

ESMO 2023

BioNTech Data

October 2023

BIONTECH

BioNTech at ESMO 2023

Modality	Program	Abstract #	Type	Abstract Title	Date, Time & Location
mRNA	BNT116	1503TiP	TiP	A Phase 2 study of cemiplimab plus BNT116 versus cemiplimab alone in first-line treatment of patients with advanced non-small cell lung cancer with PD-L1 expression $\geq 50\%$	<ul style="list-style-type: none"> Onsite Poster display date Monday, 23 October 2023 Session: NSCLC. metastatic
Protein-based therapeutics	BNT314	1072P	Poster	DuoBody-EpCAMx4-1BB mediates conditional T-cell co-stimulation and promotes antitumor activity in preclinical models	<ul style="list-style-type: none"> Onsite Poster display date Monday, 23 October 2023 Session: Investigational Immunotherapy
	DB-1305	689P	Poster	DB-1305 (a Trop-2 targeted antibody-drug-conjugate [ADC]) in patients with advanced solid tumors: Preliminary clinical results from the Phase 1/2a study	<ul style="list-style-type: none"> Onsite Poster display date Monday, 23 October 2023 Session: Developmental Therapeutics
Cell therapies	BNT211	LBA35	Mini oral	BNT211-01: Interim results from a repeat dose escalation study of CLDN6 CAR-T cells manufactured with an automated process \pm a CLDN6-encoding CAR-T cell-Amplifying RNA Vaccine (CARVac)	<ul style="list-style-type: none"> Mini oral session - Developmental therapeutics Monday, 23 October 2023 4:30-6 PM CET Valencia Auditorium, Hall 10
	BNT221	1017O	Proffered paper	NTC-001: A Phase I study to test safety and efficacy of BNT221, a non-engineered neoantigen-specific T cell product, in patients with advanced or metastatic melanoma	<ul style="list-style-type: none"> Proffered Paper session - Investigational immunotherapy Monday, 23 October 2023 10:15-11:40 AM CET Burgos Auditorium, Hall 3

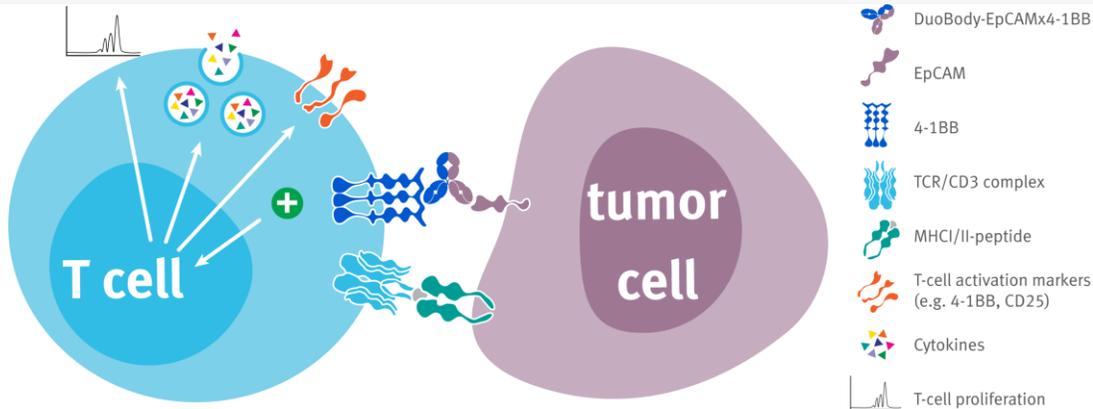
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BNT314/GEN1059

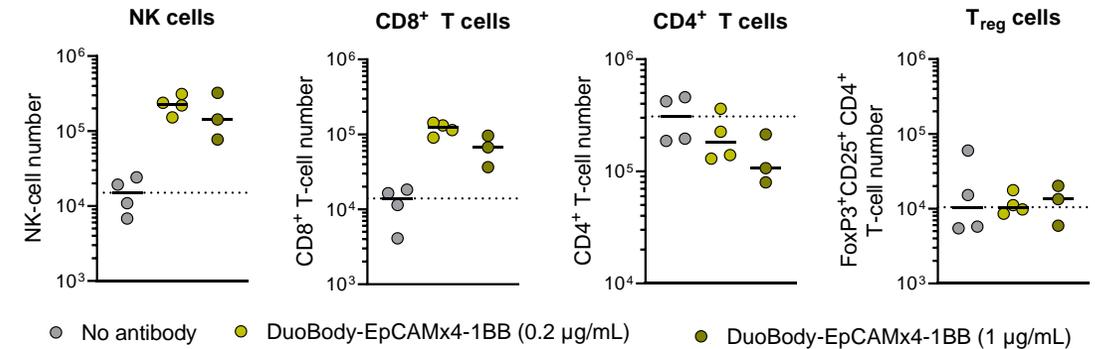
DuoBody-EpCAMx4-1BB mediates conditional T-cell co-stimulation and promotes antitumor activity in preclinical models

BNT314/GEN1059¹ – Designed to Boost Antitumor Immune Response Through EpCAM-Dependent 4-1BB Agonistic Activity

Mechanism of action



Expansion of tumor-infiltrating lymphocytes in human TIL cultures



- By cross-linking EpCAM⁺ tumor cells with activated 4-1BB⁺ T cells, BNT314/GEN1059 exhibits conditional 4-1BB agonistic activity, resulting in enhanced T-cell proliferation and effector functions, such as cytokine secretion and cytotoxic activity
- BNT314/GEN1059 is hypothesized to boost existing antitumor immune responses and may be further exploited in combination with other immunotherapy

First preclinical disclosure at ESMO 2023:

DuoBody-EpCAMx4-1BB mediates conditional T-cell co-stimulation and promotes antitumor activity in preclinical models.

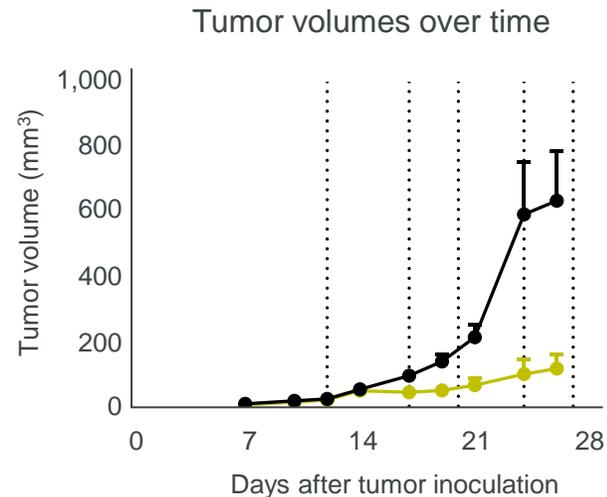
Fellermeier-Kopf et al. Presented at ESMO 2023. #1072P

1. BNT314 (GEN1059) is partnered with Genmab based on 50/50 sharing of costs and profits. EpCAM = epithelial cell adhesion molecule; TCR = T cell receptor; CD = cluster of differentiation; MHC = major histocompatibility complex; NK cell = natural killer cell; Treg cell = regulatory T cell.

