# PRESS RELEASE

## BioNTech and Genmab Initiate First-In-Human Phase I/IIa Trial of Bispecific Antibody DuoBody®-PD-L1x4-1BB in Solid Tumors

**Mainz, Germany, June 17, 2019** – BioNTech SE, a clinical-stage biotechnology company focused on patient-specific immunotherapies for the treatment of cancer and other serious diseases, announced today that the first-in-human Phase I/IIa study with DuoBody-PD-L1x4-1BB has been initiated. DuoBody PD-L1x4-1BB is a bispecific antibody in joint development with Genmab A/S, which is being studied in patients with metastatic or unresectable malignant solid tumors, who are not candidates for standard therapy. DuoBody-PD-L1x4-1BB is the first product candidate from the companies' worldwide 50% cost-sharing 50% profit-sharing collaboration to enter the clinic. The objective of the collaboration, signed in 2015 and expanded in 2016 to include additional targets and technologies, is to develop and commercialize multiple novel bispecific antibodies with superior *in vivo* efficacy that specifically activate the immune system against cancer cells.

"The achievement of starting a Phase I/IIa clinical trial with a product candidate developed in only four years is a validation of our highly productive partnership with Genmab," said **Prof. Ugur Sahin, CEO of BioNTech**. "DuoBody-PD-L1x4-1BB's pan-cancer, dual-immuno-stimulatory mode of action contributes an additional layer of treatment options to our overall cancer pipeline. It also serves BioNTech's strategy of exploiting novel targets and mechanisms to harness the full potential of the immune system for cancer immunotherapy."

DuoBody-PD-L1x4-1BB is a novel bispecific antibody that combines checkpoint blockade of the inhibitory PD-1:PD-L1 signaling axis with conditional stimulation of T cells by activation of the 4-1BB receptor, thereby enhancing the proliferation of activated T cells to efficiently target cancer cells. The original idea and concept for this approach to combine immune-brake removing (PD-L1) and acceleration properties (4-1BB) to combat cancer are based on research conducted at BioNTech. The open-label safety trial of DuoBody-PD-L1x4-1BB (ClinicalTrials.gov Identifier NCT03917381) consists of two parts: a dose escalation part (Phase I, first-in-human) and an expansion part (Phase IIa). As primary endpoint, the multi-center trial will foremost assess safety including dose limiting toxicity and adverse events.

**About BioNTech**

BioNTech SE is Europe's largest privately held biopharmaceutical company pioneering the development of precision immunotherapies for individualized treatment of cancer and prevention of infectious diseases. The company combines all building blocks for more precise and individualized immunotherapies under one roof – from diagnostics and drug development to manufacturing. Its cutting-edge technologies range from individualized mRNA-based product candidates through innovative chimeric antigen receptors and T-cell receptor-based compounds to novel checkpoint immunomodulators and small molecules. BioNTech's product development approach has been validated by seven corporate partnerships with, in chronological order, Genmab, Eli Lilly and Company, Sanofi, Bayer Animal Health, Genentech, a member of the Roche Group, Genevant and Pfizer, and its scientific approach through over 60 peer-reviewed scientific publications. Founded in 2008, BioNTech's financial shareholders include the Struengmann Family Office as its majority shareholder, Fidelity Management & Research Company, Invus, Janus Henderson Investors, MIG Fonds, Redmile Group, Salvia and several European family offices. For more information, please see: www.biontech.de.

DuoBody® is a registered trademark of Genmab A/S.

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