARS-CoV-2 mRNA vaccines sensitize tumours to immune checkpoint blockade

https://doi.org/10.1038/s41586-025-09655-y
Received: 6 November 2024
Accepted: 19 September 2025
Published online: 22 October 2025
Open access
Check for updates

Adam J. Grippin[1,29✉], Christiano Marconi[2,29], Sage Copling[3,29], Nan Li[1,29], Chen Braun[1], Cole Woody[1], Elliana Young[4], Priti Gupta[1], Min Wang[1], Annette Wu[1], Seong Dong Jeong[5,6], Dhruvkumar Soni[2], Frances Weidert[2], Chao Xie[2], Eden Goldenberg[2], Andrew Kim[3], Chong Zhao[2], Anna DeVries[2], Paul Castillo[2,7], Rishabh Lohray[8], Michael K. Rooney[1], Benjamin R. Schrank[1], Yifan Wang[1], Yifan Ma[1], Enoch Chang[1], Ramez Kouzy[1], Kyle Dyson[9], Jordan Jafarnia[3], Nina Nariman[3], Gregory Gladish[10], Jacob New[11], Ada Argueta[1], Diana Amaya[1], Nagheme Thomas[2], Andria Doty[2], Joe Chen[1], Nikhil Copling[12], Gabriel Alatrash[1], Julie Simon[13], Alicia Bea Davies[13], William Dennis[1], Richard Liang[1], Jeff Lewis[14], Xiong Wei[14], Waree Rinsurongkawong[14], Ara A. Vaporciyan[15], Andrew Johns[16], D3CODE Team[17*], Jack Lee[18], Ji-Hyun Lee[19], Ryan Sun[18], Padmanee Sharma[16,20,21], Hai Tran[14], Jianjun Zhang[14], Don L. Gibbons[14], Jennifer Wargo[13], Betty Y. S. Kim[5,6], John V. Heymach[14], Hector R. Mendez-Gomez[2], Wen Jiang[1], Elias J. Sayour[2,7,30✉] & Steven H. Lin[1,30✉]

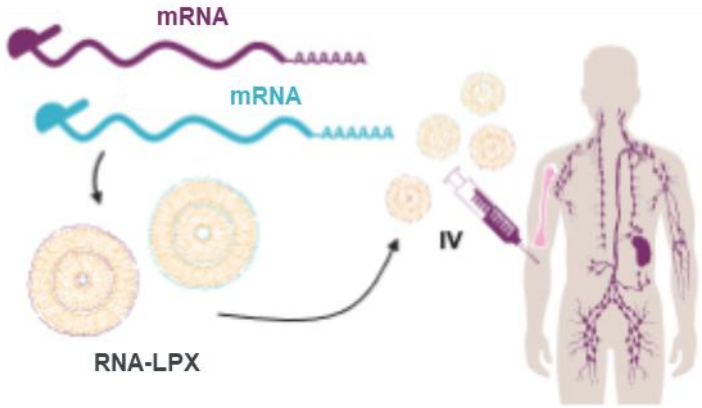


Adam Grippin et al, Nature, 2025; Controlling for 39 covariables with COX proportional hazards regression

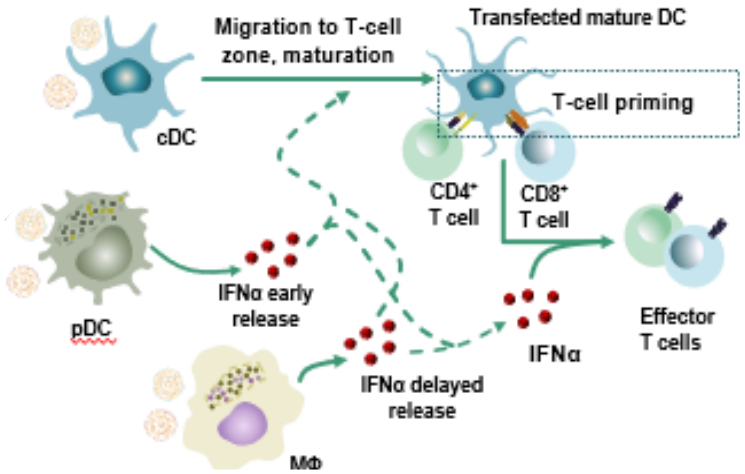
BIONTECH

mRNA Immunotherapies for Systemic Delivery and Induction of Potent Polyspecific Immune Responses Against Cancer Antigens

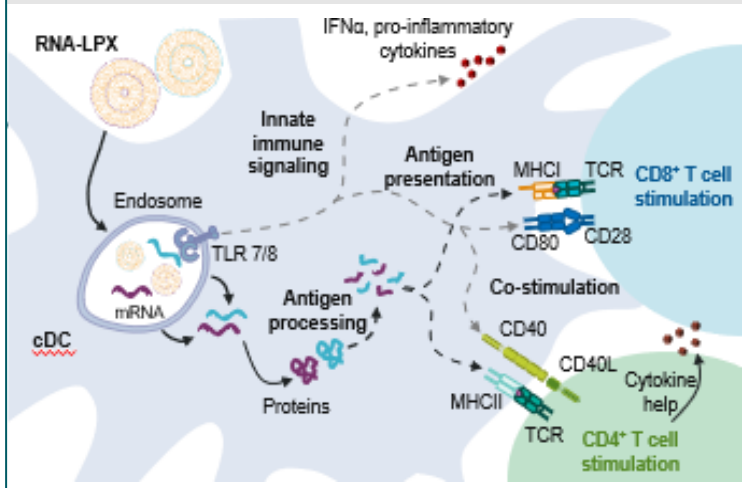
Uridine-based mRNA-lipoplexes (RNA-LPX) administered IV for preferential delivery to the APCs in spleen, lymph nodes and bone marrow



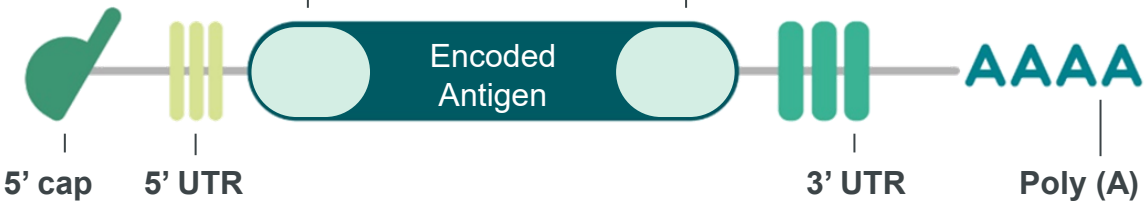
RNA-LPX is optimized for immune response stimulation



RNA-LPX combines targeted antigen delivery with stimulation innate immune signature



Secretory signal peptide
for translocation of the nascent polypeptide chain into the endoplasmic reticulum



MITD (MHC class I trafficking domain)

5`cap, UTRs, poly(A) tail engineered for optimized stability and translational performance
Long single-stranded mRNA format, uridine chemistry and LPX to activate innate immune signature