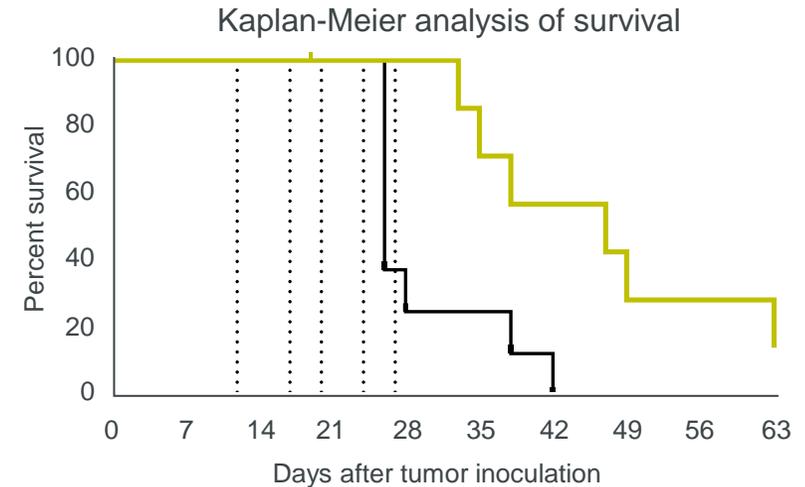
BNT314/GEN1059¹ – Designed to Boost Antitumor Immune Response Through EpCAM-Dependent 4-1BB Agonistic Activity

Antitumor activity in human EpCAM-transgenic mice

Fellermeier-Kopf et al. Presented at ESMO 2023. #1072P



● mbsIgG2a-hEpCAMxm4-1BB]****
● Isotype control]****

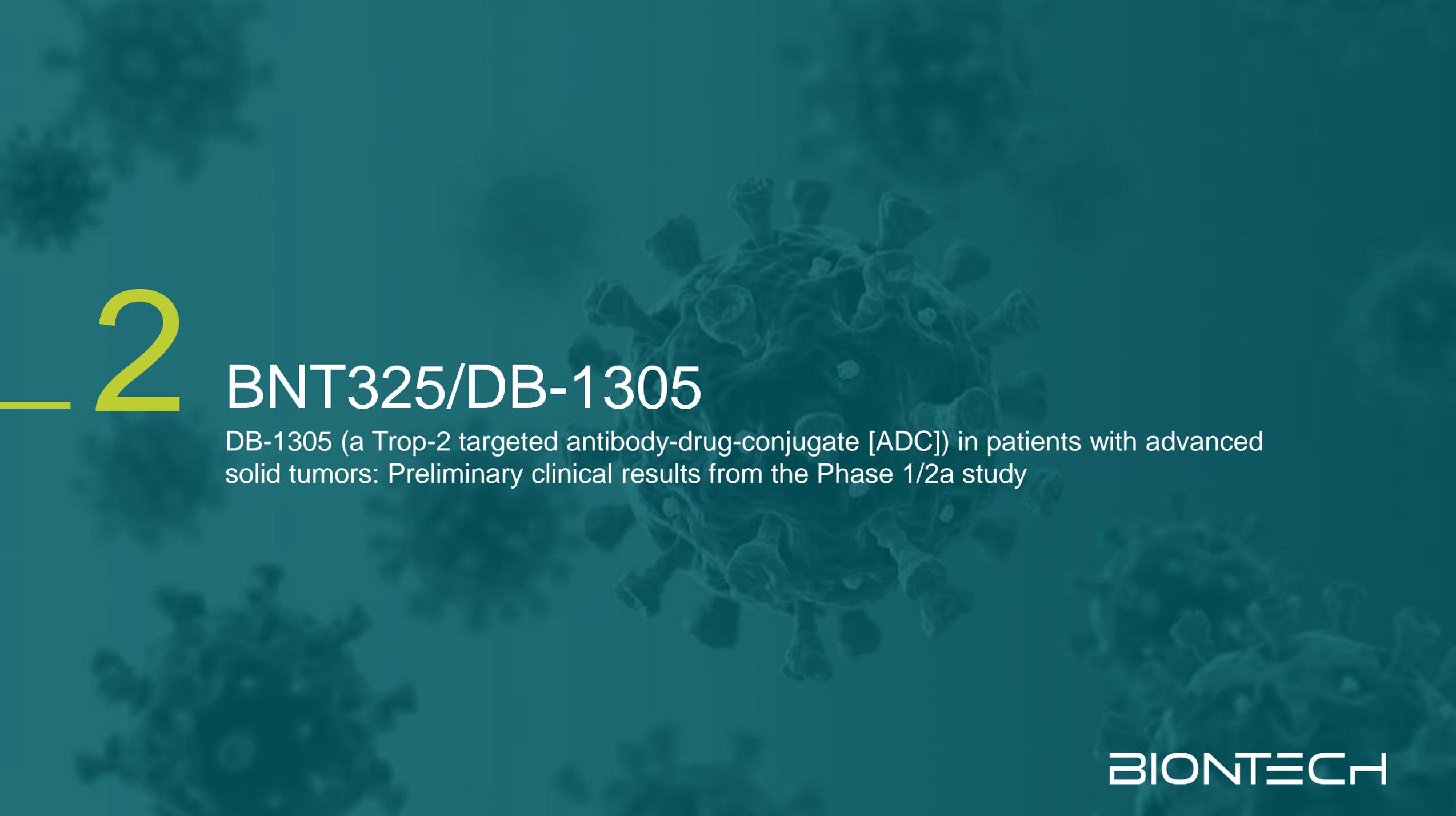


● mbsIgG2a-hEpCAMxm4-1BB]**
● Isotype control]**

Results suggest that BNT314/GEN1059 may boost antitumor immunity in cancer patients with EpCAM+ tumors.

The clinical safety and preliminary antitumor activity of DuoBody-EpCAMx4-1BB will be investigated in patients with solid tumors in a first-in-human trial.

1. BNT314 (GEN1059) is partnered with Genmab based on 50/50 sharing of costs and profits.
EpCAM = epithelial cell adhesion molecule



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BNT325/DB-1305

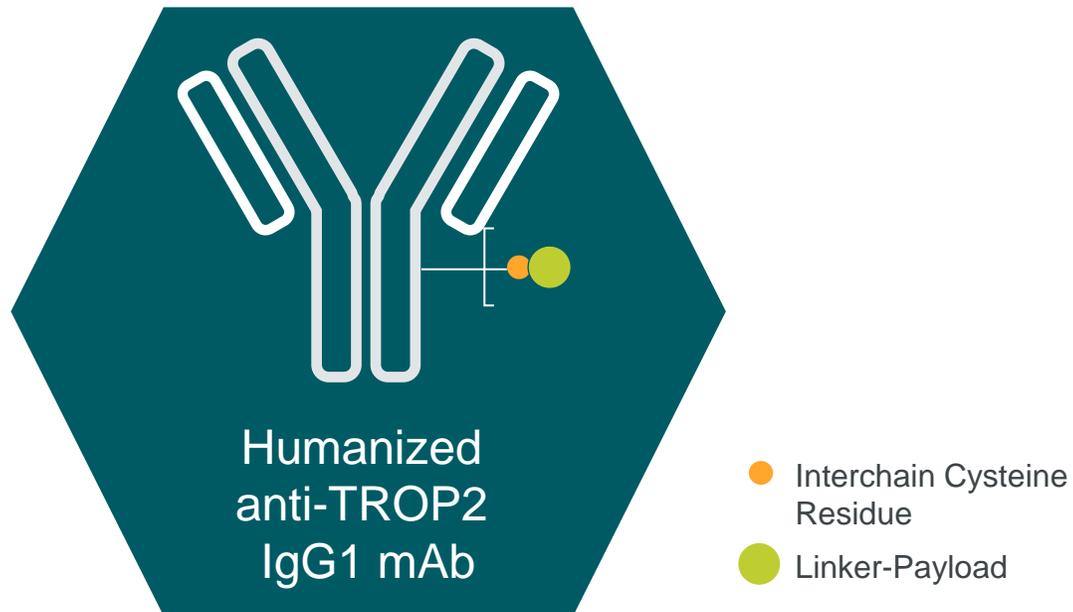
DB-1305 (a Trop-2 targeted antibody-drug-conjugate [ADC]) in patients with advanced solid tumors: Preliminary clinical results from the Phase 1/2a study

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BNT325/DB-1305¹ - TROP2 ADC

The three components of BNT325/DB-1305¹:

- Humanized anti-TROP2 IgG1 mAb
- Proprietary DNA topoisomerase I inhibitor (P1021)
- Cleavable linker



