



## BioNTech Provides Strategic Business Update and Outlines 2026 Areas of Focus at 44th Annual J.P. Morgan Healthcare Conference

January 12, 2026

- 2026 poised to be a catalyst-rich year for BioNTech with continued late-stage pipeline progress with candidates across immunomodulators, antibody-drug conjugates and mRNA immunotherapies
- Expected 2026 oncology milestones include seven late-stage data readouts and to have 15 Phase 3 clinical trials ongoing by year end
- Additional late-stage trial readouts through 2030+ set to create multiple launch opportunities across tumor types, building BioNTech into a multi-product oncology company
- Financial strength with € 17.2 billion in cash and cash equivalents plus security investments<sup>1</sup>, COVID-19 vaccine revenue stream, disciplined R&D spend, and strategic partnerships will continue to enable sustainable innovation
- Presentation and webcast at the 44th Annual J.P. Morgan Healthcare Conference from 2:15 – 2:55 pm PT / 11:15 – 11:55 pm CET on Tuesday, January 13, 2026

**Mainz, Germany, January 12, 2026** – [BioNTech SE](#) (Nasdaq: BNTX, “BioNTech” or “the Company”) will provide a strategic business update and outline the Company’s focus areas for 2026, including an overview of expected near- to longer-term milestones, at the 44th Annual J.P. Morgan Healthcare Conference this week in San Francisco, California.

“We concluded 2025 with strong momentum, driven by our execution in research and development, partnerships, acquisitions, and our financial strength. We continued to advance our next wave of innovation, including the initiation of novel-novel combination trials. These achievements have successfully positioned us as a late-stage biopharmaceutical company,” said **Prof. Ugur Sahin, M.D., Chief Executive Officer and Co-Founder of BioNTech**. “We see 2026 as a year when science translates into tangible results. We will report on a series of milestones, including readouts from late-stage trials and earlier trials evaluating novel-novel combinations, as well as new Phase 3 clinical trial initiations. If positive, they will help unlock our path towards multiple near- and mid-term product launch opportunities with the aim to benefit patients across cancer types.”

Ugur Sahin will present at the 44th Annual J.P. Morgan Healthcare Conference from 2:15 – 2:55 pm PT / 11:15 – 11:55 pm CET on Tuesday, January 13, 2026. The live webcast of the presentation can be accessed via the “[Events & Presentations](#)” page in the Investor Relations section of the Company’s website. The slide deck will be available there after the presentation. A replay of the webcast will be archived on the Company’s website for 30 days following the conference.

### Oncology Areas of Focus for 2026

BioNTech will continue to execute its strategy in 2026 towards becoming a multi-product oncology company. Its diversified oncology pipeline comprises late-stage candidates spanning immunomodulators, antibody drug conjugates (“ADCs”), and mRNA cancer immunotherapies. BioNTech is developing several assets with pan-tumor potential, including novel-novel combination approaches, with the aim of addressing the full continuum from early- to late-stage disease across selected tumor types.

#### 1. Late-Stage Acceleration

BioNTech is focused on advancing its late-stage oncology pipeline towards potential launches. Within the past two years, the Company has more than doubled the number of Phase 2 and 3 oncology trials across key modalities with now more than 25 Phase 2 or 3 trials ongoing. In 2026, BioNTech plans to initiate six additional Phase 3 clinical trials, bringing the total number of anticipated Phase 3 clinical trials to 15, and expects seven late-stage data readouts. The clinical trials and resulting data will inform regulatory and launch plans.

#### 2. Combination Therapy Momentum

BioNTech has more than ten novel-novel combination clinical trials in its pipeline with multiple data updates expected in 2026. These trials explore pumitamidg (BNT327/BMS986545), which is being partnered with Bristol Myers Squibb (“BMS”), in combination with other investigational immunomodulators, ADCs, and mRNA cancer immunotherapies and will inform the dose selection and explore anti-tumor activity in multiple tumors for later-stage development.

#### 3. From Modalities to Disease Area

With the maturation of the oncology pipeline, BioNTech will focus on specific disease areas across major cancer types, including lung, breast, gynecologic, gastrointestinal, and genitourinary cancers.

### Expected 2026 Milestones

	Program	Modality	Trial Phase	Indication
Late-Stage Trial Readouts	Trastuzumab pamirtecán (“T-Pam”) <sup>4</sup>	ADC	Single-arm Phase 2	2L+ HER2-expressing endometrial cancer
			Phase 3	Chemo naïve HR+ HER2-low breast cancer
	Gotistobart <sup>2</sup>	Immunomodulator	Phase 3	2L+ sqNSCLC
			Phase 2	2L+ mCRPC
	BNT113	mRNA cancer immunotherapy	Phase 3	1L HPV16+ PD-L1+ HNSCC

