BioNTech to Showcase Oncology Late-Stage Pipeline Progress and Pumitamig Novel-Novel Combination Data at ESMO 2026

October 19, 2026

- *Late-breaking oral presentation will feature first data from the global ROSETTA Lung-107 Phase 2 clinical trial evaluating pumitamig, a PD-L1×VEGF-A bispecific immunomodulator, plus docetaxel in patients with metastatic non-small cell lung cancer following prior immunotherapy plus chemotherapy*
- *Global Phase 2 data for pumitamig plus elfetabart drozuntecan, a B7-H3-targeting antibody-drug conjugate, expand the body of evidence for this novel-novel combination in multiple advanced solid tumors*
- *Updates from across the pumitamig clinical development program underscore its pan-tumor potential, including in lung and breast cancer patients with brain metastases and patients with neuroendocrine neoplasms*

MAINZ, Germany, October 19, 2026 – BioNTech SE (Nasdaq: BNTX, "BioNTech" or "the Company") will present new clinical data from its late-stage oncology pipeline with 16 abstracts spanning the Company's tumor focus areas, including lung and breast cancer, at the European Society for Medical Oncology ("ESMO") 2026 Congress held in Madrid, Spain, from October 23–27, 2026.

Key oral presentations will focus on clinical data for pumitamig (BNT327/BMS986545), a PD-L1×VEGF-A bispecific immunomodulator being jointly developed with Bristol Myers Squibb ("BMS"), plus docetaxel in second-line metastatic non-small cell lung cancer ("NSCLC") as well as pumitamig in combination with elfetabart drozuntecan (elfe-D or BNT324/DB-1311), a B7-H3-targeting antibody-drug conjugate ("ADC") being jointly developed with Duality Biologics (Suzhou) Co. Ltd. ("DualityBio"), across several advanced solid tumors – complementing the data in lung cancer presented earlier this year. This new clinical data advances BioNTech's differentiated novel-novel combination approach. Additional presentations for pumitamig and ADCs reflect BioNTech's tumor-focused strategy aimed at addressing significant unmet medical needs across various stages of disease.

"Sixteen abstracts spanning ten tumor types – this is our significant data presence at this year's ESMO. It demonstrates momentum for our late-stage oncology pipeline across strategic key assets and tumor areas such as lung and breast cancer," said **Prof. Özlem Türeci, M.D., Co-Founder and Chief Medical Officer at BioNTech**. "For our PD-L1xVEGF immunomodulator pumitamig, we will be sharing new data that highlights its pan-tumor potential, including in challenging treatment settings where patients still show limited benefit from current standard of care therapies. Our goal is to establish pumitamig as a potential backbone for future combination regimens across multiple tumor types, including novel-novel treatment combinations. At this year's conference, we will showcase the potential of this approach in two presentations featuring ADC combinations, aimed to further enhance outcomes for patients."

Highlights from BioNTech's presentations at ESMO 2026:

Pumitamig – an investigational PD-L1×VEGF-A bispecific immunomodulator:

- **NSCLC:** First data from the global ROSETTA Lung-107 Phase 2 clinical trial (NCT06841055) evaluating pumitamig plus docetaxel in patients with metastatic NSCLC whose disease progressed after immunotherapy plus chemotherapy will be presented in a late-breaking oral presentation. This clinical trial extends evidence for pumitamig's non-small cell lung cancer development program into the second-line setting where there remains high unmet medical need, representing the third global Phase 2 dataset in lung cancer.
- **SCLC and TNBC with brain metastases:** Results from a subgroup analysis of two Phase 2 clinical trials (NCT06449209; NCT06449222) evaluating pumitamig plus chemotherapy in patients with small cell lung cancer ("SCLC") or triple-negative breast cancer ("TNBC") showed systemic efficacy generally consistent in patients with and without brain metastases. These early data suggest intracranial efficacy and add to the clinical evidence for pumitamig plus chemotherapy in tumor types where brain metastases often occur and remain challenging to treat as many systemic therapies have limited ability to cross the blood-brain barrier.
- **2L neuroendocrine neoplasms:** First results from a Phase 2 clinical trial conducted in China (NCT05879055) evaluating pumitamig plus FOLFIRI (folinic acid, fluorouracil, and irinotecan) chemotherapy in patients with unresectable neuroendocrine neoplasms after first-line platinum-based chemotherapy showed encouraging preliminary antitumor activity and a manageable safety profile. These data broaden the clinical evidence for pumitamig across diverse tumor types.