Key Attributes of BNT325/DB-1305

- Selectively endocytosed into the lysosome of Trop-2+ cells
- Optimized drug-to-antibody ratio: ~4
- Tumor-selective cleavable linker
- Stable linker-payload
- High potency of payload with a short systemic half-life
- Payload mechanism of action: topoisomerase I inhibitor
- Bystander antitumor effect

¹. Partnered with DualityBio;

FIH Phase 1/2 to Evaluate Safety, Tolerability and Antitumor Activity of BNT325/DB-1305¹ in Patients with Advanced/Metastatic Solid Tumors

Phase 1/2a study design (NCT05438329)

Multicenter, non-randomized, open-label, multiple-dose, first-in-human (FIH) study, n = 235

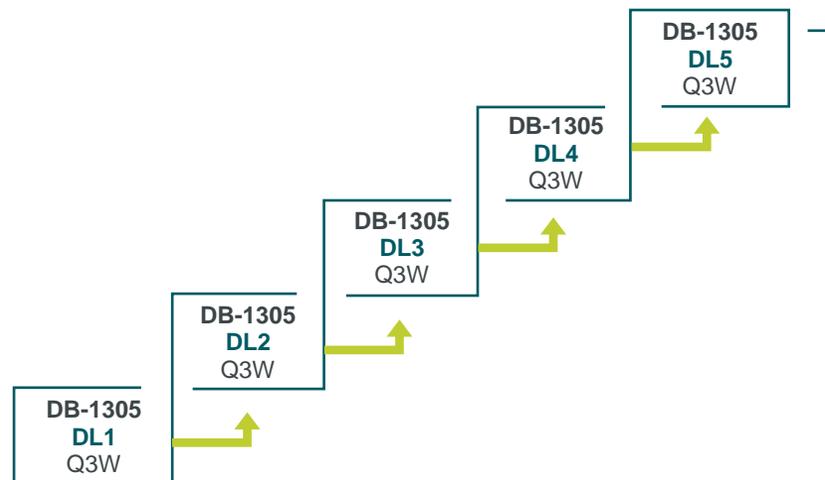
Inclusion criteria

- Advanced/unresectable, recurrent or metastatic solid tumors
- Relapsed or progressed on or after standard systemic treatments
- ECOG 0-1
- Adequate organ function

Key endpoints

- **Primary:** Phase 1: Assessment of DLT, TEAE, SAE, MTD, RP2D. Phase 2a: TEAEs, SAEs, ORR
- **Secondary:** Pharmacokinetic measures (AUC, C_{max}, T_{max}, T_{1/2})

Part 1: Dose Escalation



Part 2a: Dose expansion

RP2D
Q3W

Indications

- Small cell lung cancer (SCLC)
- HR+/HER2-neg breast cancer
- NSCLC with no EGFR-sensitizing mutation, ALK gene translocation or onco-driver gene mutations
- TNBC without prior sacituzumab govitecan treatment
- TNBC with treatment failure on sacituzumab govitecan

Disease progression, withdrawal of consent, unacceptable toxicity

1. Partnered with DualityBio. ECOG = Eastern Cooperative Oncology Group; DL = dose level; Q3W = every three weeks; RP2D = recommended Phase 2 dose; HR = hormone receptor; HER2 = human epidermal growth factor 2 receptor; NSCLC = non-small cell lung cancer; TNBC = triple negative breast cancer; DLT = dose-limiting toxicity; TEAE = treatment emergent adverse events; SAE = serious adverse events; MTD = maximum tolerated dose; ORR = objective response rate; AUC = Area under concentration-time curve; C_{max} = maximum observed plasma concentration; T_{max} = time to C_{max}; T_{1/2} = terminal elimination half-life

BNT325/DB-1305¹ in Heavily Pretreated Patients with Multiple Solid Tumors

Phase 1/2a FIH study (NCT05438329): Baseline characteristics

Marathe O. et al. Presented at ESMO 2023. Poster #689P.

Baseline patient characteristics	Total (n=44)
Age , median (range)	59.0 (40.0-78.0)
Female , n (%)	26 (59.1)
Region , n (%)	
United States	21 (47.7)
China	23 (52.3)
ECOG performance status , n (%)	
0	7 (15.9)
1	37 (84.1)

Baseline patient characteristics	Total (n=44)
Median prior lines of therapy , median (range)	3.0 (1-6)
Cancer types , n (%)	
Non-small cell lung cancer	30 (68.2)
Colorectal cancer	4 (9.1)
HR+HER2- breast cancer	2 (4.5)
Ovarian cancer	2 (4.5)
Ampullary carcinoma	1 (2.3)
Appendiceal cancer	1 (2.3)
Duodenal cancer	1 (2.3)
Gastric or gastroesophageal junction adenocarcinoma	1 (2.3)
Primary malignant neoplasm of fallopian tube	1 (2.3)
Triple negative breast cancer	1 (2.3)
Prior anticancer systemic therapy , n (%)	
With prior immunotherapy therapy	20 (45.5)
With prior platinum therapy	39 (88.6)

1. Partnered with DualityBio.
 FIH = first in human; ECOG = Eastern Cooperative Oncology Group ; HR = hormone receptor; HER2 = human epidermal growth factor receptor 2;

BNT325/DB-1305¹ Demonstrated Antitumor Activity in Patients With NSCLC and Other Solid Tumors

Phase 1/2a FIH study (NCT05438329): Clinical Efficacy

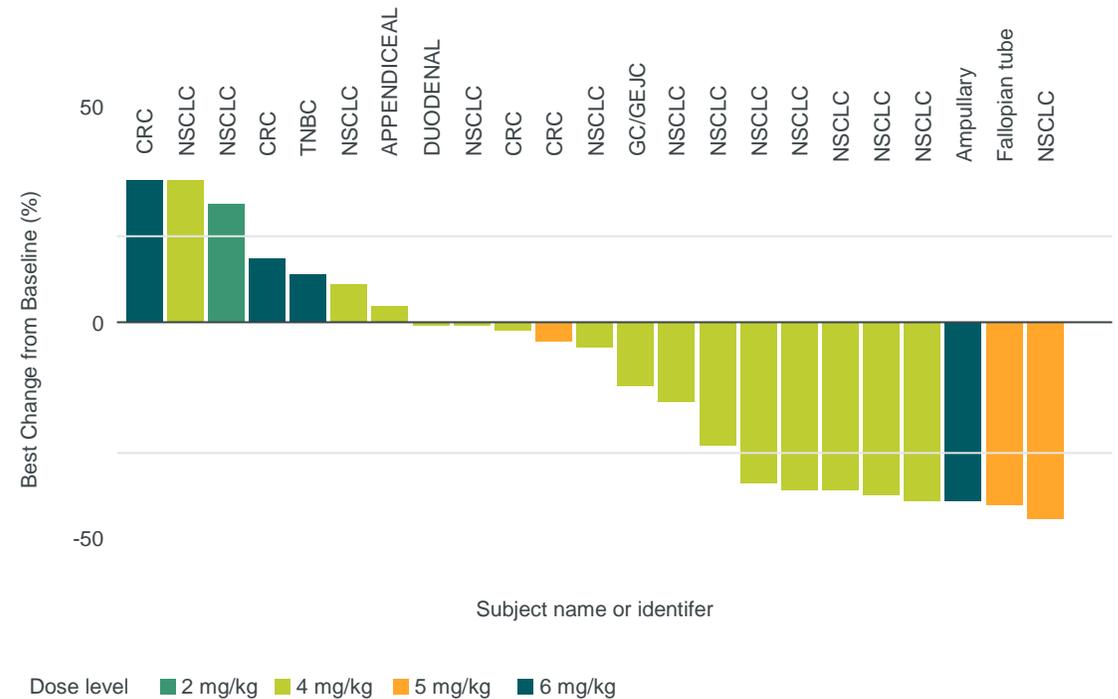
Marathe O. et al. Presented at ESMO 2023. Poster #689P.

