



BioNTech Strengthens Manufacturing Capabilities with First In-House Plasmid DNA Manufacturing Facility

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- *Plasmids are an important starting material for the manufacturing of mRNA- and cell-based drugs*
- *The new plasmid manufacturing facility aims to increase BioNTech's autonomy and flexibility in manufacturing an important starting material for its oncology and COVID-19 vaccine pipeline*
- *The investment of approximately €40 million is part of a long-term development plan for BioNTech's manufacturing site in Marburg*
- *German Chancellor Olaf Scholz is visiting the facility together with BioNTech co-founders Prof. Ugur Sahin, Chief Executive Officer, and Prof. Özlem Türeci, Chief Medical Officer*

MAINZ, Germany, February 2, 2023 – [BioNTech SE](#) (Nasdaq: BNTX, “BioNTech” or “the Company”) today announced construction completion of the Company's first proprietary plasmid DNA manufacturing facility in Marburg, Germany. Plasmid DNA is an important starting material for the manufacturing of mRNA-based vaccines and therapies, as well as cell therapies. With the new facility, BioNTech plans to independently manufacture plasmid DNA for clinical product candidates and commercial products in the areas of cancer and infectious diseases. German Chancellor Olaf Scholz is visiting the new manufacturing facility in Marburg today together with BioNTech co-founders Prof. Ugur Sahin, M.D., Chief Executive Officer, and Prof. Özlem Türeci, M.D., Chief Medical Officer.

BioNTech plans to independently manufacture the majority of its own current regular demand for DNA plasmids in the new manufacturing facility, once it is operational and pending regulatory approvals. Temporary peaks in demand will continue to be covered through partnered suppliers. This aims to increase BioNTech's flexibility and autonomy in manufacturing of starting materials for its oncology and COVID-19 vaccine pipelines as well as the Company's independence for pandemic preparedness due to local production. The Company also expects the new manufacturing facility to enable faster production cycles and shorter delivery times for plasmid DNA for a number of clinical product candidates and commercial products.

“Medical biotechnology is a key technology of the 21st century. The pandemic has proven Germany's capability as a location for innovation and manufacturing of medicines. Germany and Europe are becoming more resilient by building local value chains. BioNTech's investment is very good news,” said **Olaf Scholz, Chancellor of the Federal Republic of Germany**.

“Since we acquired our manufacturing site in Marburg in the fall of 2020, we have continuously invested in the site to expand our manufacturing capacities and capabilities. Plasmid manufacturing is an exciting and important part of mRNA manufacturing that we expect to be able to cover in-house soon,” said **Prof. Ugur Sahin, M.D., Chief Executive Officer and Co-Founder of BioNTech**. “We plan to manufacture mRNA-based products for a broad range of clinical trial candidates at our Marburg site while we are preparing production measures for the commercial manufacturing of personalized oncology therapeutics.”

The new manufacturing facility comprises two plants covering both clinical (“small scale”) and commercial (“large scale”) plasmid DNA manufacturing. The clinical-scale plant has been operational since August 2022. In this plant, BioNTech is currently manufacturing plasmids for the Company's FixVac platform product candidates, such as BNT111. BioNTech expects to manufacture plasmid DNA that can be utilized as starting material to manufacture mRNA for several hundred million vaccine doses or therapies annually, depending on the product or product candidate. The commercial plant is anticipated to be operational by the end of 2023, subject to regulatory approval. BioNTech expects a total investment of around €40 million in the new manufacturing facility.

BioNTech's site in Marburg is one of the largest manufacturing facilities for mRNA-based vaccines in Europe. As part of its long-term development plan, BioNTech has continuously invested in the site and more than doubled the number of employees to around 700 over the past two years. Beyond the already established commercial production of the Pfizer-BioNTech COVID-19 vaccine, the development plan also includes three additional potential growth areas:

- A technology hub for innovative manufacturing solutions such as the [BioNTainer](#), which encompasses the first two fully-operational modular production facilities on-site.
- The manufacturing of mRNA vaccines on a clinical scale in support of the Company's clinical trials. The focus here is currently on candidates from the Company's proprietary FixVac platform.
- Plasmid DNA manufacturing to produce key starting materials for mRNA- and cell-based drugs in-house.

The plasmid DNA produced in Marburg is planned to be used globally and serve as the basis for the manufacturing of mRNA- and cell-based products on a clinical or commercial scale. BioNTech's product pipeline currently comprises 22 product candidates that are being evaluated in 26 clinical trials. The Company is conducting clinical trials in more than 30 countries worldwide, most of them being held in Germany, Spain, Belgium, the United Kingdom and the United States.

Further media material can be downloaded in BioNTech's [newsroom](#), including a fact sheet on plasmid production as well as photographs. This section will be updated during the course of the day.

About Plasmid DNA

Plasmids are small, ring-shaped DNA sequences that can occur in bacteria in addition to their genomic DNA. They often encode additional acquired genetic information which for instance can confer antibiotic resistance on the bacterium. Plasmids are used in the biopharmaceutical industry as vectors or transport vehicles for, amongst other things, the multiplication of genetic information or DNA sequences. A copy of a DNA sequence obtained from a plasmid can be used as a template to manufacture more than 500 mRNA strands. After mRNA manufacturing, the DNA templates are

filtered and discarded, and are therefore not part of the final vaccines or therapies.

About BioNTech

Biopharmaceutical New Technologies 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.

BioNTech Forward-Looking Statements

This statement contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may include, but may not be limited to, direct or indirect statements concerning: BioNTech's plans to establish its new plasmid DNA manufacturing facility with the aim to increase its autonomy and flexibility in manufacturing of plasmids; the expected ability of the facility to enable faster production cycles and shorter delivery routes; BioNTech's expectations for the annual manufacturing capacity of the plasmid plants and the amount of mRNA and the resulting vaccine doses or therapies that could be manufactured based on this capacity; the expected timing for the commercial-scale facility to become operational, including construction completion until commissioning as well as regulatory approval of the plasmid DNA manufacturing facility; the investments made in and planned for the site and the new plasmid manufacturing facility; BioNTech's ability to manufacture mRNA-based products for a broad range of candidates for clinical trials at its Marburg site; BioNTech's potential ability to prepare commercial manufacturing for personalized oncology therapeutics at its Marburg site; BioNTech's long-term development plan for BioNTech's Marburg site; the expected global use and distribution of the plasmids produced in Marburg; BioNTech's ability to develop, test and commercialize products and product candidates, including the timing to initiate clinical trials; BioNTech's anticipated market opportunity and size for its product candidates; and the rate and degree of market acceptance of BioNTech's investigational medicines, if approved. Any forward-looking statements in this statement 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.

For a discussion of these and other risks and uncertainties, see BioNTech's Quarterly Report on Form 6-K for the quarter ended September 30, 2022, filed with the U.S. Securities and Exchange Commission ("SEC") on November 7, 2022, 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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