Full Exploitation of Cancer Target Space for Induction of Anti-Cancer Immunity

mRNA-LPX platform

iNeST[1]

individualized **Ne**oantigen-**S**pecific immuno**T**herapy

Neo-antigens

Individualized therapy

Individual patient samples (blood and tissue)

Artificial intelligence-driven neoantigen prediction

Individualized immuno-therapy

Mapping of mutations

On-demand tailored RNA manufacturing

Fixed Antigen **Vac**cine

FixVac

Multiple shared antigens

Off-the-shelf therapy

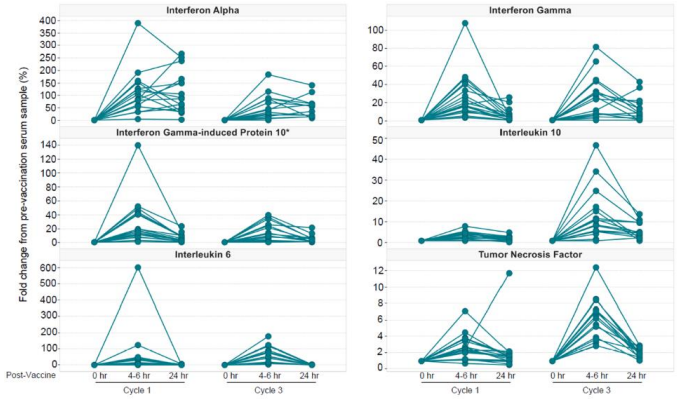
Fixed combination of shared tumor antigens[2]

Multi-antigen approach tailored to each indication

Proinflammatory innate immune signature

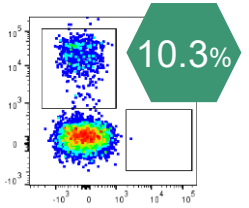
Strong vaccine-induced *de* novo CD8+ T cell responses across different cancer types[3]

Cytokines I NSCLC, BNT116, LuCa-MERIT-1 trial

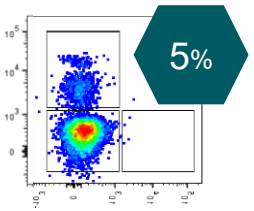


Fold change in cytokine levels from pre-vaccination to 4-6 hours post vaccination and 24 hours post vaccination

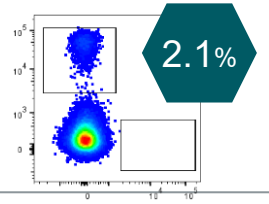
Mutation/Neoantigen
TNBC, BNT114
TNBC-MERIT trial



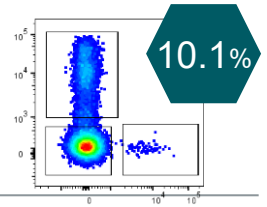
HPV16-E7
Head & Neck Cancer
BNT113, HARE-40 trial



MAGE-A3
Melanoma, BNT111, Lipo-MERIT trial



NY-ESO-1
Melanoma, BNT111, Lipo-MERIT trial



1 Partnered with Genentech, a member of the Roche Group. 2 Antigens vary across programs; 3. T-cell responses analyzed by *ex vivo* multimer staining analysis in blood.

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Clinical Trial Execution Across iNeST and FixVac Portfolios

Individualized immunotherapy: iNeST					FixVac		
Autogene cevumeran[1]					BNT111[2]	BNT113	BNT116
Adjuvant			1L	R/R	R/R	1L	Multiple settings
MIUC Phase 2	CRC Phase 2	PDAC Phase 2	Melanoma Phase 2	Solid tumors Phase 1	Melanoma Phase 2	HPV16+ PDL1+ HNSCC Phase 2/3	NSCLC Phase 1 & 2
+ Nivolumab	Monotherapy	+ Atezolizumab + mFOLFIRINOX	+ Pembrolizumab	Monotherapy and + Atezolizumab	+ Cemiplimab	+ Pembrolizumab	Mono & combinations including BNT324/DB1311[2], BNT326/YL202[1] and Pumitamig[3]
Recruitment ongoing	Recruitment ongoing Data presented from epi sub-study at **ASCO 2024** and from biomarker sub-study at **ESMO-GI 2024**	Recruitment ongoing Data from Phase 1 trial published in 2023 (Rojas et al., **Nature**) Follow up data published in February 2025 (Sethna et al., **Nature**)	Trial completed (n=125) Primary endpoint (significant PFS improvement) not met. Numerical OS benefit trend observed. Data presented at **ESMO 2025**	Trial completed (n=272) Data published (Lopez et al., **Nature Medicine 2025**)	Trial completed (n=184) **Positive topline data** announced in 2024 Data presented at **ESMO 2025**	Recruitment ongoing Trial updated to Phase 2/3	Recruitment completed in Phase 2 in 1L NSCLC[2] Presented at **SITC 2023, AACR 2024** and **SITC 2024.** Data in frail patients presented at **AACR 2025** Data in patients after cCRT presented at **WCLC 2025**

1. Partnered with: 1. Genentech, a member of the Roche Group; 2. In collaboration with Regeneron.

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iNeST[1] Phase 2 in 1L Melanoma – Study Design and Primary endpoint

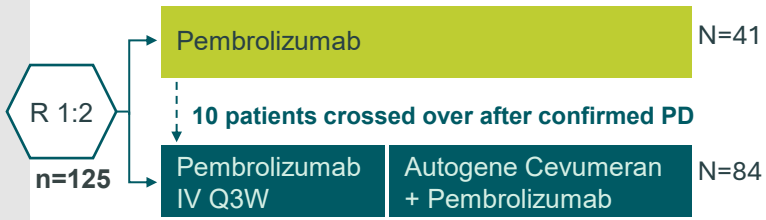
Trial Design

Key inclusion criteria

- Unresectable/metastatic melanoma
- Naïve to metastatic treatment setting

Stratification factors

- PD-L1 (≥5% vs. <5% or unknown)
- M-stage & LDH



Key Endpoints

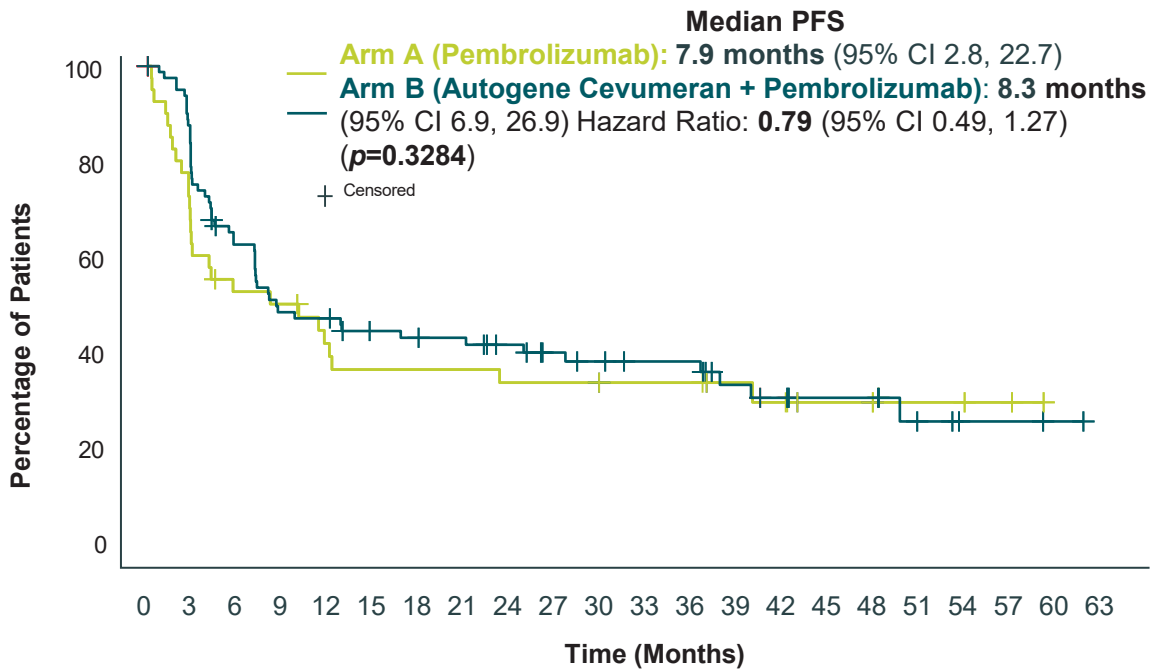
Primary endpoint: PFS
Secondary endpoints: OS and safety