Anti-tumor activity in heavily pretreated patients with 3 median prior lines of treatment

	Unconfirmed ORR, %	Unconfirmed DCR, %
All patients (n=23)	30.4	87.0
NSCLC (n=13)	46.2	92.3

- Antitumor activity was also observed in a patient with fallopian tube cancer: 1 unconfirmed PR at 5 mg/kg: ORR, 1/1

Best tumor response for all patients with post-baseline scans (n=23):



1. Partnered with DualityBio.

FIH = first in human; ORR = objective response rate; DCR = disease control rate; NSCLC = non-small cell lung cancer; CRC = colorectal cancer; TNBC = triple-negative breast cancer; GC = gastric cancer; GEJC = gastroesophageal junction cancer.

BNT325/DB-1305¹ Was Tolerable and TRAEs Were Manageable in Lower Dose Levels

Phase 1/2a FIH study (NCT05438329): Safety

Marathe O. et al. Presented at ESMO 2023. Poster #689P.

Overall safety

	2 mg/kg (n=1) n (%)	4 mg/kg (n=20) n (%)	5 mg/kg (n=17) n (%)	6 mg/kg (n=6) n (%)	Total (n=44) n (%)
Any TRAEs	0	19 (95.0)	15 (88.2)	6 (100)	40 (90.9)
Grade ≥3	0	7 (35.0)	5 (29.4)	3 (50.0)	15 (34.1)
Serious TRAEs	0	3 (15.0)	4 (23.5)	3 (50.0)	10 (22.7)
Lead to dose reduction	0	1 (5.0)	2 (11.8)	3 (50.0)	6 (13.6)
Lead to dose interruption	0	6 (30.0)	5 (29.4)	4 (66.7)	15 (34.1)
Lead to dose discontinuation	0	1 (5.0)	0	0	1 (2.3)
Dose-limiting toxicities	0	0	0	3 (50)	3 (6.8)

One patient died by suicide on day 18 after first dose and one patient experienced double pneumonia related AE on day 49.

Summary of AEs (≥20%) and all AESI (n=44)

	TEAEs		TRAEs		AESI*	
	All grade n (%)	Grade ≥3 n (%)	All grade n (%)	Grade ≥3 n (%)	All grade n (%)	Grade ≥3 n (%)
Stomatitis	33 (75.0)	10 (22.7)	33 (75.0)	10 (22.7)	33 (75.0)	10 (22.7)
Nausea	13 (29.5)	1 (2.3)	12 (27.3)	1 (2.3)	-	-
Lymphocyte count decreased	10 (22.7)	6 (13.6)	0	0	-	-
Infusion related reaction	9 (20.5)	0	9 (20.5)	0	9 (25.0)	0
Decreased appetite	9 (20.5)	0	7 (15.9)	0	-	-
Mucosal inflammation	1 (2.3)	1 (2.3)	1 (2.3)	1 (2.3)	1 (2.3)	1 (2.3)
Interstitial lung disease	1 (2.3)	0	1 (2.3)	0	1 (2.3)	0

* AESI includes interstitial lung disease/pneumonitis, infusion related reaction, diarrhea, stomatitis/mucosal inflammation, and combined elevations of aminotransferases and bilirubin.

BNT325/DB-1305 was tolerable and all AEs were manageable in lower dose levels (i.e., 2 and 4 mg/kg)

- Three patients dosed at 6 mg/kg experienced dose-limiting toxicities (i.e., stomatitis, febrile neutropenia, and white blood cell decreased), and the maximum tolerated dose was established as 5 mg/kg
- No TEAEs led to death

1. Partnered with DualityBio.

TRAE = treatment related adverse event; FIH = first in human. AESI=Adverse event of special interest. TEAE=Treatment emergent adverse event.

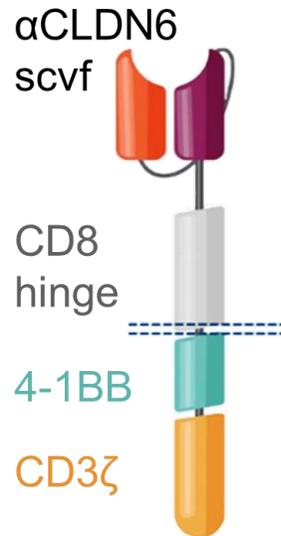
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BNT211

BNT211-01: Interim results from a repeat dose escalation study of CLDN6 CAR-T cells manufactured with an automated process ± a CLDN6-encoding CAR-T cell-Amplifying RNA Vaccine (CARVac)

BNT211: First-in-Class Approach for CLDN6+ Solid Tumors

CLDN6 CAR T



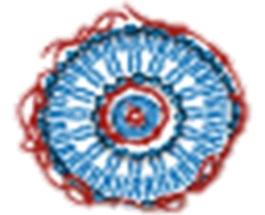
- ✓ Highly sensitive and specific 2nd-generation CAR against CLDN6
- ✓ CLDN6 is absent from healthy adult tissue, but expressed in a variety of cancers¹



CLDN6 CARVac

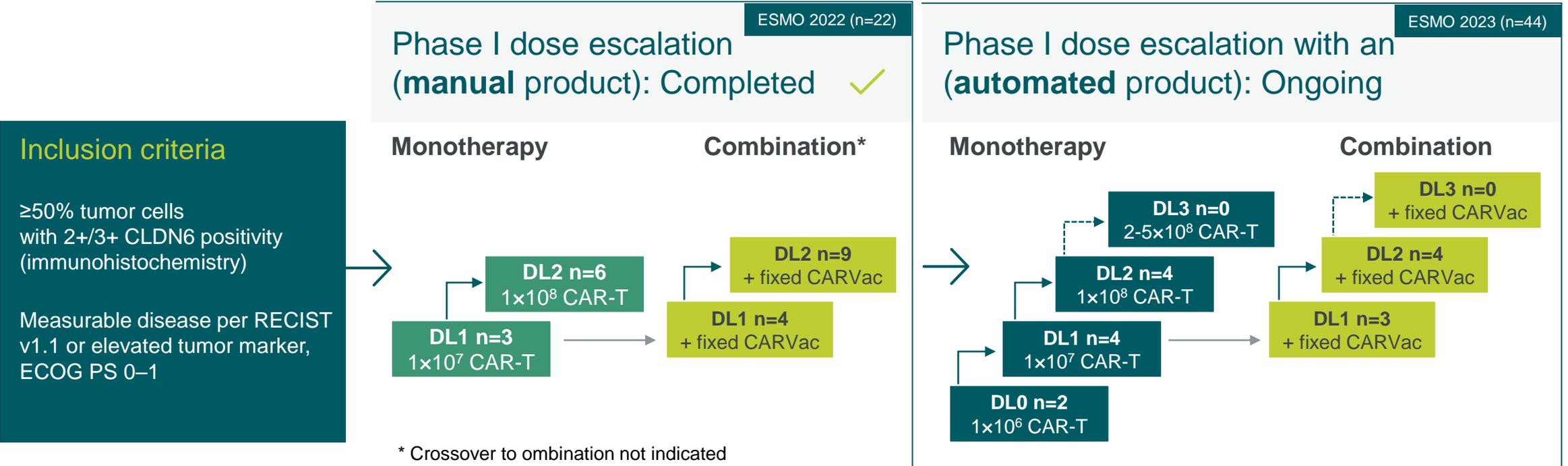
- ✓ Clinically proven RNA-lipoplex vaccine for body-wide delivery of antigens to dendritic cells^{1,2}
- ✓ Amplification and persistence of CAR-T cells by repeat administration³

Full-length CLDN6 RNA



Liposomes

BNT211: Phase 1/2a, FIH, Open-Label, Multicenter, Dose Escalation Trial in R/R Advanced CLDN6+ Solid Tumors (NCT04503278)



Key endpoints

- Primary:** Safety and tolerability, DLTs
- Secondary:** Immunogenicity, ORR, DCR, DoR, PFS

Dosing:

- Escalating doses of CLDN6 CAR-T cells ± CLDN6 CARVac
- Lymphodepletion prior to CAR-T cell infusion on Day 1 (DLTs assessed for 28 days)
- CLDN6 CARVac fixed dose (from Day 4, 50µg then 100µg) Q3W × 5, then Q6W

Assessments: Efficacy assessments Q6W (RECIST v1.1) & tumor marker monitoring

Aim of current analysis:

Determine the safety and preliminary efficacy of the automated CLDN6-CAR T product ± CARVac

Data cut-off: 10 Sep 2023. * Crossover to combination not indicated. CAR = chimeric antigen receptor; CARVac = CAR T-cell amplifying RNA vaccine; CLDN6 = claudin-6; DCR = disease control rate; DL = dose level; DLT = dose-limiting toxicity; DoR = duration of response; ECOG PS = Eastern Cooperative Oncology Group performance status; ORR = objective response rate; PFS = progression-free survival; RECIST = response evaluation criteria in solid tumors; R/R = relapsed/refractory; QXW; every X weeks.

