BioNTech and OncoC4 Present Positive Phase 1/2 Data for Antibody Candidate BNT316/ONC-392 in Hard-to-Treat NSCLC at ASCO

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- *BNT316/ONC-392 is a next-generation anti-CTLA-4 monoclonal antibody candidate jointly developed by BioNTech and OncoC4 as monotherapy or combination therapy in a range of solid tumor indications, including* non-small cell lung cancer (NSCLC)
- *Interim data of BNT316/ONC-392 from the ongoing Phase 1/2 trial to be presented at this year's ASCO Annual Meeting demonstrate encouraging signs of clinical anti-tumor activity and a manageable safety profile in patients with metastatic, PD-(L)1-resistant NSCLC*
- *Initiation of a pivotal Phase 3 trial with BNT316/ONC-392 as monotherapy in immunotherapy-resistant NSCLC patients is planned in Q3 2023, following FDA's Fast Track designation in 2022*
- Lung cancer remains one of the most commonly diagnosed malignant cancer types and the leading cause of cancer deaths worldwide, with NSCLC[1] making up approximately 85% of all lung cancers

MAINZ, Germany, and ROCKVILLE, Maryland, USA, June 2, 2023 (GLOBE NEWSWIRE) — BioNTech SE (Nasdaq: BNTX, "BioNTech") and OncoC4, Inc. ("OncoC4"), today announced positive preliminary data from the ongoing Phase 1/2 trial with the companies' anti-CTLA-4 antibody candidate, BNT316/ONC-392 (gotistobart), in a patient cohort with metastatic, PD-(L)1-resistant non-small cell lung cancer ("NSCLC"). The preliminary results show encouraging clinical anti-tumor activity for BNT316/ONC-392 as a monotherapy in a hard-to-treat patient population, as well as a manageable safety profile. The data will be presented in a poster discussion session at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting by Kai He, M.D., Ph.D., Pelotonia Institute for Immuno-Oncology, The Ohio State University Comprehensive Cancer Center – Arthur G. James Cancer Hospital and Richard J. Solove Research Institute, Columbus, Ohio, USA.

The results featured at the ASCO Annual Meeting include a total of 27 patients with metastatic, PD-(L)1-resistant NSCLC, available for tumor response assessment who have received at least two doses of 10 mg/kg of BNT316/ONC-392. At data cut-off, the overall response rate ("ORR") among evaluable patients was 29.6%, with a disease control rate ("DCR") of 70.4%, including 1 complete response, 7 partial responses and 11 patients with stable disease. BNT316/ONC-392 continues to be well tolerated with a manageable safety profile. Immune-related adverse events (irAE) of Grade 3 and 4 were observed in 10 patients (30%), which is considered lower than what was reported for similar drugs.

"Metastatic NSCLC has a very poor prognosis with a 5-year survival rate of only 9%[2]. These new data highlight the potential of BNT316/ONC-392 to provide a new approach to leveraging CTLA-4 as an effective target to address advanced, hard-to-treat tumors, further broadening our oncology toolkit," said **Prof. Özlem Türeci, M.D., Chief Medical Officer and Co-Founder at BioNTech.** "Our goal is to accelerate the development of this program in NSCLC towards pivotal Phase 3 evaluation in line with our mission of providing the optimal therapeutic strategy for each cancer patient."

"The clinical activity and safety profile validate the improved therapeutic index of BNT316/ONC-392," said **Pan Zheng, M.D., Ph.D. Chief Medical Officer and Co-Founder at OncoC4.** "We are especially encouraged by the readouts from the PD-(L)1-resistant NSCLC. Responses were observed regardless of PD-L1 status, and among those who failed multiple lines of immunotherapy and chemotherapy, including PD-1 and CTLA-4 combination therapy."

Lung cancer remains one of the most commonly diagnosed malignant cancer types and the leading cause of cancer deaths worldwide, with NSCLC[1] making up approximately 85% of all lung cancers. The new data further support the initiation of a pivotal Phase 3 study with BNT316/ONC-392 as monotherapy for immunotherapy-resistant NSCLC, for which the candidate received Fast Track designation from the U.S. Food and Drug Administration ("FDA") in 2022. The Phase 3 trial, PRESERVE-003 (NCT05671510), is planned to start in Q3 2023.

