



BioNTech to Showcase Progress Across Late-Stage Oncology Pipeline at the 2026 ASCO Annual Meeting

May 22, 2026

- *Pumitamig data from the ongoing Phase 2/3 ROSETTA Lung-02 trial in first-line non-small cell lung cancer mark the third global data set to consistently show encouraging anti-tumor activity for pumitamig in combination with chemotherapy*
- *Gotistobart Phase 2 overall survival data in patients with platinum-resistant ovarian cancer add to the growing body of evidence supporting its potential as a chemotherapy-free treatment option*
- *Continued advancement of late-stage oncology pipeline with 25+ Phase 2 and Phase 3 clinical trials, including 13 ongoing pivotal trials as well as novel-novel combination trials across major cancer types*

MAINZ, Germany, May 22, 2026 – [BioNTech SE](#) (Nasdaq: BNTX, “BioNTech” or “the Company”) will present new clinical data and trial updates from its late-stage oncology pipeline and innovative combination programs at the 2026 American Society of Clinical Oncology (“ASCO”) Annual Meeting held in Chicago, from May 29 to June 02. Two oral presentations will highlight new data for key strategic assets pumitamig and gotistobart. In addition, four trial in progress poster presentations will illustrate advancement of the Company’s ongoing pivotal trials and novel-novel combination trials, including antibody-drug conjugates (“ADC”).

“Achieving more for patients with cancer through translating science into innovative therapies is our unwavering ambition at BioNTech,” said **Prof. Özlem Türeci, M.D., Co-Founder and Chief Medical Officer at BioNTech**. “At this year’s ASCO, our presentations underscore our oncology strategy of building a diversified portfolio of complementary modalities delivering differentiated therapeutic profiles across tumor types with high unmet medical need. We are focused on accelerating key strategic programs, both as monotherapies and combinations with standard of care treatments, to deliver our first wave of oncology innovations to patients. Simultaneously, and building on this momentum, we are advancing novel-novel combination approaches, including ADC-based regimens, to unlock the full synergistic potential of our pipeline.”

Highlights of BioNTech’s late-stage oncology programs to be presented at ASCO 2026:

Pumitamig (BNT327/BMS986545) – an investigational bispecific immunomodulator combining PD-L1 checkpoint inhibition and VEGF-A neutralization, developed in collaboration with Bristol Myers Squibb Company (“BMS”):

- **1L NSCLC:** Data from the interim analysis of the Phase 2 dose-optimization part of the global Phase 2/3 ROSETTA Lung-02 clinical trial ([NCT06712316](#)) showed encouraging anti-tumor activity in first-line (“1L”) non-small cell lung cancer (“NSCLC”). The trial evaluated pumitamig plus chemotherapy in patients with non-squamous and squamous NSCLC without actionable genomic alterations and across PD-L1 expression levels. These data mark the third global data set to consistently show encouraging anti-tumor activity for pumitamig plus chemotherapy, adding to the reported global data in small cell lung cancer and triple-negative breast cancer. The results inform the ongoing pivotal Phase 3 part of ROSETTA Lung-02 evaluating pumitamig plus chemotherapy versus pembrolizumab plus chemotherapy. Updated data from a later cut-off date will be presented in a rapid oral presentation.

Gotistobart (BNT316/ONC-392) – an investigational tumor microenvironment-selective regulatory T cell depletion candidate targeting CTLA-4, developed in collaboration with OncoC4, Inc. (“OncoC4”):

- **PROC:** Data from the Phase 2 PRESERVE-004 clinical trial ([NCT05446298](#)) evaluating gotistobart plus pembrolizumab in heavily pre-treated patients with platinum-resistant ovarian cancer (“PROC”) showed durable anti-tumor activity and clinically meaningful overall survival outcomes. Together with a manageable safety profile, the results add to the growing body of evidence supporting gotistobart’s potential as a chemotherapy-free treatment option, complementing the recently [announced](#) data in second and later line squamous non-small cell lung cancer.

BioNTech is advancing a diversified oncology pipeline spanning next-generation immunomodulators, ADCs, and mRNA cancer immunotherapies, both as monotherapies and novel treatment combination approaches. With more than 25 Phase 2 and Phase 3 clinical trials, including 13 ongoing pivotal trials as well as 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 on the [ASCO website](#). Further information on BioNTech’s late-stage oncology portfolio can be accessed [here](#).

Full presentation details:

Medicine	Abstract Title	Abstract Number/Presentation Details
Pumitamig	Phase 2 data from ROSETTA Lung-02, a global randomized Phase 2/3 trial of pumitamig (PDL1 x VEGF-A bsAb) + chemotherapy in 1L NSCLC	Abstract # 8513 Rapid Oral Abstract Session Lung Cancer - Non-Small Cell Metastatic May 30, 2026, 1:15 - 2:45pm CDT

	Phase 2/3 trial of pumitamid (PD-L1 xVEGF-A bsab) plus chemotherapy versus bevacizumab plus chemotherapy in previously untreated, unresectable, or metastatic colorectal cancer (ROSETTA CRC-203)	Abstract # TPS3672 Poster Session Genitourinary Cancer - Prostate, Testicular, and Penile Poster Board: 229a May 31, 2026: 9:00am-12:00pm CDT
Gotistobart	Overall survival for patients with pre-treated platinum-resistant ovarian cancer receiving gotistobart in combination with pembrolizumab	Abstract # 5511 Rapid Oral Abstract session Gynecologic Cancer May 30, 2026: 8:00 - 9:30am CDT
BNT326/YL202	BNT326-01: A Phase 1b/2 trial of BNT326/YL202 (HER3 ADC) as monotherapy and in combination with pumitamid (anti-PD-L1 x VEGF bsAb) in patients with advanced solid tumors	Abstract # TPS3160 Poster Session Developmental Therapeutics -Molecularly Targeted Agents and Tumor Biology Poster Board: 294b May 30, 2026: 1:30 - 4:30pm CDT
BNT324/DB-1311	BNT324-03: A Phase 3, randomized, open-label trial of BNT324/DB-1311, a B7H3 ADC, versus docetaxel in patients with taxane-naïve metastatic castration-resistant prostate cancer (mCRPC)	Abstract # TPS5137 Poster Session Genitourinary Cancer - Prostate, Testicular, and Penile Poster Board: 229a May 31, 2026: 9:00am - 12:00pm CDT
Trastuzumab pamirtecan (BNT323/DB-1303)	Fern-EC-01 (BNT323-01): A phase 3 trial of trastuzumab pamirtecan (HER2 ADC) versus investigator's choice of chemotherapy in patients with previously treated, HER2-expressing, recurrent endometrial cancer (EC)	Abstract # TPS5645 Poster Session Gynecologic Cancer Poster Board: 302b June 1, 2026: 9:00am - 12:00pm CDT

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 pumitamid (BNT327/BMS986545) in multiple indications, the investigational anti-CTLA-4 antibody gotistobart (BNT316/ONC-392) in multiple indications, the investigational B7H3-targeted ADC BNT324/DB-1311 in metastatic castration-resistant prostate cancer, the investigational HER2-targeted ADC trastuzumab pamirtecan (BNT323/DB-1303) in recurrent endometrial cancer, and the investigational HER3-targeted ADC BNT326/YL202 as monotherapy and in combination with pumitamid in NSCLC and advanced solid tumors; 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; the ability of BioNTech's mRNA technology to demonstrate clinical efficacy outside of BioNTech's infectious disease platform; 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; BioNTech's and its counterparties' ability to manage and source necessary energy resources; 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 March 31, 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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