BioNTech Highlights Late-Stage Lung Cancer Pipeline Momentum and First Global Data for Pumitamig/Elfetabart Drozuntecan Novel-Novel Combination at WCLC 2026

August 20, 2026

- *Pumitamig plus B7H3-targeting elfetabart drozuntecan delivers the first data in lung cancer for any PD-(L)1xVEGF bispecific immunomodulator combined with an antibody-drug conjugate, underscoring BioNTech's leadership in novel-novel combination treatment strategies*
- *Updated overall survival data for gotistobart from the PRESERVE-003 Phase 3 clinical trial will add to the growing body of evidence for this chemotherapy-free treatment approach in the second- and later-line treatment of advanced squamous non-small cell lung cancer following prior immunotherapy*
- *BioNTech is advancing a diversified development program in lung cancer treatment spanning more than 16 ongoing clinical trials across subtypes, biomarkers and treatment settings, including five ongoing Phase 3 clinical trials and two novel-novel combination trials*

MAINZ, Germany, August 20, 2026 – BioNTech SE (Nasdaq: BNTX, "BioNTech" or "the Company") will present new clinical data from its diversified development program in lung cancer treatment at the IASLC 2026 World Conference on Lung Cancer ("WCLC") in Seoul, Republic of Korea, from September 12-15, 2026.

The breadth of data highlights the latest progress across key strategic assets, pumitamig (BNT327/BMS986545) and gotistobart (BNT316/ONC-392), as well as BioNTech's mRNA-based immunotherapy approaches, highlighting the strength of BioNTech's lung cancer treatment pipeline. Additionally, a late breaking oral presentation will detail data from the novel-novel combination trial of pumitamig with the investigational B7H3-targeted antibody-drug conjugate ("ADC") elfetabart drozuntecan (elfe-D or BNT324/DB-1311), representing the first combination data for any PD-(L)1xVEGF bispecific immunomodulator and an ADC in lung cancer.

"Progress in lung cancer care means both improving treatment outcomes for patients and, importantly, finding better options for more patients who still do not sufficiently benefit from current standard therapies," said **Prof. Özlem Türeci, M.D., Co-Founder and Chief Medical Officer at BioNTech**. "The data we are presenting at this year's WCLC provide further clinical evidence for our late-stage assets, gotistobart and pumitamig, and help to define the role of next-generation immunomodulators in addressing unmet medical needs in lung cancer. We are also presenting the first clinical evidence from a novel-novel treatment combination in lung cancer as part of our evaluation of pumitamig as a potential backbone for combination strategies of complementary mechanisms. Taken together, these data will inform the next steps in our clinical development programs and our broader efforts to expand treatment options for patients."

Highlights from BioNTech's presentations at WCLC 2026:

Novel-novel combination trial of pumitamig, developed in collaboration with Bristol Myers Squibb Company ("BMS"), and elfetabart drozuntecan, developed in collaboration with Duality Biologics (Suzhou) Co. Ltd. ("DualityBio"):

- **Advanced/metastatic SCLC and NSCLC**: First data from the global Phase 1/2 trial (NCT06892548) evaluating pumitamig in combination with the B7H3-targeting ADC elfetabart drozuntecan in patients with advanced or metastatic small cell lung cancer ("SCLC") and NSCLC will be presented for this novel-novel treatment combination approach, underlining BioNTech's leadership in novel-novel combination treatment strategies.

Gotistobart – a tumor microenvironment-selective regulatory T cell depletion candidate targeting CTLA-4, developed in collaboration with OncoC4, Inc. ("OncoC4"):

- **2L+ squamous NSCLC**: Updated overall survival data from stage 1 of the PRESERVE-003 Phase 3 clinical trial (NCT05671510) of gotistobart in patients with squamous non-small cell lung cancer ("NSCLC") who progressed on prior PD-(L)1 inhibitor treatment will be presented. The results further contribute to the growing body of evidence for this chemotherapy-free treatment approach. The pivotal stage 2 part of the trial is ongoing.

All abstracts are available through the WCLC website. Further information on BioNTech's lung cancer pipeline can be accessed here.