Key Findings

- PFS: not met
- OS: difference at 12 and 24 months in favor of the combination
- Immunogenicity: robust neoantigen-specific T-cell responses with multi-epitope breadth; vaccine-expanded clones persisted well beyond induction
- Safety: well tolerated; mostly Grade 1–2 TRAEs; no new safety signals

Investigator-assessed PFS

Sullivan et al. ESMO 2025 #954P



1. Partnered with Genentech.2. Larkin, NEJM 2019; 3. Wolchok NEJM 2025; 4. Robert, Lancet Oncol 2019

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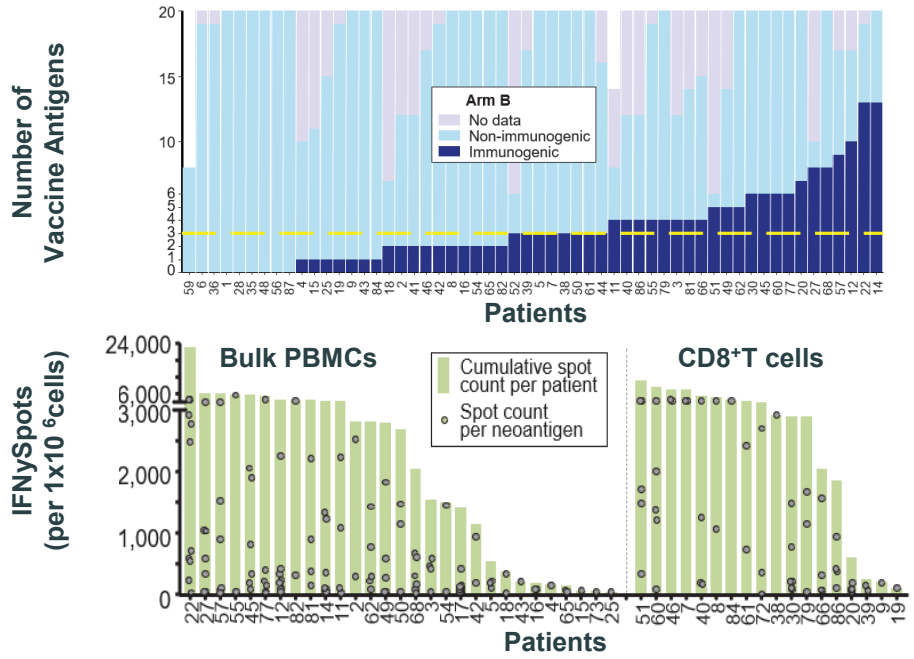
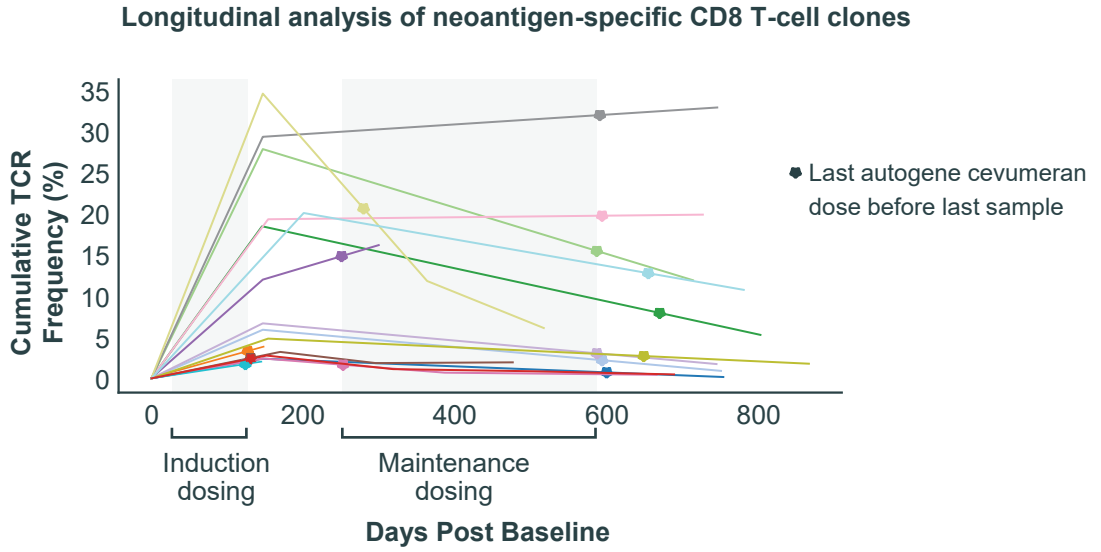
Autogene Cevumeran Drives Broad, Durable T-Cell Responses in Majority of Patients

- High patient-level immunogenicity: 47/56 (84%) patients mounted ≥1 e*x vivo* T-cell response
- Breadth, not just presence: Median 3 immunogenic neoantigens per patient (range ~1–13)
- Vast majority are *de novo* CD8+ T cell responses and they are of high magnitude
- 84% “immune responder” rate; 16% had no ELISpot signal at the measured timepoint(s)
- Neoantigen specific T-cell clones were detectable up to 1.5 years after last autogene cevumeran dose (median longitudinal follow up: 154 days, range 21 – 559 days).