BNT211: Dose-Dependent Increase in Adverse Events, Further Evaluation Ongoing to Determine RP2D

Phase 1/2 FIH study (NCT04503278): Baseline characteristics and safety

Haanen J. et al. Presented at ESMO 2023. Abstract #LBA35.

Cohort	DL0(n=2)	DL1 (n=4)	DL1 + CARVac (n=4)	DL2 (n=13) ¹	DL2 + CARVac (n=14) ²	DL3 (n=7)	Total (n=44)
Patient baseline characteristics							
Age, years	55.5 (50–61)	54.5 (36–62)	51.0 (42–65)	45.0 (30–69)	48.0 (26–60)	50.5 (29–63)	48.0 (26–69)
Gender, male/female	1/1	3/1	2/2	7/6	8/6	4/3	25/19
Indication, n							
Epithelial ovarian cancer (EOC)	1	1	2	6	5	2	17
Germ cell tumor (GCT)	1	0	1	5	6	3	16
Other indications ³	0	3	1	2	3	2	11
CLDN6 2+/3+ cells, %	82.5 (80–85)	97.5 (80–100)	97.5 (50–100)	95.0 (80–100)	100 (70–100)	80.0 (50–100)	95 (50–100)
Prior treatment lines	3.0 (2–4)	4.0 (3–7)	4.0 (2–9)	4.0 (2–7)	4.0 (2–9)	3.5 (2-6)	4.0 (2–9)
Treatment and safety outcome							
Duration of follow-up, days	321.5 (242-401)	44.5 (22-87)	90.5 (13-189)	71.5 (30-317)	120.5 (9-199)	90 (44-121)	94.5 (9-401)
CARVac injections ⁴ , n	NA	NA	3 (1-5)	NA	4 (1-7)	NA	4 (1-7)
Patients with TEAEs ≥G3 related to IMPs ⁵ , n	1	1	1	12	9	6	30
Patients with TESAEs related to IMPs ⁶ , n	1	0	0	4	4	5	14
Patients with DLTs ⁷ , n	0	0	0	1	2	1	4
Patients with CRS ⁸ , n	1	0	2	6	9	5	23
Patients with ICANS ⁹ , n	0	0	0	1	1	0	2
Deaths ¹⁰ , n	1	3	2	2	4	0	12

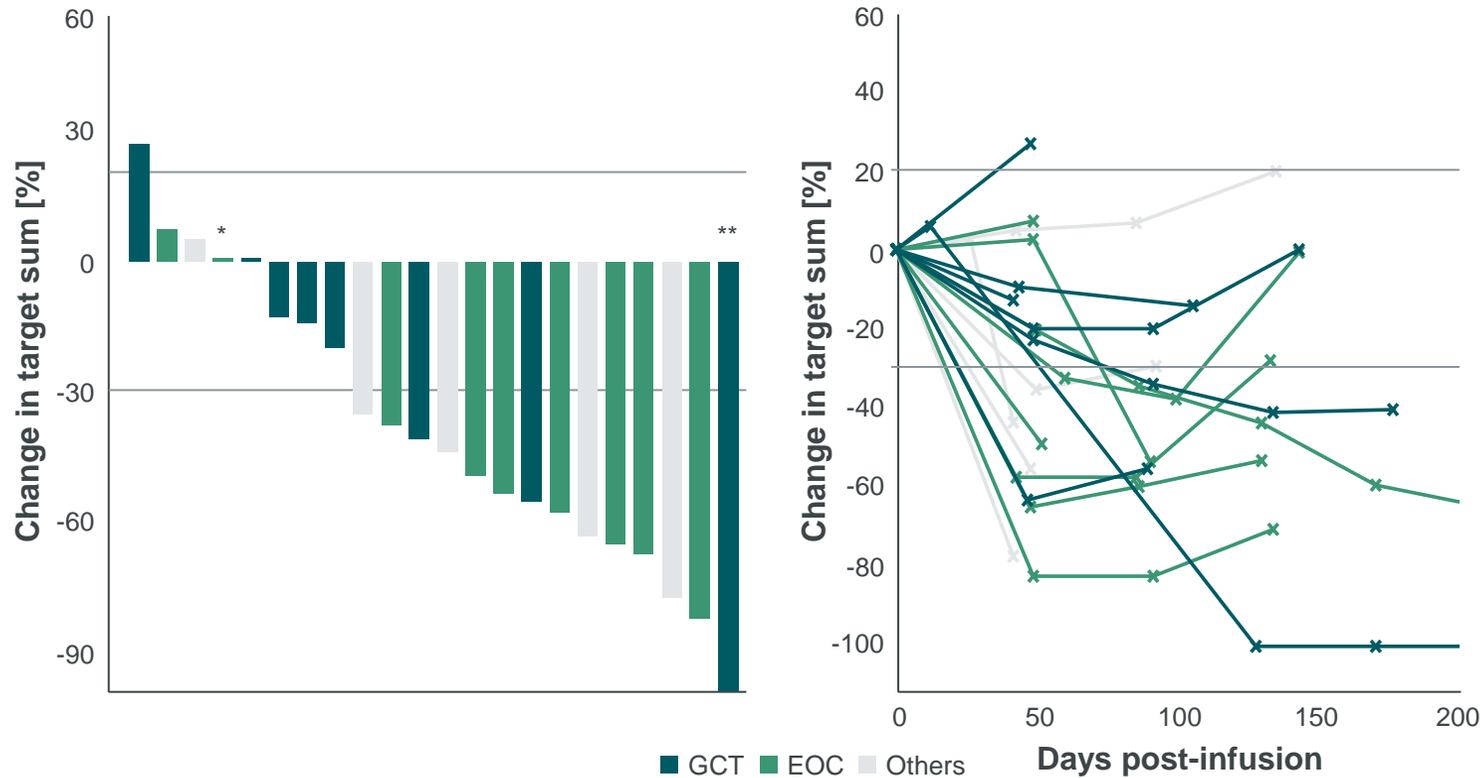
Data cut-off: 10 Sep 2023. 1 Cohort includes 3 patients dosed with 5x10⁷ CAR-T. 2 Cohort includes 1 patient that did not reach full dose (2x10⁷) and 1 patient treated that received full dose after 50% reduced lymphodepletion. 3 Other indications: 4 patients with lung cancer (different subtypes), 3 with desmoplastic round cell tumors, 2 with esophageal cancer, 1 with endometrial carcinoma and 1 with sinonasal carcinoma. 4 Crossover of patients is not indicated, as option was enabled by safety review committee decision after dose decision for monotherapy cohort without impacting efficacy read out. 5 Most TEAEs ≥G3 were attributed to CAR-T IMP (27/30). Most frequent TEAEs were laboratory findings (43.2%) including decreased blood cell counts, elevated liver function tests as well as levels of bilirubin and ferritin. Accordingly, cytopenia (25%) together with immune system (7%) and hepatobiliary disorders (5%) were reported frequently. 6 Most frequent non-related TESAEs were infections. 7 DLTs include 2 cases of pancytopenia, 1 case of hemophagocytic lymphohistiocytosis and 1 case of liver toxicity together with sepsis. 8 CRS was limited to G1-2 for 21/23 patients with 1 G3 and 1 G4 event. 9 Neurotoxicity was mild and self-limiting in 2 patients. 10 Most patient deaths (11/12) were related to disease progression and 1 patient died from sepsis. Values given as median (range). CAR = chimeric antigen receptor; CLDN6 = claudin-6; CRS = cytokine release syndrome; DL = dose level; DLT = dose-limiting toxicity; G = Grade; ICANS = immune effector cell-associated neurotoxicity syndrome; IMP = investigational medicinal product; TESA = treatment-emergent (serious) adverse event.