Full presentation details:

Candidate	Abstract Title	Abstract Number/Presentation Details
Pumitamig + elfetabart drozuntecan	Pumitamig (PD-L1 x VEGF-A bsAb) + Elfetabart Drozuntecan (Elfe-D, B7H3 ADC) in Patients with Advanced/Metastatic Lung Cancer (NSCLC or SCLC)	Abstract # OA14.01 Oral Presentation The Breakthrough Immunotherapy for Advanced NSCLC Sep 15, 2026: 12:30 - 01:45pm KST
Pumitamig	First-line Pumitamig (PD-L1 × VEGF-A bsAb) Plus Chemotherapy in Unresectable Malignant Mesothelioma: Long-term PFS and OS	Abstract #MO04.09 Mini Oral Novel Therapeutics and Molecular Insights in Thymic Malignancies and Pleural Mesothelioma Sep 13, 2026: 4:45 - 6:00pm KST

	ROSETTA Lung-201: A Phase 3 Trial of Pumitamig Monotherapy vs Durvalumab in Unresectable Stage III NSCLC Post-Chemoradiation	Abstract #P2.330 Poster Clinical Trials in Progress Sep 14, 2026: 10:30am - 12:00pm KST
	ROSETTA Lung-202: A Phase 3 trial of first-line pumitamig monotherapy vs pembrolizumab in locally advanced/metastatic NSCLC	Abstract #P2.355 Poster Clinical Trials in Progress Sep 14, 2026: 10:30am - 12:00pm KST
Gotistobart	Gotistobart vs Docetaxel in Metastatic Squamous NSCLC After PD-(L)1 Progression: Updated Overall Survival of the stage 1 of PRESERVE-003	Abstract #MO07.04 Mini Oral Novel Immunotherapeutic Strategies in mNSCLC Sep 14, 2026: 5:00 - 6:15pm KST
BNT116	Neoadjuvant BNT116 + Cemiplimab + Carboplatin + Paclitaxel in Resectable NSCLC: Preliminary Results From a Phase I Trial	Abstract #MO06.03 Mini Oral Emerging Precision Approaches in Perioperative Therapy for Resectable NSCLC Integrating Targeted Therapy, Immunotherapy, Biomarkers, and Multimodal Strategies Sep 14, 2026: 3:30 - 4:45pm KST

About BioNTech in Lung Cancer Treatment
Lung cancer is one of BioNTech's key focus areas. Through a diversified portfolio of investigational next-generation immunomodulators, ADCs and mRNA-based cancer immunotherapies, the Company is pursuing multiple approaches designed to address significant unmet needs for patients across lung cancer subtypes, histologies and treatment settings. BioNTech's clinical pipeline encompasses both monotherapies and combinations with standard of care treatments, as well as novel-novel combination regimens aimed at delivering differentiated therapeutic profiles for the treatment of patients with lung cancer. With 16 ongoing lung cancer trials, including five pivotal Phase 3 and two novel-novel combination trials, BioNTech is advancing a comprehensive development strategy with the aim of improving outcomes for patients across the continuum of lung cancer.

About BioNTech
BioNTech is a global next generation biopharmaceutical company pioneering novel investigative therapies for cancer and other serious diseases. In oncology, BioNTech is committed to transforming how cancer is treated. Its ambition is to develop innovative medicines with pan-tumor or synergistic potential to address cancer from multiple angles and across the full continuum of the disease from early- to late-stage. Its growing late-stage oncology pipeline comprises complementary treatment approaches spanning immunomodulators, antibody drug conjugates, and mRNA cancer immunotherapies. BioNTech has partnered with multiple global and specialized pharmaceutical collaborators leveraging complementary expertise and resources to accelerate innovation and drive progress, including Bristol Myers Squibb, Duality Biologics, Genentech, a member of the Roche Group, Genmab, MediLink, OncoC4, and Pfizer.

For more information, please visit www.BioNTech.com.

BioNTech Forward-Looking Statements
This press release 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: the initiation, timing, progress and results of BioNTech's research and development programs in oncology, including the targeted timing and number of additional potentially registrational trials; BioNTech's and its collaborators' current and future preclinical and clinical trials in oncology, including the investigational bispecific immunomodulator pumitamig (BNT327/BMS986545) in unresectable malignant mesothelioma, the investigational anti-CTLA-4 antibody gotistobart (BNT316/ONC-392) in metastatic squamous NSCLC, the investigational B7H3-targeted ADC elfetabart drozuntecan (BNT324/DB-1311) in combination with pumitamig in (N)SCLC, and the investigational mRNA cancer immunotherapy candidate BNT116 in resectable NSCLC; the nature and characterization of and timing for release of clinical data across BioNTech's platforms, which is subject to peer review, regulatory review and market interpretation; the planned next steps in BioNTech's pipeline programs, including, but not limited to, statements regarding timing or plans for initiation or enrollment of clinical trials, or submission for and receipt of product approvals and potential commercialization with respect to BioNTech's product candidates; and the potential safety and efficacy of BioNTech's product candidates. 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 press release 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; the ability to produce comparable clinical results in future clinical trials; the timing of and BioNTech's ability to obtain and maintain regulatory approval for its product candidates; discussions with regulatory agencies regarding timing and requirements for additional clinical trials; the impact of tariffs and escalations in trade policy; 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; 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 its product candidates, if approved; BioNTech's ability to manage its development and related expenses; regulatory and political developments; 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 June 30, 2026 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 press release in the event of new information, future developments or otherwise.

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