BioNTech and OncoC4 Present Updated Data Showing Gotistobart Nearly Doubled Median Overall Survival versus Standard-of-Care Chemotherapy in Previously Treated Squamous Non-Small Cell Lung Cancer Patients

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- *Gotistobart continues to show potential as chemotherapy-free monotherapy to reignite anti-tumor immunity in previously treated patients with squamous non-small cell lung cancer, where median survival with current standard of care treatments is less than one year*[1]
- *Gotistobart demonstrated a median overall survival of 18.5 months compared to 10.0 months with standard-of-care chemotherapy in updated data from stage 1 of the PRESERVE-003 Phase 3 clinical trial, nearly doubling median survival in this patient population*
- *Findings are consistent with gotistobart's differentiated mechanism of action as an investigational immunomodulator that selectively enhances regulatory T cell depletion through CTLA-4-targeting in the tumor microenvironment*

MAINZ, Germany, and ROCKVILLE, USA, September 14, 2026 – BioNTech SE (Nasdaq: BNTX, "BioNTech") and OncoC4, Inc. ("OncoC4") today announced the first median overall survival ("OS") data from the non-pivotal stage 1 of the global randomized PRESERVE-003 Phase 3 clinical trial (NCT05671510) of gotistobart (also known as BNT316 or ONC-392), in patients with squamous non-small lung cancer ("NSCLC") whose disease progressed on prior immunotherapy and chemotherapy. Gotistobart is an investigational CTLA-4-targeting immunotherapy designed to selectively deplete regulatory T cells ("Tregs") within the tumor microenvironment and restore anti-tumor immune activity.

The data showed that treatment with gotistobart led to a statistically significant and clinically meaningful OS benefit, nearly doubling survival compared with standard-of-care chemotherapy in this patient population. The data were presented at the International Association for the Study of Lung Cancer ("IASLC") 2026 World Conference on Lung Cancer ("WCLC").

"Patients with squamous NSCLC continue to face limited treatment options after progression on immunotherapy. Current survival expectations with established therapies remain less than a year, and despite numerous development efforts, chemotherapy has remained the standard of care in this setting for more than a decade," said **Rama Balaraman, M.D., Principal Investigator and medical oncologist at Ocala Oncology Center, Florida, United States.** "The magnitude of the survival benefit observed with gotistobart as a chemotherapy-free treatment approach in the PRESERVE-003 clinical trial is highly encouraging. If confirmed in the pivotal portion of the Phase 3 trial, these findings could transform the standard of care in a setting where new therapies are urgently needed."

At the data cut-off on July 17, 2026, with a median follow-up of 25.4 months, 87 patients with metastatic squamous NSCLC had been randomized to receive either gotistobart monotherapy 6 mg/kg with two 10 mg/kg loading doses (N=45) or docetaxel 75 mg/m^2 (N=42) in the second-line or later treatment setting. The median OS was 18.5 months for patients treated with gotistobart compared to 10.0 months for patients treated with docetaxel (HR: 0.56; nominal p-value=0.0295). The safety profile of gotistobart was consistent with previously reported data and remained manageable. Grade ≥3 treatment-related adverse events ("AEs") were reported in 20/45 (44.4%) patients receiving gotistobart and 20/42 (48.8%) patients receiving docetaxel.

"These data underscore gotistobart's potential to redefine treatment for patients with hard-to-treat squamous NSCLC whose disease has progressed after initial therapy and who face limited options," said **Prof. Özlem Türeci, M.D., Co-Founder and Chief Medical Officer at BioNTech.** "In second- and later lines of treatment, the clinical relevance of novel therapeutic options depends on the ability to re-engage a suppressed or exhausted anti-tumor immune response and overcome acquired resistance. This update highlights gotistobart's unique mode of action and our ambition to translate our deep understanding of the immune system into meaningful survival benefit for patients with lung cancer – particularly in areas where patients still need more. We look forward to continuing our work with our colleagues at OncoC4 to further explore and realize gotistobart's full potential."

"The data support the differentiated mechanism of action of gotistobart as a tumor microenvironment-selective Treg modulator and reinforce our confidence in the therapeutic potential of this distinct CTLA-4-targeting approach to meaningfully shift the treatment landscape in this indication," said **Pan Zheng, M.D., Ph.D., Co-Founder and Chief Medical Officer at OncoC4.** "We are encouraged by the clinical activity and safety profile observed to date and remain focused on advancing gotistobart for patients with this difficult-to-treat disease."