BNT211 Demonstrates Encouraging Signs of Activity at Dose Level 2

Phase 1/2 FIH study (NCT04503278): Efficacy at all dose level 2

Haanen J. et al. Presented at ESMO 2023. Abstract #LBA35.

Best response and change in target sum (DL2 only)



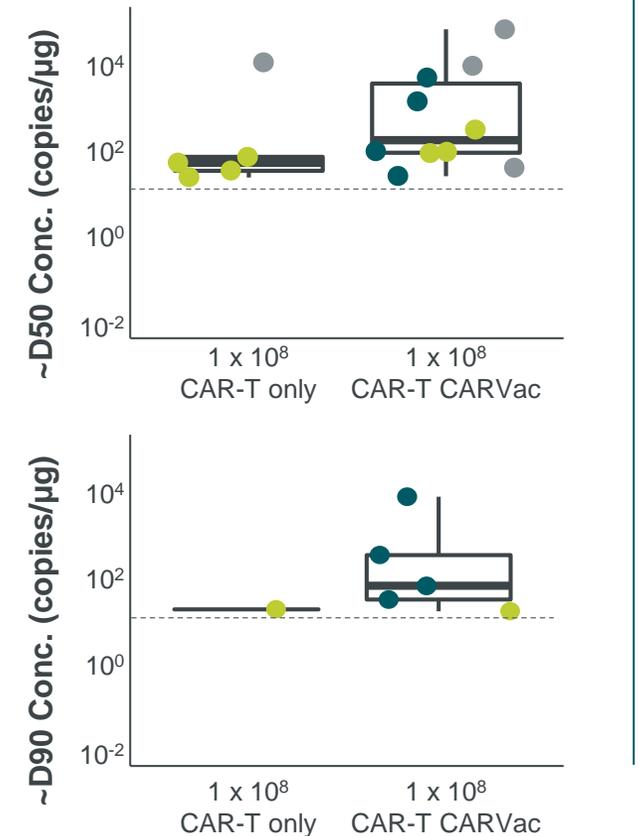
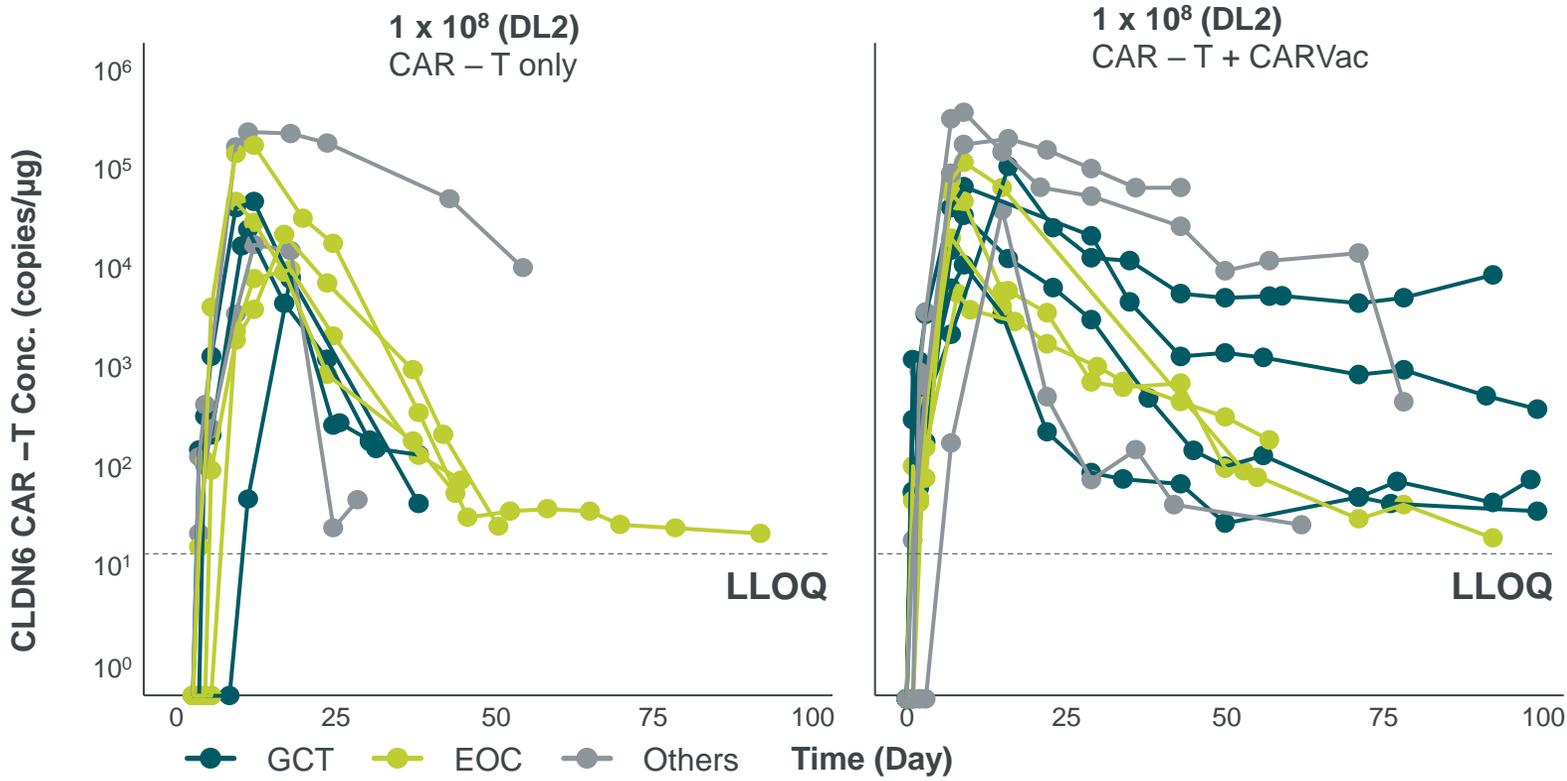
CLDN6 CAR-T	<DL2	DL2	>DL2	Total
Safety evaluable patients, n	10	27	7	44
Efficacy evaluable patients, n	9	22	7	38
Patients with PR/CR, n	1	13	3	17
Patients with SD, n	1	8	2	11
Patients with PD, n	7	1	2	10
ORR, %	11.1	59.1	42.9	44.7
DCR, %	22.2	95.5	71.4	73.7

Data cut-off: 10 Sep 2023. Waterfall plot showing best percent change from baseline in sum of target lesion diameters and spider plot showing percent change in target sum from baseline over time for patients treated with CLDN6 CAR-T ± CLDN6 CARVac at DL2 (N = 22). * Patient had non-measurable disease per RECIST 1.1 and BOR was assessed by tumor marker response. ** Patient achieved complete response after surgical removal of tumors. Response data was pending for 5 patients at the data cut-off. Dotted lines show standard response evaluation criteria used to determine objective tumor response for target lesions per RECIST 1.1 (CR = -100%, PR = 30 to -100%, SD = -30 to 20%, and PD = 20% or higher). Graphs contain additional data entered manually into the database following the data cut-off date that was not available in formal outputs. BOR = best overall response; CR = complete response; DCR = disease control rate; DL = dose level; EOC = epithelial ovarian cancer; GCT = germ cell tumor; PD = progressive disease; ORR = objective response rate; PR = partial response; SD = stable disease.