	<b>Pumitamig<sup>1</sup></b>	Immunomodulator	Phase 3 in China	1L TNBC
	<b>Autogene cevumeran<sup>3</sup></b>	mRNA cancer immunotherapy	Phase 2	Adj. ctDNA+ stage II (high risk) / stage III CRC
<b>Early-Stage Pumitamig &amp; ADC Trial Readouts</b>	<b>Pumitamig<sup>1</sup></b>	Immunomodulator	Phase 2	1L NSCLC
			Phase 2	1L ES-SCLC
			Phase 2 in China	1L HCC
			Phase 2 in China	1L MSS-CRC
	<b>Pumitamig<sup>1</sup> + T-Pam (HER2-ADC)<sup>4</sup></b>		Phase 1/2	Breast cancer
	<b>Pumitamig<sup>1</sup> + BNT324/DB-1311 (B7H3-ADC)<sup>4</sup></b>		Phase 1/2	Advanced solid tumors
	<b>Pumitamig<sup>1</sup> + BNT325/DB-1305 (TROP2-ADC)<sup>4</sup></b>	Immunomodulator + ADC	Phase 2	TNBC
<b>Pumitamig<sup>1</sup> + BNT326/YL202 (HER3-ADC)<sup>5</sup></b>		Phase 1/2	2L+ EGFRm NSCLC	
<b>BNT324/DB-1311 (B7H3-ADC)<sup>4</sup></b>	ADC	Phase 1/2	2L+ mCRPC	
<b>Phase 3 Trial Initiations</b>	<b>Pumitamig<sup>1</sup></b>	Immunomodulator	Phase 3	1L MSS-CRC
			Phase 3	1L HER2- PD-L1+ gastric cancer
			Phase 3	1L HNSCC
	<b>BNT324 /DB-1311 (B7H3-ADC)<sup>4</sup></b>	ADC	Phase 3	1L mCRPC
<b>BLA Submission</b>	<b>T-Pam (HER2-ADC)<sup>4</sup></b>	ADC	-	2L+ HER2-expressing endometrial cancer

Partnered with: 1. BMS; 2. OncoC4, Inc. ("OncoC4"); 3. Genentech, a member of the Roche Group; 4. Duality Biologics (Suzhou) Co. Ltd. ("DualityBio"); 5. MediLink Therapeutics (Suzhou) Co., Ltd. ("MediLink").

Abbreviations: 1L = first line; 2L = second line; adj. = adjuvant; HER2 = human epidermal growth factor receptor 2; HR = hormone receptor; (sq) NSCLC = (squamous) non-small cell lung cancer; mCRPC = metastatic castration resistant prostate cancer; HPV16 = human papilloma virus 16; PD-L1 = programmed cell death protein ligand 1; HNSCC = head and neck squamous cell carcinoma; TNBC = triple-negative breast cancer; ctDNA = circulating tumor DNA; (MSS-)CRC = (microsatellite stable-) colorectal cancer; ES-SCLC = extensive-stage small cell lung cancer; HCC = hepatocellular carcinoma; EGFRm = mutated epidermal growth factor receptor

#### Overview of oncology data readouts expected by 2030+

BioNTech expects at least 17 late-stage data readouts, including from pivotal trials, by 2030+. The respective trials are set to inform multiple launch opportunities for BioNTech to become a multi-product oncology company by 2030. Potential further data readouts will be added with the evolution and maturation of the clinical pipeline.

Tumor type		Incidence <sup>1</sup>	Assets	Late-Stage/ Pivotal Trials	Expected Data Readouts <sup>2</sup>
Lung	1L NSCLC	400k	Pumitamig <sup>3</sup>	ROSETTA Lung-02	2029
			Gotistobart <sup>4</sup>	PRESERVE-003	2026
	1L ES-SCLC	80k	Pumitamig <sup>3</sup>	ROSETTA Lung-01	2028
Breast	1L TNBC – all comers	25k	Pumitamig <sup>3</sup>	Phase 3 in China	2026
	1L TNBC – CPS < 10	15k	Pumitamig <sup>3</sup>	ROSETTA Breast-01	2029
	2L+ HR+ BC – HER2-low	50k	T-Pam <sup>5</sup>	DYNASTY Breast-02	2026
Genitourinary	1L RCC	25k	Pumitamig <sup>3</sup>	ROSETTA RCC-208 <sup>7</sup>	2030+
	1L CRPC	100k	BNT324/DB-1311 <sup>5</sup>	BNT324-03	2029
	Adj. MIUC	50k	Autogene cevumeran <sup>6</sup>	IMCODE004	2029
Gastrointestinal	1L mMSS-CRC	220k	Pumitamig <sup>3</sup>	ROSETTA CRC-203	2030+

