



BioNTech Announces Plans for a Clinical Trial hub in Taiwan for mRNA-based Cancer Immunotherapies as Part of Asia-Pacific Expansion

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- *BioNTech plans to accelerate clinical development of its mRNA-based cancer immunotherapies in the Asia-Pacific region by expanding its clinical footprint to East Asia*
- *First clinical trial sites planned to be activated in Taiwan to initially evaluate BioNTech's product candidate BNT113 against head and neck cancer*
- *Multiple product candidates of BioNTech's oncology pipeline may be rolled out in clinical trials across various countries and regions in East Asia to support product development and launches of potential treatments in the region*
- *Plans are part of BioNTech's broader Asia-Pacific strategy, which has the aim of developing, manufacturing and broadening the access to innovative mRNA-based immunotherapies in Asia with a focus on addressing the most common types of cancers*
- *BioNTech has already established subsidiaries in Singapore, Shanghai, and Melbourne, as well as registered a representative office in Taipei, which BioNTech aims to serve as regional innovation hubs in its global network*

MAINZ, GERMANY, December 16, 2022 —[BioNTech SE](#) (Nasdaq: BNTX, "BioNTech" or the "Company") today announced plans to accelerate and broaden the clinical development of its cancer immunotherapy pipeline in the Asia-Pacific region by expanding its clinical footprint to East Asia. The first regional clinical trial sites for the Company's mRNA-based cancer immunotherapies are planned to be activated in Taiwan to initially evaluate BioNTech's cancer product candidate BNT113 against head and neck cancer. BNT113 is expected to be the first product candidate from a potential wave of novel cancer immunotherapies that BioNTech anticipates to evaluate in the region. These plans are part of BioNTech's Asia-Pacific strategy, which has the aim of developing, manufacturing and broadening the access to innovative medicines in Asia, with a focus on treatments addressing the most common types of cancer. As part of these plans, BioNTech has been collaborating with the YongLin Healthcare Foundation and in November 2022, BioNTech signed a Memorandum of Understanding (MoU) with Retain Biotech Corp. ("Retain"), a Taiwan-based organization that is sponsored by the YongLin Healthcare Foundation and engaged in precision medicine, genomic medicine and cell therapy in oncology.

"Taiwan is one of the renowned biomedical hubs in the Asia-Pacific region given its state-of-the-art health care system, medical research capacity and collaborative approach to work with leading companies and institutions around the world. Our Asia-Pacific strategy is based on powerful partnerships and a joint vision," said **Sean Marett, Chief Business and Chief Commercial Officer of BioNTech**. "We are looking forward to working with Retain in our efforts to facilitate the clinical development of novel immunotherapies in oncology. Our aim is to accelerate the development of innovative therapies to help address cancers that are highly prevalent in the region."

As part of the MoU, Retain is expected to initially support clinical evaluation of BioNTech's mRNA-based product candidate BNT113 for the treatment of head and neck cancer in a randomized Phase 2 clinical trial across the region. Head and neck cancer is the seventh most common cancer globally, with one of the highest incidences being observed in the Asia-Pacific region.¹ BNT113 is based on BioNTech's proprietary mRNA platform FixVac. The Company plans to evaluate the candidate in the broader Asia-Pacific region with first clinical trial sites in Australia's state of Victoria as well as in Taiwan. In addition, BioNTech and Retain plan to assess the potential to expand clinical activities to Japan, South Korea, Singapore and other East Asian countries and regions for a number of additional product candidates from BioNTech's oncology pipeline which currently encompasses a total of 18 product candidates in 23 ongoing clinical trials.

As part of BioNTech's Asia-Pacific strategy, the Company is in parallel establishing clinical and commercial-scale manufacturing in the region. In November 2022, BioNTech announced its acquisition of a GMP-certified manufacturing facility in [Singapore](#) in support of the R&D and potential launch activities for product candidates across the Asia-Pacific region and with the potential to expand the production beyond mRNA, such as cell therapies. In addition, BioNTech announced plans to set-up a clinical scale end-to-end mRNA manufacturing facility based on its BioNTainer solution in [Melbourne](#) aiming to enable access to mRNA technology and promote research collaborations in the Asia-Pacific region.

BioNTech has already established subsidiaries in Singapore, Shanghai, and Melbourne, as well as registered a representative office in Taipei, which BioNTech aims to serve as regional innovation hubs as part of the Company's global network. BioNTech expects to create hundreds of jobs across these regional sites by 2024 across multiple functions.

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 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 plans for a clinical trial hub in Taiwan; BioNTech’s investigational program candidate BNT113; the timing, for any data readouts of the BNT113 phase 2 trial; the registrational potential of BNT113; the nature and characterization of and timing for release of clinical data across BioNTech’s platforms, which is subject to peer review, regulatory review and market interpretation; the planned next steps in BioNTech’s pipeline programs and specifically including, but not limited to, statements regarding timing or plans for initiation of clinical trials, enrollment or submission for and receipt of product approvals with respect to BioNTech’s product candidates; the ability of BioNTech’s mRNA technology to demonstrate clinical efficacy outside of BioNTech’s infectious disease platform; the potential safety and efficacy of our other product candidates; and BioNTech’s anticipated market opportunity and size for its product candidates, the rate and degree of market acceptance of BioNTech’s investigational medicines, if approved; BioNTech’s plans for expansion of its manufacturing capacity and capabilities, facilities, and geographical presence; BioNTech’s expected product sales and revenues; the consummation and anticipated costs, benefits and synergies of BioNTech’s expansion in the Asia-Pacific; and BioNTech’s ability to effectively scale its production capabilities and manufacture its products, including BioNTech and Pfizer’s COVID-19 vaccine, and BioNTech’s investigational product candidates. Any forward-looking statements in this press release are based on BioNTech’s current expectations and beliefs of future events. The forward-looking statements in this press release are neither promises nor guarantees, and 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 from those expressed or implied by these forward-looking statements.

For a discussion of these and other risks and uncertainties, see BioNTech’s Quarterly Report as Form 6-K for the quarter ended September 30, 2022, filed with the 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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¹ Sung H, Ferlay J, Siegel R L et al. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. *CA Cancer J Clin* 2021; 71: 209-249.