BNT211: CARVac cohort demonstrating a prolonged persistence of CAR-T cells

Phase 1/2 FIH study (NCT04503278): Pharmacokinetic data

Haanen J. et al. Presented at ESMO 2023. Abstract #LBA35.



Data cut-off: 1 Sep 2023. BioNTech data on file derived from peripheral blood applying semi-quantitative PCR directed against CAR transgene. Displayed as copies of transgene per µg of DNA input of isolated PBMC. Pending data up to day 50: 2 patients each in monotherapy and combination cohort. Pending data up to day 90: 3 patients for monotherapy, and 4 patients for combination cohort. CAR = chimeric antigen receptor; CARVac = CAR T-cell amplifying RNA vaccine; DL = dose level; EOC = epithelial ovarian cancer; GCT = germ cell tumor; LLOQ = lower limit of quantification; PBMC = peripheral blood mononuclear cells. ESMO Congress 2023, Dr. John Haanen; Content of this presentation is copyright and responsibility of the author. Permission is required for re-use.

BNT211 ESMO Data: Key Takeaway Messages



Safety: Toxicities at higher dose level led to further evaluation of safety via backfilling into several cohorts



Efficacy: Encouraging signs of activity with 13 responses in 22 evaluable patients at DL2 (ORR 59%, DCR 95%)



Pharmacokinetics: CARVac improved CAR-T persistence, leading to sustained, ongoing detection up to 100 days in several patients at DL2



Outlook: Backfilling to determine RP2D for CLDN6 CAR-T cells for a pivotal trial in GCT is currently ongoing

4

BNT221

Safety and efficacy of BNT221, a non-engineered neoantigen specific T cell product for adoptive cell therapy of metastatic melanoma

BNT221: A Personalized, Autologous Non-Engineered Neoantigen-Specific T Cell Product

- A systematic, highly reproducible approach to expand neoantigen-specific T cells
- Fully personalized product
- Drug product contains polyclonal neoantigen CD4+ and CD8+ T cell responses
- Potential to circumvent antigen escape

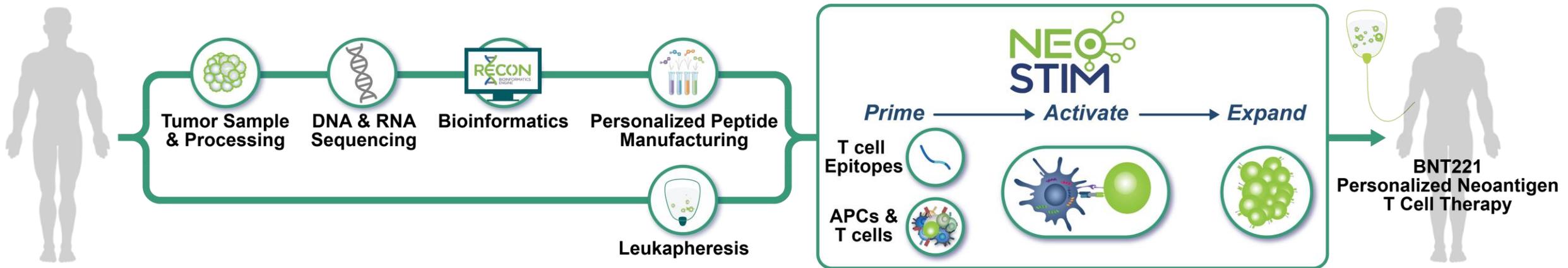
NEO-STIM®

PBMC starting material

- Material obtained from leukapheresis

Clinical opportunity

- Broad clinical opportunity due to targeting of personalized mutations



PBMC = peripheral blood mononuclear cell.

Phase 1 First-in-Human Trial (NCT04625205) Evaluating BNT221 in Advanced or Metastatic Melanoma

Inclusion criteria

Adults 18-75 yrs, unresectable or metastatic melanoma

Progressive disease or intolerant to α PD-1/PD-L1 and α CTLA-4 directed therapies; ≤ 3 prior regimens in metastatic setting

At least 1 site RECIST1.1 measurable disease (active CNS metastasis excluded)

ECOG 0-1

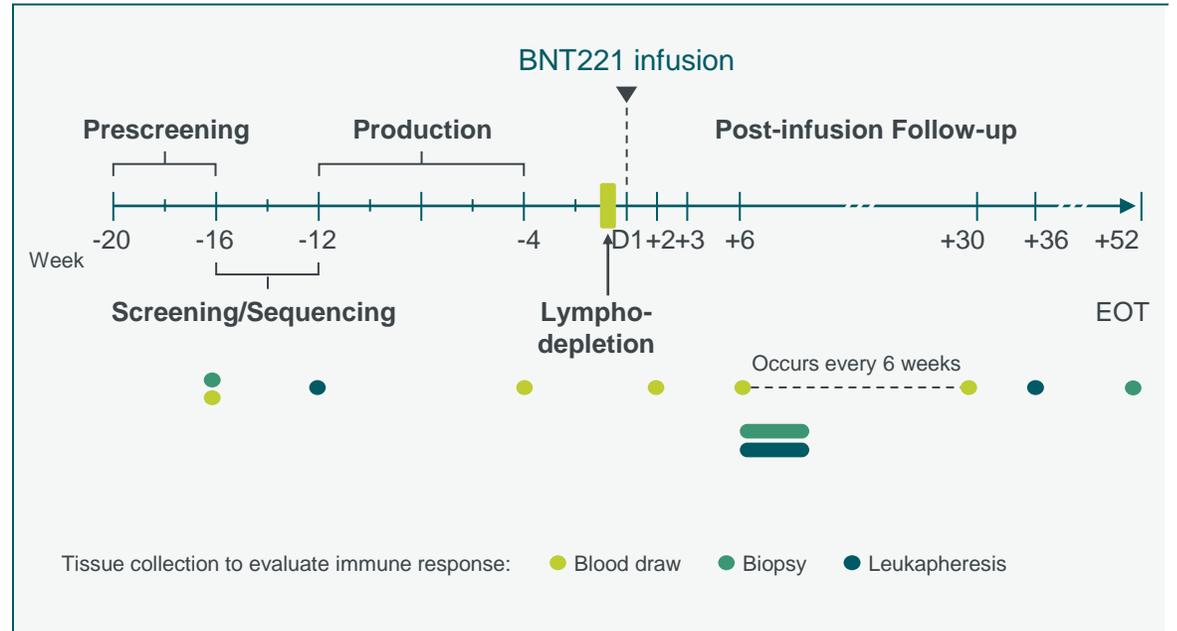
No active auto-immune diseases

BNT221 Monotherapy dose finding

$1 \times 10^8 - 1 \times 10^9$
 $2 \times 10^9 - 1 \times 10^{10}$

Expansion cohorts

Combination
BNT221 + α PD-1



Key endpoints

- Primary:** Safety + MTD BNT221 monotherapy, + α PD-1
- Secondary:** ORR (RECIST 1.1), response duration, clinical benefit rate
- Exploratory:** Immune response in peripheral blood and tumor
Immunogenicity, clinical activity correlation
Drug product characterization, correlation with clinical activity and safety

BNT221 in Heavily Pretreated Melanoma Patients

Phase 1 FIH study (NCT04625205): Baseline characteristics

Borgers J. et al. Presented at ESMO 2023. Abstract #10170.