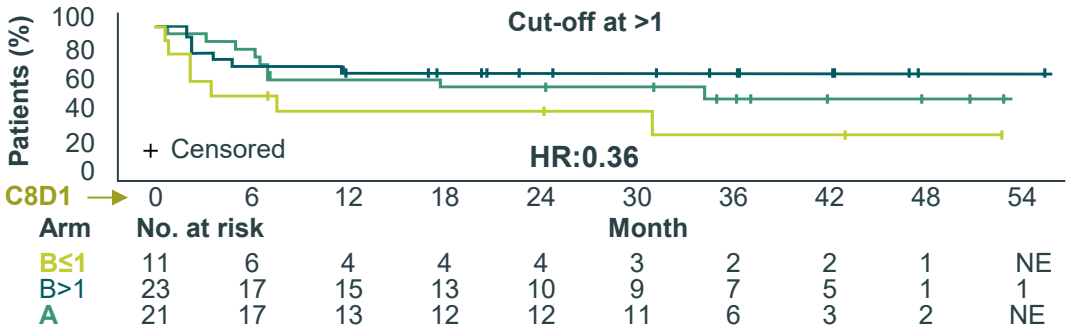


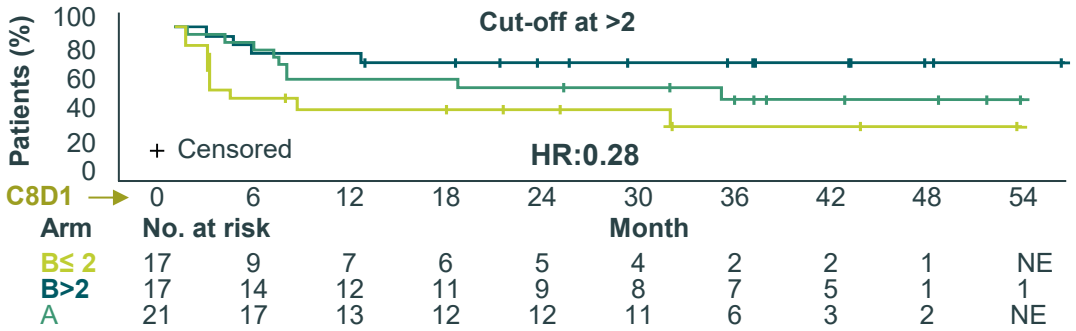


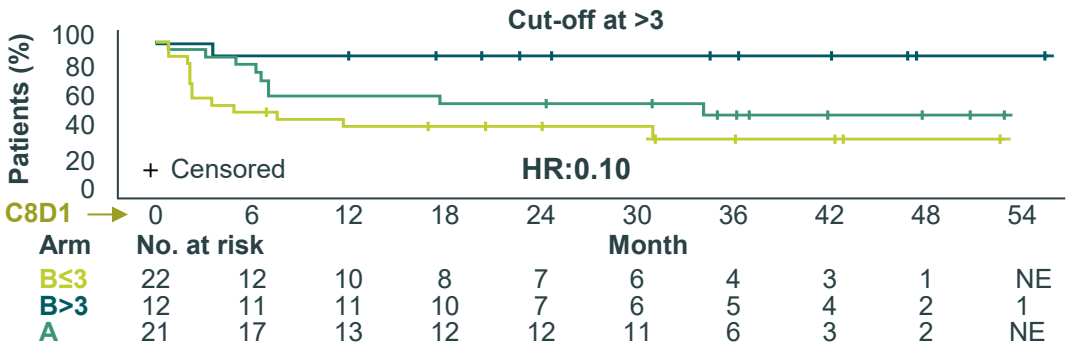
T-cell clones were detect-able up to 1.5 years after last autogene cevumeran dose (median longitudinal follow up: 154 days, range 21 – 559 days).

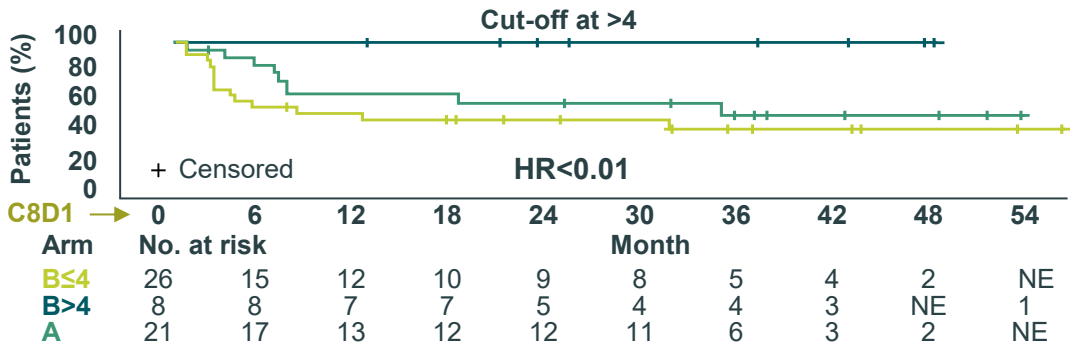
Sullivan et al. ESMO 2025 #954P

Autogene Cevumeran[1] Phase 2 in 1L Melanoma









Combination, higher breadth — Combination lower breadth — Pembrolizumab arm

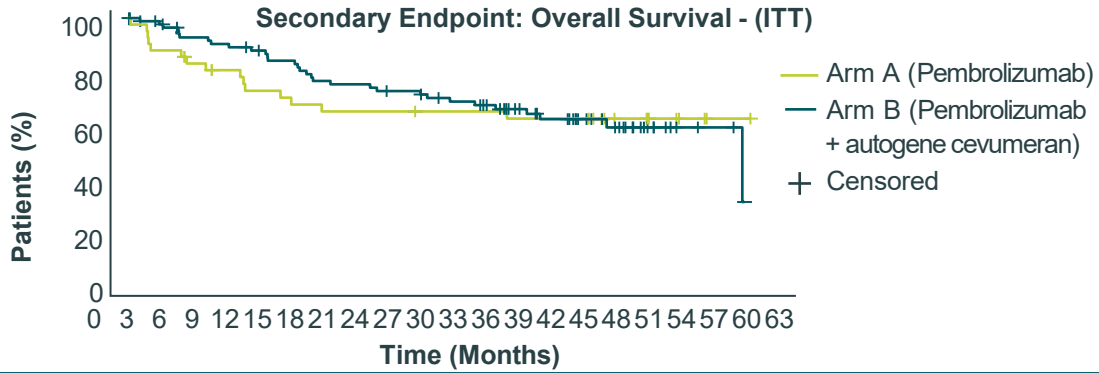
Trend of incremental PFS improvement observed in patients with higher neoantigen response breadth[2]

1. Partnered with Genentech, a member of the Roche Group; 2. Exploratory, non-powered analyses; Group "<= cutoff" includes ELISpot negative patients

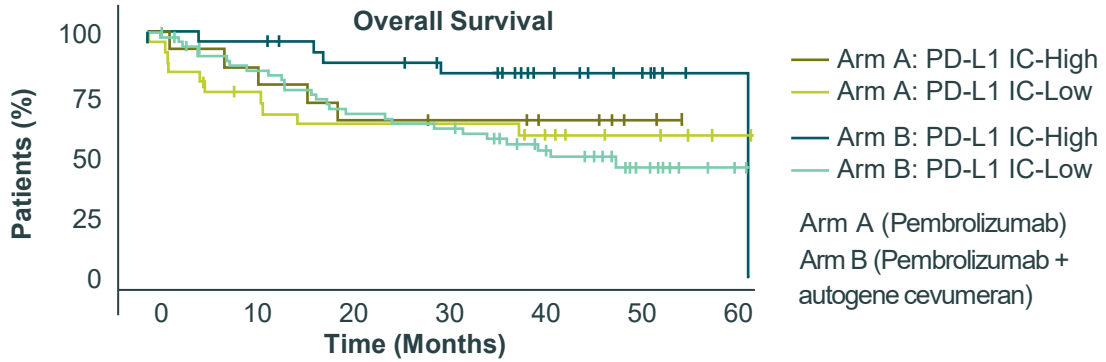
BIONTECH

Autogene Cevumeran[1] Phase 2 Data in 1L Melanoma Yield Insights That Support Current Development Focus