About BNT316/ONC-392

BNT316/ONC-392 (gotistobart) is a next-generation anti-CTLA-4 antibody candidate jointly developed by BioNTech and OncoC4. BNT316/ONC-392 is currently in late-stage clinical development as monotherapy or combination therapy in various cancer indications. The immune checkpoint receptor CTLA-4 inhibits T cell immune response and reduces the activity of T cells in recognizing and eliminating cancer cells. Blocking CTLA-4 preserves T cell activity and enhances anti-tumor activity. BNT316/ONC-392 was designed to preserve CTLA-4 recycling and thus immunosuppressive T cells (regulatory T cells, or "Tregs") function in the peripheral tissues. This aims to give rise to fewer immune-related adverse effects and a more favorable safety profile. BNT316/ONC-392 is currently being evaluated in an ongoing Phase 1/2 trial (NCT04140526) in patients with advanced solid tumors as single agent or in combination with pembrolizumab. In addition, the candidate is also being evaluated in an additional Phase 2 trial as a combination therapy with pembrolizumab in platinum-resistant ovarian cancer (NCT05446298).

About NSCLC

Non-small cell lung cancer (NSCLC) covers all epithelial lung cancers other than small cell lung cancer and includes squamous cell carcinoma, large cell carcinoma, and adenocarcinoma. It is the most common type of lung cancer, accounting for up to 85% of cases[1], with risk factors ranging from smoking to asbestos exposure and pulmonary fibrosis[3]. With a 5-year relative survival rate of 23% in the United States (2012-2018), NSCLC is a devastating disease with limited treatment options depending on the stage and location of the tumor.[3] Current standard of care includes surgery and radiotherapy in combination with chemotherapy.[3]

About BioNTech

Biopharmaceutical New Technologies (BioNTech) is a next generation immunotherapy company pioneering novel therapies for cancer and other

serious diseases. The Company exploits a wide array of computational discovery and therapeutic drug platforms for the rapid development of novel biopharmaceuticals. Its broad portfolio of oncology product candidates includes individualized and off-the-shelf mRNA-based therapies, innovative chimeric antigen receptor T cells, bispecific immune checkpoint modulators, targeted cancer antibodies and small molecules. Based on its deep expertise in mRNA vaccine development and in-house manufacturing capabilities, BioNTech and its collaborators are 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 pharmaceutical collaborators, including Genmab, Sanofi, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma and Pfizer.

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

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 biologicals for cancer treatment. Its lead clinical candidate is ONC-392, a next generation anti-CTLA-4 antibody that allows CTLA-4 to recycle and maintain its protective function against autoimmune diseases while enhancing anti-tumor activity at the same time. In addition, OncoC4 has a pipeline of first-in-class preclinical product candidates focusing on the CD24-Siglecs cancer immune evasion pathway.

More information: www.oncoc4.com.

BioNTech Forward-Looking Statements
This press release contains "forward-looking statements" of BioNTech within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may include, but may not be limited to, statements concerning: BioNTech's collaboration with OncoC4, Inc., the ability of the anti-CTLA-4 monoclonal antibody candidate BNT316/ONC-392 to eliminate immunosuppressive regulatory T cells and enhance anti-tumor activity in various cancer indications; the development of BNT316/ONC-392 as a monotherapy or combination therapy in various cancer indications; the timing and success of a Phase 3 study evaluating BNT316/ONC-392 as a monotherapy against the current standard of care in PD-1-resistant NSCLC; and the timing and success of a Phase 2 trial of BNT316/ONC-392 as a combination therapy with pembrolizumab in platinum-resistant ovarian cancer. Any forward-looking statements in this press release are based on BioNTech's current expectations and beliefs of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: the ability of BioNTech to develop and, if approved, commercialize these potential immunotherapies.

For a discussion of these and other risks and uncertainties, see BioNTech's Quarterly Report on Form 6-K for the quarter ended March 31, 2023, filed with the U.S. Securities and Exchange Commission ("SEC") on May 8, 2023, which is available on the SEC's website at www.sec.gov. All information in this press release is as of the date of the release, and BioNTech undertakes no duty to update this information unless required by law.

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[1] CA Cancer J Clin. 2021 May;71(3):209-249
[2] https://www.cancer.org/cancer/types/lung-cancer/detection-diagnosis-staging/survival-rates.html
[3] https://www.cancer.gov/types/lung/hp/non-small-cell-lung-treatment-pdq#_37_toc