The pivotal stage 2 portion of PRESERVE-003 is currently ongoing at more than 160 sites globally. Gotistobart previously demonstrated a clinically meaningful OS benefit and durable anti-tumor activity versus docetaxel in stage 1 of the PRESERVE-003 Phase 3 trial in patients with squamous NSCLC who had progressed on PD-(L)1 inhibitors. This data was published in *Nature Medicine* and presented at the 2026 European Lung Cancer Congress ("ELCC") and the IASLC ASCO 2025 North America Conference on Lung Cancer ("NACLC").

About the PRESERVE-003 clinical trial

PRESERVE-003 (NCT05671510; EUCT:2023-505311-20-01; CTR20232927) is a two-stage, open-label Phase 3 trial evaluating the efficacy and safety of gotistobart as monotherapy compared to the standard-of-care chemotherapy (docetaxel) in squamous NSCLC patients, who have progressed on PD-(L)1 inhibitors and platinum-based chemotherapy. The non-pivotal stage of the trial included all NSCLC patients. The ongoing pivotal stage enrolled patients with squamous NSCLC. The primary endpoint is overall survival. Secondary endpoints include overall response rate, progression-free survival, and safety profile.

About gotistobart (BNT316/ONC-392)

Gotistobart (BNT316/ONC-392) is an investigational immunotherapy that enhances Treg depletion within the tumor microenvironment through targeting CTLA-4 to reignite antitumor immunity and which is being jointly developed by BioNTech and OncoC4.[2,3,4,5,6,7,8,9] As a pH-sensitive

monoclonal antibody, gotistobart is designed to enable CTLA-4 protein recycling. After binding to the CTLA-4 receptor on the cell surface, the complex is internalized, and the pH change causes the antibody to unbind, allowing CTLA-4 to return to the surface to preserve the immune checkpoint function at peripheral organs and to enhance anti-tumor immunity in the tumor microenvironment.[9]

Gotistobart is currently in late-stage clinical development as a monotherapy and as a component of combination therapy in various cancer indications. Gotistobart received Fast Track Designation from the U.S. Food and Drug Administration ("FDA") in 2022 for the treatment of patients with metastatic NSCLC whose disease progressed on prior anti-PD-(L)1 therapy and Orphan Drug Designation for the treatment of patients with squamous NSCLC in 2025. The candidate also received Breakthrough Therapy Designation from China's National Medical Products Administration ("NMPA") in 2025.

About squamous non-small cell lung cancer
With a 5-year relative survival rate of 15% and a median overall survival of 11 months in the United States (2000-2017), squamous NSCLC is a devastating disease with limited treatment options.[1] Current standard-of-care includes surgery and radiotherapy in combination with chemotherapy.[10] Treatment options for second-line therapy after first-line immunotherapy and chemotherapy are limited to chemotherapy or palliative therapy in advanced/metastatic squamous NSCLC and remain more limited than for non-squamous NSCLC.

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 collaboration with OncoC4; BioNTech and OncoC4's ability to successfully co-develop and co-commercialize gotistobart (also known as BNT316 or ONC-392), if approved; the rate and degree of market acceptance of gotistobart, if approved; the initiation, timing, progress, and results of BioNTech's research and development programs, including data from the non-pivotal stage 1 of the global randomized Phase 3 trial PRESERVE-003 and 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 gotistobart 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; 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 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.

About OncoC4
Based in Rockville, Maryland, OncoC4 is a privately held, late clinical-stage biopharmaceutical company that is actively engaged in the discovery and development of novel biologics for the treatment of cancer and immunological diseases. OncoC4's pipeline features assets with first-in-class and best-in-class potential targeting both novel and well-validated targets across oncology and immunological diseases. Among them, AI-081 is a wholly owned bispecific antibody candidate targeting PD-1 and VEGF that is currently in phase 2 trial for oncology indications. ONC-841 is a first-in-class anti-SIGLEC-10 antibody currently in a Phase 2 trial for oncology indications and a Phase 1 trial for neurodegenerative diseases. OncoC4 has a strategic collaboration with BioNTech to co-develop gotistobart (BNT316/ONC-392), a tumor microenvironment-selective Treg depletion candidate targeting CTLA-4, in multiple solid tumor indications, including an ongoing pivotal clinical trial in squamous non-small cell lung cancer.

More information: www.oncoc4.com.

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