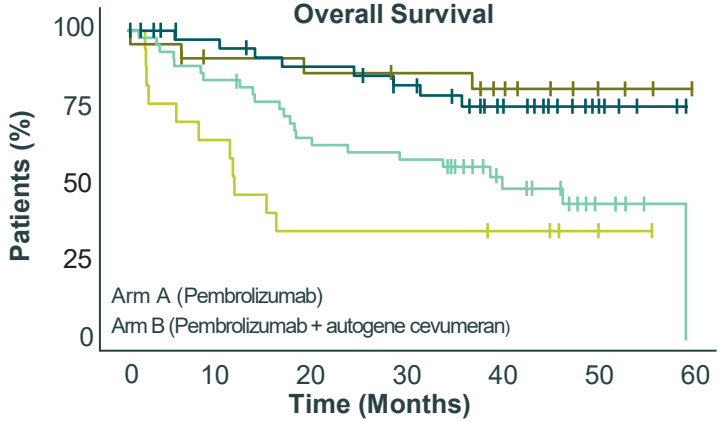
Numerical overall survival trend favoring the combination observed at 12-month and 24-month; no formal testing was performed for this secondary endpoint[2]

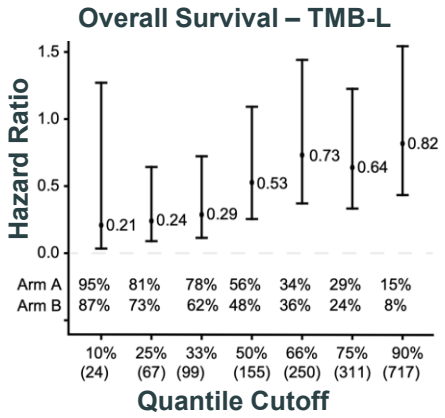


A trend of improved OS in patients with immune cell PD-L1 High vs. PD-L1-Low in the autogene cevumeran combination arm vs. the pembrolizumab arm



A trend of improved OS in patients with tumors with low mutation burden treated with autogene cevumeran combination vs. the pembrolizumab arm





Sullivan et al. ESMO 2025 #954P

1. Partnered with Genentech, a member of the Roche Group; 2. The primary analysis occurred after 79 PFS events; the median follow-up time for PFS was 36 months and for OS was 45.1 months in the ITT population.

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Ongoing and Next Steps | mRNA Cancer Immunotherapies

Evaluating **autogene cevumeran[2]** in **adjuvant-stage disease**

Phase 2

Autogene cevumeran[2] in adjuvant ctDNA+ stage II (high risk) / stage III MSS-CRC

Update planned for 2026

Phase 2

Autogene cevumeran[2] + chemotherapy + atezolizumab in adjuvant PDAC

Phase 2

Autogene cevumeran[2] + chemotherapy + nivolumab in adj. MIUC

Evaluating novel **combinations for FixVac**

Phase 2/3

BNT113 + pembrolizumab in HPV16+, PD-L1+ 1L HNSCC

Data expected in 2026

BNT116 + pumitamig[1]

BNT116 + gotistobart[3]

BNT116 + ADCs

Novel combination in 2026

Partnered with: 1. Bristol Myers Squibb; 2. Genentech, member of the Roche Group; 3. OncoC4.

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6 BioNTech's Path to Value Creation

Ramón Zapata
Chief Financial Officer

BIONTECH

Key 2025 Achievements Position BioNTech for Continued Oncology Innovation and Future Growth

Maintained Leadership in the COVID-19 Space

- ✓ **Launched variant-adapted COVID-19 vaccine**
- ✓ **Leading COVID-19 market share** globally (>50%)

Advanced Key Oncology Pan-Tumor **Programs** and Clinical Execution

- ✓ **>20 phase 2 and 3 oncology trials** ongoing
- ✓ **30+** novel-novel combination cohorts ongoing across tumors

Executed Key Strategic **Partnerships** and Acquisitions

- ✓ **Completed Biotheus acquisition**
- ✓ **Strategic BMS partnership** to maximize pumitamig

Strengthened Financial Position to Drive Sustained Innovation

- ✓ **Increased 2025 revenue guidance** to €2.6-2.8 billion[1]
- ✓ **€16.7 billion in cash**, cash equivalents and securities[2]

1 BioNTech increased revenue guidance and now expects its revenues for the full 2025 financial year to be in the range of €2,600 - €2,800 million, from previous range of €1,700 - €2,200 million; please refer to 3Q25 earnings press release and quarterly report on Form 6-K for risks and uncertainties. 2. As of September 30, 2025.

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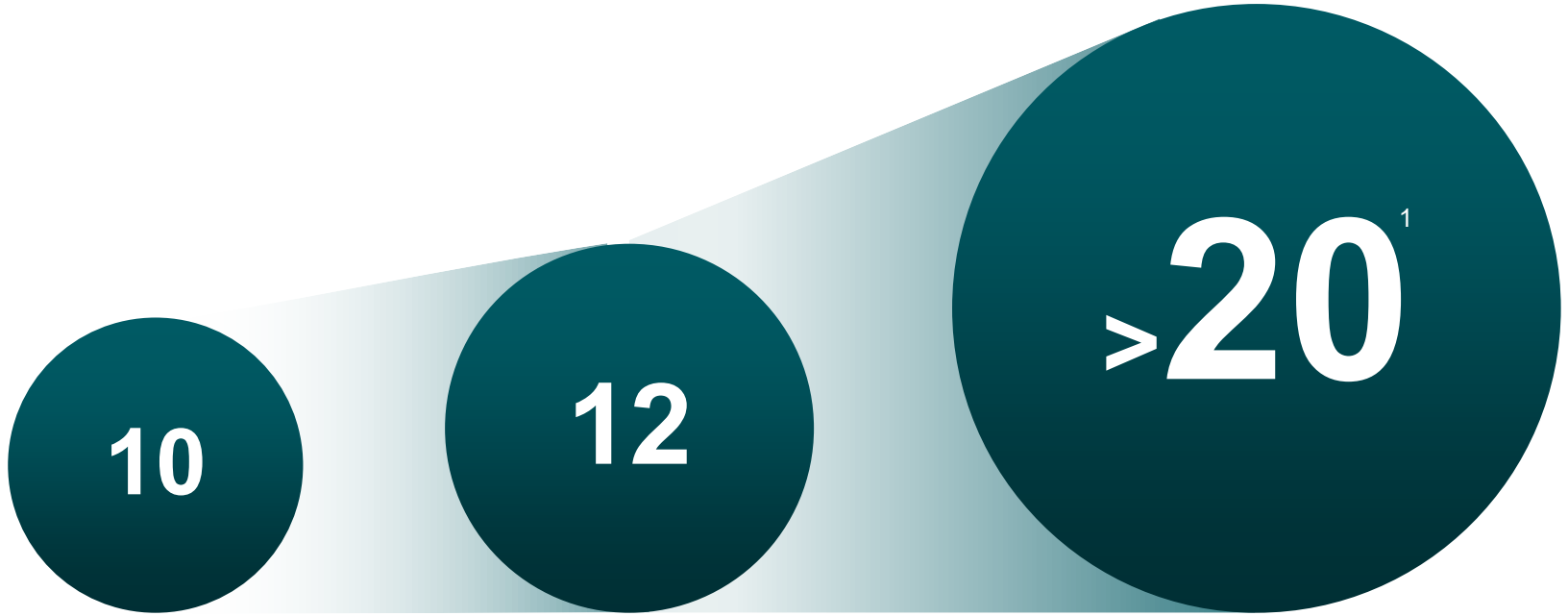
Driving Impact with Expansion of Later-Stage Oncology Pivotal Trials, While Maintaining R&D Expenditure