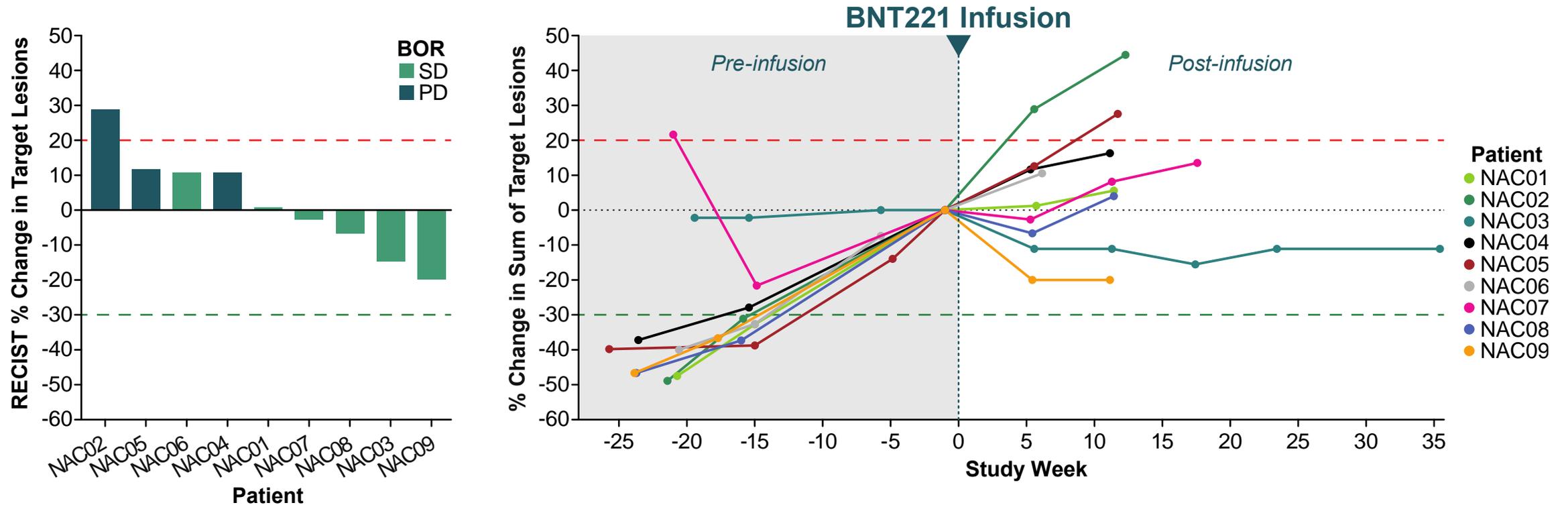
Baseline patient characteristics	Total (n=9)
Median age (range)	57 (32-72)
Sex M/F, n (%)	2 (22%) / 7 (78%)
ECOG 0-1, n (%)	9 (100%)
Stage IV at entry, n (%)	9 (100%)
Serum LDH increased, n (%)	1 (11%)
Tumor Burden at Prescreen median sum of TL, range (mm)	44 (16-177)
Prior lines of systemic therapy median (min/max)	3 (2/4)
Prior α PD-1 therapy, n (%)	9 (100%)
Adjuvant	6 (67%)
Metastatic	4 (44%)
Both	1 (11%)
Prior α CTLA-4 therapy, n (%)	9 (100%)
Prior BRAF/MEK-directed therapy, n (%)	2 (22%)
Other, n (%)	2 (22%)

- All patients had received anti-PD1 and anti-CTLA-4 therapy
- Patients had received a median of 3 prior therapies

Activity Signals Observed Post Single Infusion BNT221 Monotherapy

Phase 1 FIH study (NCT04625205): Clinical Efficacy

Borgers J. et al. Presented at ESMO 2023. Abstract #10170.



Tumor regressions, including prolonged SD in this aPD-1 and aCTLA4 pretreated population

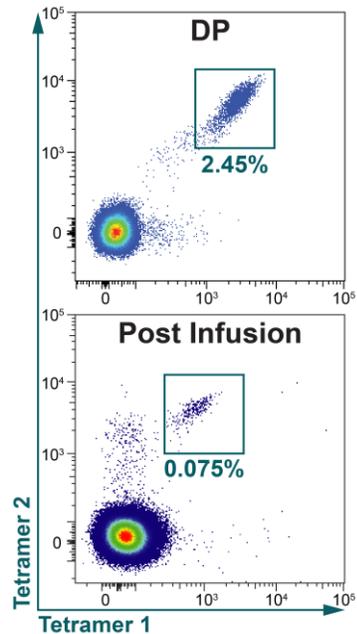
NAC: neoantigen cell dose received; PD: progressive disease; SD: stable disease.

BNT221: Polyclonal T-Cell Responses in Drug Product are Detectable in Peripheral Blood Post-Infusion

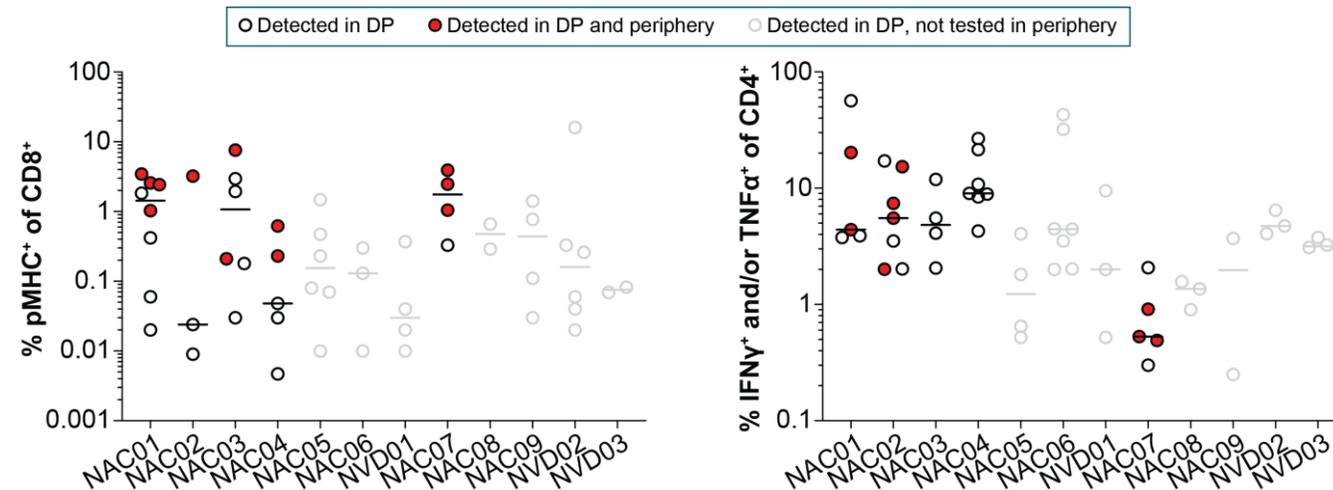
Phase 1 FIH study (NCT04625205): T cell response

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Detection of specific CD8+ T cells by tetramer



Subset of responses in drug product are detected in periphery at 3-6 weeks



- Of 12 patients tested, 2 had neoantigen-specific cells detected by flow cytometry in peripheral blood prior to infusion
- Of the 5 patients with available sample 3-6 weeks post-infusion, all 5 had detectable CD8+ responses and 3 had detectable CD4+ responses

First-in-Human Trial Shows Promising Proof of Concept for BNT221 - a Novel Neoantigen-Focused Cell Therapy Approach



Safety: BNT221 demonstrated a manageable safety profile with no DLTs



Efficacy: In this α PD-1 and α CTLA-4 pretreated population, monotherapy with BNT221 resulted in tumor shrinkage for 4/9 patients



Immune response: BNT221 generates a polyclonal neoantigen-specific T cell product that can be detected post-infusion



Outlook:

- Combination of BNT221 with α PD-1 is currently being tested in the clinic
- Apply translational learnings to further optimize the next-generation NEO-STIM process