Novel-novel combination of pumitamig and elfetabart drozuntecan, an investigational B7-H3-targeted ADC:

- **Advanced solid tumors:** First results from the global Phase 2 clinical trial (NCT06953089) evaluating pumitamig in combination with elfetabart drozuntecan in patients with advanced solid tumors showed encouraging preliminary antitumor activity across multiple tumor types and a manageable safety profile, with minimal overlapping toxicities observed. These data support the potential of pumitamig as a backbone in novel treatment combinations, furthering BioNTech's combination strategy across multiple tumor types with high unmet medical need.

BioNTech is advancing a diversified oncology pipeline spanning next-generation immunomodulators, ADCs, and mRNA cancer immunotherapies, both as monotherapies and novel-novel combination approaches. With 13 ongoing Phase 3 trials as well as multiple novel-novel combination trials, BioNTech is focused on developing innovative approaches to address the challenges of cancer treatment among the Company's tumor focus areas

from early- to late-stage conditions.

All abstracts are available through the ESMO website. Further information on BioNTech's oncology pipeline can be accessed here.

Full presentation details:

Candidate	Abstract Title	Abstract Number/Presentation Details
Pumitamig	A global phase 2, open-label trial of pumitamig (PD-L1 × VEGF-A bsAb) + docetaxel post-chemoimmunotherapy in mNSCLC: First data from ROSETTA Lung-107	Abstract #LBA76 Rapid Oral Presentation NSCLC, Metastatic Oct 25, 2026: 8:30 - 10:00am CET
	Efficacy of pumitamig (PD-L1 × VEGF-A bsAb) plus chemotherapy in patients with SCLC or TNBC with brain metastases: A subgroup analysis of two phase 2 trials	Abstract #1951RO Rapid Oral Presentation Investigational Immunotherapy Oct 24, 2026: 8:30 - 10:00am CEST
	First results from a phase 2 trial of second-line pumitamig (PD-L1 × VEGF-A bsAb) plus chemotherapy in unresectable neuroendocrine neoplasms	Abstract #2393O Proffered Paper Presentation NETs and Endocrine Tumours Oct 26, 2026: 10:15 - 11:45am CET
	ROSETTA RCC-208: A phase 1/2, open-label, randomized study of pumitamig alone or in combination with ipilimumab or cabozantinib in advanced renal cell carcinoma (RCC)	Abstract #3639TiP Poster Presentation Renal Cancer Oct 23, 2026: 3:15 - 4:00pm CEST
	ROSETTA Gastric-204: A randomized, phase 2/3 study of first-line (1L) pumitamig + chemotherapy versus nivolumab (NIVO) + chemotherapy in advanced or metastatic gastric cancer (GC), gastroesophageal junction adenocarcinoma (GEJC), or esophageal adenocarcinoma (EAC)	Abstract #3081eTiP ePoster Presentation Oesophagogastric Cancer Oct 23 - 27, 2026
	A phase 1/2 trial of first-line pumitamig monotherapy or pumitamig plus ipilimumab in advanced or unresectable hepatocellular carcinoma (ROSETTA HCC-206)	Abstract #1762eTiP ePoster Presentation Hepatocellular Carcinoma Oct 23 - 27, 2026
Pumitamig + elfetabart drozuntecan	Elfetabart drozuntecan (Elfe-D; DB-1311/BNT324 [B7H3 ADC]) + pumitamig (PD-L1 x VEGF-A bsAb) in patients with advanced solid tumors: First results from a global phase 2 trial	Abstract #999O Proffered Paper Presentation Developmental Therapeutics Oct 24, 2026: 2:45 - 4:15pm CEST