1 YTD October 31, 2025. Visualization illustrative and not to scale.

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Financial Levers Enable BioNTech's Dynamic R&D Investment

R&D Investment Control Levers

- **Active portfolio management strategy** sets high bar for late-stage investment and balance with high risk/reward programs
- **Innovative, tailored partnerships** to advance priority programs cost effectively, while strengthening P&L
- **Early-stage programs empowered** with dedicated budgets and opportunistic biotech in-licensing agreements

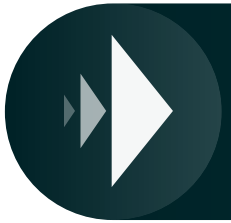
Innovative BMS Partnership Structured to Accelerate and Maximize Pumitamig, While Strengthening BioNTech Short- and Long-Term P&L

BIONTECH | Bristol Myers Squibb®

- Advancing trials in 10+ indications, including registrational trials, and plans to initiate in 1L microsatellite stable CRC and 1L gastric cancer
- 50/50 partnership and cost sharing structure de-risks R&D activities
- $3.5 billion up-front and non-contingent payments + $7.6 billion in milestone payments

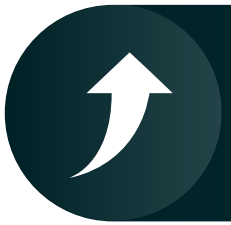
Maximizing potential of next-generation PD-L1xVEGF-A bispecific antibody, pumitamig, with global co-development and co-commercialization BMS partnership

BioNTech Key Principles on the Path to Value Creation



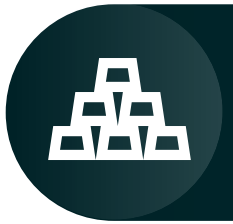
Strategic Portfolio Management: Shift to Later-Stage De-risked Programs

Shifting pipeline focus to later-stage programs with higher POS and de-risk through partnerships



Optimizing Productivity: Do More with Less Through Operational Excellence

Focus resources on highest priority programs, optimize cost base to support sustainable development trajectory



Financial Efficiency: Ensuring Cash Runway and Capital Resilience

Strong financial position provides strategic optionality

Speed and Scalability: Commercial Readiness and First-to-Market Approach

Ensure operational agility and organizational readiness to scale rapidly, build commercial infrastructure, prioritize speed to market

BioNTech Operating from Position of Strength

2026

Key Areas of Focus

1

Combination Therapy Momentum

Anticipate additional datasets from novel-novel combination trials with pumitamig

2

Modalities to Disease Areas

2026 marks BioNTech's movement to a focused disease area specific approach

3

Late-Stage Acceleration

Expect key late-stage data readouts for initial wave of oncology assets

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BioNTech Investor Relations

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Appendix

BioNTech's Oncology Pipeline – Phase 2 and Phase 3 Clinical Trials

Phase 2

- **Pumitamig**[1] (PD-L1 x VEGF-A)
  1L HCC + CTx[6]
- **Pumitamig**[1] (PD-L1 x VEGF-A)
  1L/2L+ (ES-)SCLC, + CTx
- **Gotistobart**[4] (CTLA-4)
  PROC, + pembrolizumab
- **Pumitamig**[1] **or BNT325/DB-1305 + BNT324/DB-1311**[3] **combination**
  Multiple solid tumors
- **Trastuzumab-Pamirtecan**[3] (HER2)
  multiple solid tumors
- **Autogene cevumeran**[2]
  Adj. ctDNA+ stage II or III CRC
- **Autogene cevumeran**[2]
  Adj. PDAC, + atezolizumab + mFOLFIRINOX
- **Autogene cevumeran**[2]
  Adj. MIUC, + nivolumab
- **BNT116**[5]
  1L adv. PD-L1 ≥ 50% NSCLC, + cemiplimab
- **Pumitamig**[1] (PD-L1 x VEGF-A)
  2L NSCLC, + CTx
- **Pumitamig**[1] (PD-L1 x VEGF-A)
  PDAC, +CTx — PLANNED
- **Pumitamig**[1] (PD-L1 x VEGF-A)
  1L/2L met. TNBC, + CTx
- **Pumitamig**[1] (PD-L1 x VEGF-A)
  2L ES-SCLC, + CTx[6]
- **Pumitamig**[1] (PD-L1 x VEGF-A)
  GBM — PLANNED
- **Pumitamig**[1] (PD-L1 x VEGF-A)
  1L ES-SCLC + CTx[6]
- **Pumitamig**[1] (PD-L1 x VEGF-A)
  EGFR TKI experienced, EGFRm NSCLC, + CTx[6]
- **Pumitamig**[1] (PD-L1 x VEGF-A)
  1L MPM, + CTx[6]
- **Pumitamig**[1] (PD-L1 x VEGF-A)
  1L CRC[6] — NEW
- **Pumitamig**[1] (PD-L1 x VEGF-A)
  2L NEN, + CTx[6]

Next generation IO | Targeted therapy | mRNA immunotherapy

Phase 3

- **Pumitamig**[1] (PD-L1 x VEGF-A)
  1L SCLC, + CTx
- **Pumitamig**[1] (PD-L1 x VEGF-A)
  1L CRC, + CTx — PLANNED
- **Pumitamig**[1] (PD-L1 x VEGF-A)
  1L NSCLC, + CTx
- **Pumitamig**[1] (PD-L1 x VEGF-A)
  1L TNBC, + CTx — PLANNED
- **Pumitamig**[1] (PD-L1 x VEGF-A)
  2L SCLC, + CTx[6]
- **Pumitamig**[1] (PD-L1 x VEGF-A)
  1L Gastric cancer — PLANNED
- **Pumitamig**[1] (PD-L1 x VEGF-A)
  1L TNBC, + CTx[6]
- **Gotistobart**[4] (CTLA-4)
  aPD-1/PD-L1 experienced squamous NSCLC
- **Trastuzumab-Pamirtecan**[3] (HER2)
  HR+/HER2-low met. breast cancer
- **Trastuzumab-Pamirtecan**[3](HER2)
  2L HER2+ endometrial cancer — NEW
- **BNT113**
  1L r./met. HPV16+ PD-L-1+ HNC, + pembrolizumab

Partnered with 1. Bristol Myers Squibb; 2. Genentech, member of Roche Group; 3. DualityBio; 4. OncoC4; 5. In collaboration with Regeneron; 6. Trial ongoing in China.