	<b>1L Gastric</b> – HER2-neg, PD-L1+	<b>35k</b>	Pumitamig <sup>3</sup>	ROSETTA Gastric-204	2030+
	<b>1L HCC</b>	<b>25k</b>	Pumitamig <sup>3</sup>	ROSETTA HCC-206 <sup>7</sup>	2030+
	<b>Adj. CRC</b> – ctDNA+	<b>70k</b>	Autogene cevumeran <sup>6</sup>	BNT122-01	2026
	<b>Adj. PDAC</b>	<b>40k</b>	Autogene cevumeran <sup>6</sup>	IMCODE003	2029
<b>Gynecologic</b>	<b>2L+ Endometrial</b> – HER2-expressing	<b>30k</b>	T-Pam <sup>5</sup>	Single-Arm Phase 2	2026
			T-Pam <sup>5</sup>	Fern-EC-01	2028
	<b>1L HNSCC</b>	<b>150k</b>	Pumitamig <sup>3</sup>	ROSETTA HNSCC-205	2030+
<b>Additional Tumors</b>	<b>1L HNSCC</b> – PDL1 CPS ≥ 1, HPV16+	<b>50k</b>	BNT113	AHEAD-MERIT	2026

1. Estimated 1L or adjuvant incidence (incidence + newly recurrent patients) in 2030 in the G7 markets derived from Oracle CancerMPact as of Dec 2025; incidence information is for informational purposes only and is not intended to indicate the potential market size or reach of BioNTech's and its collaborators' product candidates, if approved; 2. Expected data readouts may be from interim or final analyses, and in some cases may not translate into commercial launches; partnered with 3. BMS; 4. OncoC4; 5. DualityBio; 6. Genentech, a member of the Roche group; 7. These are Phase 1/2 trials. The anticipated pivotal trials evaluating pumitamig in these tumor types are expected to readout after 2030.

Abbreviations: CPS = combined positive score; BC = breast cancer; MIUC = muscle-invasive urothelial carcinoma; PDAC = pancreatic ductal adenocarcinoma.

### Financial Position and Outlook

BioNTech maintained a strong financial position throughout 2025, driven by its revenue-generating COVID-19 vaccine business and strategic partnership with BMS. BioNTech held approximately €17.2 billion in cash, cash equivalents and security investments<sup>1</sup> as of December 31, 2025. In November 2025, the Company increased its 2025 revenue guidance to a range of €2.6-2.8 billion, and lowered expense guidance ranges for R&D, SG&A and capital expenditures.

In 2026, BioNTech anticipates a modest decline in Comirnaty revenues compared to 2025, reflecting COVID-19 vaccine market dynamics, which are influenced by various factors, including but not limited to changing vaccine recommendations, specifically in the United States, and the continued transition from multi-year contracts to private markets in different geographies. BioNTech does not currently anticipate the recognition of revenues from the sale of any oncology products in 2026. Per the [outlined partnership terms](#), revenues to BioNTech from the collaboration with BMS in 2026 are expected to be broadly in line with 2025.

### Upcoming Investor and Analyst Events

- Full Year and Fourth Quarter 2025 Financial Results: March 10, 2026
- Annual General Meeting: May 15, 2026

### About BioNTech

Biopharmaceutical New Technologies (BioNTech) is a global next generation immunotherapy company pioneering novel investigative therapies for cancer and other serious diseases. BioNTech exploits a wide array of computational discovery and therapeutic modalities with the intent of rapid development of novel biopharmaceuticals. Its diversified portfolio of oncology product candidates aiming to address the full continuum of cancer includes immunomodulators, targeted therapies such as antibody-drug conjugates (ADCs) and innovative chimeric antigen receptor (CAR) T cell therapies, and mRNA cancer immunotherapies. Based on its deep expertise in mRNA development and in-house manufacturing capabilities, BioNTech and its collaborators are researching and developing multiple mRNA vaccine candidates for a range of infectious diseases alongside its diverse oncology pipeline. BioNTech has established a broad set of relationships with multiple global and specialized pharmaceutical collaborators, including Bristol Myers Squibb, Duality Biologics, Fosun Pharma, Genentech, a member of the Roche Group, Genmab, MedLink, OncoC4, Pfizer and Regeneron.

For more information, please visit [www.BioNTech.com](http://www.BioNTech.com).

### 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: BioNTech's collaborations, including its collaboration with Bristol Myers Squibb (BMS); BioNTech and its collaborators' ability to successfully co-develop and co-commercialize their candidates, if approved; the rate and degree of market acceptance of BioNTech and its collaborators' product candidates, if approved; the initiation, timing, progress, and results of BioNTech's research and development programs, including BioNTech's current and future clinical trials, including statements regarding the expected timing of initiation, enrollment, and completion of trials and related preparatory work and the availability of results, and the timing and outcome of applications for regulatory approvals and marketing authorizations, including expectations regarding the potential indications in which product candidates may be approved, if at all; the targeted timing and number of additional potentially registrational trials, and the registrational potential of any trial BioNTech may initiate; and discussions with regulatory agencies. 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, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with clinical data, 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 clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; the impact of tariffs and escalations in trade policy; competition related to BioNTech's product candidates; the timing of and BioNTech's ability to obtain and maintain regulatory approval for its product candidates; 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 in the United States and other countries and regions; BioNTech's ability to effectively scale its production capabilities and manufacture its products and product candidates; 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](http://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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<sup>1</sup> Preliminary, unaudited figure; consists of cash, cash equivalents and security investments, as of December 31, 2025.