Pumitamig + trastuzumab pamirtecan	Pumitamig + trastuzumab pamirtecan (T-Pam) in patients (pts) with HR+, HER2-low advanced/metastatic breast cancer (a/mBC): Phase 1 results of a phase 1/2, open-label trial (BNT323-03)	Abstract #1777P Poster Presentation HER2+ Breast Cancer Oct 24, 2026: 12:00 - 12:45pm CEST
Elfetabart drozuntecan	Elfetabart drozuntecan (Elfe-D; DB-1311/BNT324 [B7H3 ADC]) in patients with platinum-resistant ovarian cancer (PROC): Efficacy and safety data from a Phase 2 dose optimization cohort	Abstract #1255P Poster Presentation Gynaecological Cancers Oct 26, 2026: 12:00 - 12:45pm CET
	BNT324-03: A phase 3, randomized, open-label trial comparing elfetabart drozuntecan, a B7H3 antibody-drug conjugate (ADC), with docetaxel as treatment of patients (pts) with taxane-naïve metastatic castration-resistant prostate cancer (mCRPC)	Abstract #2300TiP Poster Presentation Metastatic Prostate Cancer Oct 23, 2026: 3:15 - 4:00pm CEST
Gotistobart	Gotistobart plus pembrolizumab demonstrates durable antitumor activity in advanced melanoma refractory or resistant to both prior anti-CTLA-4 and anti-PD-(L)1 therapies	Abstract #2106P Poster Presentation Melanoma Oct 24, 2026: 12:00 - 12:45 pm CEST
BNT317	BNT317: An anti–PD-1 × CD39 bispecific antibody demonstrating preclinical antitumor activity	Abstract #420P Poster Presentation Basic Science Oct 23, 2026: 3:15 - 4pm CEST
Beruzatatug pelitecan (YL202/BNT326)	Clinical outcomes of YL202/BNT326 (HER3 ADC) in advanced/metastatic HR+/HER2-null/low breast cancer (BC) in chemotherapy (chemo)-naïve and exposed patients (pts)	Abstract #1881P Poster Presentation HR+ Breast Cancer Oct 24, 2026: 12:00 - 12:45pm CEST
BNT329	A first-in-human phase 1/2 dose-escalation and expansion trial of BNT329 (an anti-carbohydrate antigen 19-9 antibody-drug conjugate [CA19-9 ADC]) in patients (pts) with advanced solid tumors that express CA19-9	Abstract #1076TiP Poster Presentation Developmental Therapeutics Oct 23, 2026: 3:15 - 4:00 pm CEST
Health Economics and Outcomes Research (HEOR)	Real-world progression-free survival (rwPFS) from chemotherapy initiation in patients with HR+/HER2– metastatic breast cancer (mBC) in the US	Abstract #1880P Poster Presentation HR+ Breast Cancer Oct 24, 2026: 12:00 - 12:45pm CEST

	Real-world outcomes with first-line pembrolizumab-based chemoimmunotherapy in patients with advanced/metastatic non-small cell lung cancer in the USA	Abstract #2705P Poster Presentation NSCLC, Metastatic Oct 26, 2026: 12:00 - 12:45pm CET

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), the investigational anti-CTLA-4 antibody gotistobart (BNT316/ONC-392), the investigational B7H3-targeting ADC elfetabart drozuntecan (BNT324/DB-1311) alone and in combination with pumitamig, the investigational HER2-targeting ADC trastuzumab pamirtecan (BNT323/DB-1303) in combination with pumitamig, the investigational anti-PD-1×CD39 antibody BNT317, the investigational HER3-targeting ADC Beruzatatug pelitecan (Beru-Pel/YL202/BNT326), and the investigational CA19-9-targeting ADC BNT329; 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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