BIONTECH

BioNTech's Oncology Pipeline – Phase 1 and Phase 1/2 Clinical Trials

Phase 1

- **BNT314/GEN1059[2] (**EpCAMx4-1BB)
  Multiple solid tumors
- **BNT317**
  Multiple solid tumors
- **BNT326/YL202[5]** (HER3)
  Multiple solid tumors
- **BNT211** (CLDN6)
  Multiple solid tumors
- **BNT116**
  Adv. NSCLC

Phase 1/2

- **Pumitamig[1]** (PD-L1 x VEGF-A)
  1L TNBC[6]
- **Pumitamig[1]** (PD-L1 x VEGF-A)
  Multiple solid tumors[6]
- **BNT312/GEN1042[2]** (CD40x4-1BB)
  Multiple solid tumors
- **Gotistobart[4]** (CTLA-4)
  mCRPC, + radiotherapy
- **Gotistobart[4]** (CTLA-4)
  Multiple solid tumors
- **Pumitamig[1] + BNT3213 combination**
  1L HCC[6]
- **Pumitamig[1] + BNT314/GEN1059[2] combination** NEW
  Advanced CRC
- **Pumitamig[1] +/- BNT3212 combination** NEW
  Multiple solid tumors
- **Pumitamig[1] + Trastuzumab-Pamirtecan[3] combination**
  Adv. or metastatic HR+/- HER2-low, ultra-low or null breast cancer
- **Pumitamig[1] + BNT324/DB-1311[3] combination**
  Adv. or metastatic HNSCC, HCC, CC, PROC, NSCLC
- **Pumitamig[1] + BNT324/DB-1311[3] combination**
  Adv. or metastatic NSCLC or SCLC
- **Pumitamig[1] + BNT325/DB-1305[3] combination**
  Multiple solid tumors, PROC, OC, TNBC, NSCLC
- **Pumitamig[1] + BNT326/YL202[5] combination** NEW
  Multiple solid tumors
- **Pumitamig[1] + BNT326/YL202[5] combination** NEW
  Advanced NSCLC
- **BNT324/DB-1311[3]** (B7-H3)
  Multiple solid tumors
- **BNT325/DB-1305[3]** (TROP2)
  Multiple solid tumors
- **BNT329** NEW
  Multiple solid tumors

Next generation IO | Targeted therapy | mRNA immunotherapy

Partnered with: 1. Bristol Myers Squibb; 2. Genmab; 3. DualityBio; 4. Onco C4; 5. MediLink; 6. Trial ongoing in China.

BIONTECH

Upcoming Data Readouts at Medical Conferences in 2025

	Indication	Milestone	Congress
Pumitamig[1]	1L/2L TNBC	Global Phase 2 dose optimization data	SABCS
Gotistobart[2]	2L sq NSCLC	Phase 3 Stage 1 data	NACLC
BNT324/DB-1311[3]	CC and PROC	Phase 1/2 data	ESMO ASIA
BNT326/YL202[4]	HR+HER2-null or low BC	Phase 1/2 data	SABCS

Partnered with: 1. Bristol Myers Squibb; 2. OncoC4; 3. DualityBio.; 4. Medilink.

Select Data Readouts Set BioNTech Up For Catalyst-Rich Period Ahead

	Indication	Milestone	Expected Timing
Pumitamig[1]	1L NSCLC	Global Phase 2 data	2026
	1L/2L TNBC	Global Phase 2 dose optimization data	2025
	1L TNBC	China Phase 3 data	2026
Gotistobart[2]	2L sq NSCLC	Phase 3 Stage 1 data / Phase 3 Stage 2 data	2025 / 2026
Trastuzumab-Pamirtican[4]	2L+ HER2-expressing EC	Phase 2 data	2026
	2L HER2-Low BC	Global Phase 3 data	2026
BNT324/DB-1311	CC and PROC	Phase 1/2 data	2025
BNT326/YL202	HR+HER2-null or low BC	Phase 1/2 data	2025
Autogene cevumeran[2]	ctDNA+ adj. CRC	Phase 2 update	2026
FixVac BNT113	HPV16+ H&N	Phase 3 data	2026

Partnered with: 1. Bristol Myers Squibb; 2. OncoC4; 3.Genentech, a member of the Roche Group; 4. DualityBio.

Abbreviation Directory (1)

4-1BB	CD137	CCA	Cholangiocarcinoma	EC	Endometrial cancer
n L	*nth* line	cCRT	Concurrent chemoradiotherapy	ECOG	Eastern Cooperative Oncology Group
AACR	American Association for Cancer Research	CDx	Cluster of differentiation	EGFR	Epidermal growth factor receptor
(bs)AB	(bispecific) Antibody	CDK4/6	Cyclin-dependent 4/6	ELCC	European Lung Cancer Congress
ADA	Anti-drug antibody	ChIP	Chromatin Immunoprecipitation	EORTC	Europ. Organanisation. for Research and Treatment of Cancer
(bs)ADC	(bispecific) Antibody-drug conjugate	CI	Confidence interval	EpCAM	Epithelial cell adhesion molecule
ADCC	Antibody-dependent cell-mediated cytotoxicity	CLDN6	Claudin 6	ESCC	Esophageal squamous cell carcinoma
ADCP	Antibody-dependent cellular phagocytosis	CPI	Checkpoint inhibitor	ESMO	European Society for Medical Oncology
adj.	Adjuvant	CPS	Combined positive score	ESMO GI	European Society for Medical Oncology Gastrointestinal
AE	Adverse event	CR	Complete response	ES-SCLC	Extensive-stage small cell lung cancer
AGA	Actionable oncogenic alteration	CRC	Colorectal cancer	ESO	Esophageal
AI	Artificial intelligence	CRPC	Castration resistant prostate cancer	ET	Endocrine therapy
ALK	Anaplastic large-cell lymphoma kinase	(c)CRT	(Concurrent) Chemoradiation therapy	EU	European Union
AST	Aspartate aminotransferase	ctDNA	Circulating tumor DNA	Fab	Fragment antigen binding
ASCO	American Society of Clinical Oncology	CTLA	Cytotoxic T-lymphocyte-associated protein	Fc(R)	Fragment crystallizable region
AU	Absorvance unit	ctrl	Control	FDA	Food and Drug Administration
AUC	Area under curve	CTx	Chemotherapy	FIH	First in human
B7-H3	B7 Homolog 3	DAR	Drug-antibody ratio	FixVac	Fixed Antigen Vaccine
BC	Breast cancer	DC	Dendritic cell	FoxP3	Forkhead-Box-Protein P3
BICR	Blinded independent central review	DCR	Disease control rate	GBM	Glioblastoma multiforme
BLA	Biologics License Applications	DDI	Drug-drug interaction	GC/GEJ	Gastric/Gastro-esophageal junction cancer
BMS	Bristol Myers Squibb	DFS	Disease-free survival	GI	Gastrointestinal
BOIN	Bayesian optimal interval	DL	Dose level	GnP	Gemcitabine plus nab-paclitaxel
BOR	Best overall response	DLT	Dose limiting toxicity	GrzmB	Granzyme B
B-RAF	Serin/Threonin-Kinase	dMMR	Deficient mismatch repair	GTEx	Genotype-Tissue Expression
BTC	Biliary tract cancer	DNA	Desoxyribonucleic acid	GU	Genitourinary
C1D1	Cycle 1 day 1	DO	Dose optimization	Gyn	Gynecological
CA 19-9	Carbohydrate antigen 19-9	DoR	Duration of response	h	Human
CC	Cervical cancer	EAC	Esophageal adenocarcinoma	H&E	Hematoxylin and Eosin

Abbreviation Directory (2)

H&N	Head and neck	JCO	Journal of Clinical Oncology	NCI PRO-CTCAE	National Cancer Institute Patient Reported Outcome Common Terminology Criteria for Adverse Events
HCC	Hepatocellular carcinoma	KD	Dissociation constant		
HER2/3	Human epidermal growth factor receptor 2/3	KK-LC-1	Kita-Kyushu lung cancer antigen 1	NCI SEER	National Cancer Institute Surveillance, Epidemiology, and End Results
HLA	Human leukocyte antigen	LALA	IgG1 variant L234A/L235A		
HNSCC	Head and neck squamous cell carcinoma	LDH	Lactate dehydrogenase	NCT	National clinical trial
HPV	Human papilloma virus	LOD	Limit of detection	NE	Not evaluable for response
HR	Hormone receptor	LPX	Lipoplex	NEJM	The New England Journal of Medicine
IASLC	International Association for the Study of Lung Cancer	LUAD	Lung adenocarcinoma	NEN	Neuroendocrine neoplasm
		LUSC	Lung squamous carcinoma	NGS	Next generation sequencing
IC	Immune checkpoint	MAGE-A3	Melanoma antigen A3	NHT	Novel hormonal therapy
IC50	Half maximal inhibitory concentration	MEKi	Mitogen-activated protein kinase kinase	NIH	National Institutes of Health
ICI	Immune checkpoint inhibitor	MHC	Major histocompatibility complex	NOD SCID	Non-Obese Diabetic-Severe Combined Immunodeficiency
IFN	Interferon	MITD	Microtubule interacting and trafficking domain	NCT	National clinical trial
IgG	Immunoglobulin G			NE	Not evaluable for response
IHC	Immunohistochemistry	MIUC	Muscle-invasive urothelial carcinoma	NEJM	The New England Journal of Medicine
IIT	Investigator initiated trial	mo	Months	NEN	Neuroendocrine neoplasm
ILD	Interstitial lung disease	MOA	Mechanism of Action	NGS	Next generation sequencing
IL-x	Interleukin x	MΦ	Macrophage	NHT	Novel hormonal therapy
IMDC	International Metastatic Renal Cell Carcinoma Database Consortium	mono	Monotherapy	NIH	National Institutes of Health
		MPM	Malignant pleural mesothelioma	NOD SCID	Non-Obese Diabetic-Severe Combined Immunodeficiency
iNeST	Individualized NeoAntigen-Specific Therapy	MRD	Minimal residual disease	NR	Not reached
IO	Immuno-oncology	mRNA	Messenger ribonucleic acid	NSCLC	Non-small cell lung cancer
Ipi	Ipilimumab	MSI-H(L)	High(low)-frequence microsatellite Instability	OC	Ovarian cancer
ISH	In-situ hybridization			OP	Operation
ITT	Intention to treat	MSS	Microsatellite stability	(c)ORR	(confirmed) Objective response rate
iv	Intravenously	MTD	Maximum tolerated dose	OS	Overall survival
IvS	*in vitro* stimulation	NA	Not applicable	OVA	Ovalbumin
JAMA	Journal of the American Medical Association	NACLC	Nort America conference on Lung Cancer	P&L	Profit and loss statement
		NCI	National Cancer Institute	PARP	Poly (ADP-ribose) polymerase

Abbreviation Directory (3)

PBMC	Peripheral blood mononuclear cell
PBS	Phosphate buffered saline
PCWG3	Prostate Cancer Working Group 3
PD	Progressive disease
PD	Pharmacodynamics
PDAC	Pancreatic ductal adenocarcinoma
PD-(L)1	Programmed cell death protein (ligand) 1
pembro	Pembrolizumab
PFS	Progression-free survival
pH	Potentia hydrogenii
Ph x	(clinical) Phase x
PK	Pharmacokinetics
pMMR	Proficient mismatch repair
PMX	Pemetrexed
PoC	Proof of concept
POS	Point of sale
PR	Partial response
PR	Progesterone receptor
PRAME	Preferentially expressed antigen in melanoma
PROC	Platinum-resistant ovarian cancer
PVRIG	Poliovirus receptor-related immunoglobulin
R	Randomized
RAS	Rat sarcoma
RCC	Renal cell carcinoma
R&D	Research and development
RECIST	Response Evaluation Criteria in Solid Tumors
RLT	Radioligand therapy
RLU	Relative light units
RP2/3D	Recommended phase 2/3 dose
RPL18	Ribosomal Protein L18
R/R	Relapsed/refractory
RT-qPCR	Real-time quantitative polymerase chain reaction
SABCS	San Antonio Breast Cancer Symposium
SCCHN	Squamous cell carcinoma of head and neck
(ES)SCLC	(Extensive/ stage) small cell lung cancer
SD	Standard deviation
SD	Stable disease
SEC	Selenocysteinyl-tRNA
SEC	United States Securities and Exchange Commission
SEER	Surveillance, epidemiology, and end results
SEM	Standard error of the mean
SITC	Society of Immunotherapy of Cancer
SNP	Single Nucleotide Polymorphism
SoC	Standard of care
SPR	Surface Plasmon Resonance
(N)Sq	(non-)squamous
TAA	Tumor-associated antigen
TCGA	The Cancer Genome Atlas
TCR	T-cell receptor
TEA	Tissue engineering acoustophoretic
TFI	Treatment-free interval
TIGIT	T cell immunoreceptor with Ig and ITIM domains
TIL	Tumor-infiltrating lymphocytes
TKI	Tyrosine kinase inhibitor
TLR	Toll-like receptor
TMB-H (or L)	Tumor mutational burden-high or low
TME	Tumor microenvironment
TNBC	Triple-negative breast cancer
TNF	Tumor necrosis factor
TOP1	Topoisomerase I
TPS	Tumor proportion score
TPTE	Transmembrane phosphatase with tensin homology
TRAE	Treatment-related adverse event
Treg	Regulatory T cell
TRON	Helmholtz Institute for Translational Oncology
TROP2	Trophoblast cell-surface antigen 2
TYR	Tyrosine
UC	Urothelial cancer
UK	United Kingdom
ULN	Upper limit of normal
U.S.	United States
UTI	Urinary tract infection
UTR	Untranslated region
VEGF(R) - A	Vascular endothelial growth factor (receptor) A
VHH	Heavy chain variable
WCLC	World Conference of Lung Cancer
WHO	World Health Organization
WT	Wild type
YTD	Year to date