



## BioNTech and Medigene Announce Global Collaboration to Advance T Cell Receptor Immunotherapies Against Cancer

February 21, 2022

- Collaboration leverages BioNTech's multi-platform immunotherapy capabilities and Medigene's T cell receptor (TCR) discovery platform to discover and develop innovative TCR immunotherapies against targets selected by BioNTech
- BioNTech to acquire preclinical PRAME TCR and receive licenses to Medigene's PD1-41BB switch receptor and precision pairing technologies
- BioNTech will hold exclusive worldwide development and commercialization rights to all TCR therapies arising from the collaboration
- Medigene will receive EUR 26 million upfront from BioNTech, as well as research funding, and will be eligible to receive development, regulatory and commercial milestone payments in addition to royalties and tiered deferred option payments on global net sales

**Mainz/Martinsried/Munich, Germany, February 21, 2022** – **BioNTech SE** (Nasdaq: BNTX, "BioNTech") and **Medigene AG** (FSE: MDG1, Prime Standard, "Medigene"), a clinical-stage immuno-oncology company focusing on the development of T cell immunotherapies, today announced that they have entered a multi-target research collaboration to develop T cell receptor (TCR) based immunotherapies against cancer. The initial term of the collaboration is three years.

Medigene will contribute its proprietary TCR discovery platform for the development of TCRs against multiple solid tumor targets nominated by BioNTech. Medigene's automated, high throughput TCR discovery platform is designed to bypass central tolerance to yield high affinity TCRs. T cell therapy has become a disruptive medical innovation in the treatment of patients with cancer. Engineered TCR-modified T cells (TCR-T cells) are reprogrammed to express a TCR that can recognize specific antigens only present on tumor cells, thereby enabling a precise and potent immune response to attack a patient's tumor.

"This collaboration with Medigene expands our cell therapy portfolio and TCR discovery capabilities, and further strengthens our ability to be a leader in the rapidly emerging field of engineered cell therapies," said **Ugur Sahin, M.D., Chief Executive Officer and Co-Founder of BioNTech**. "We look forward to working closely with Medigene to develop new treatments which address solid tumors with high unmet medical need."

**Prof. Dolores Schendel, Chief Executive Officer and Chief Scientific Officer at Medigene:** "Medigene is at the forefront of the development of TCR-T therapies for oncology. The sale and licensing deal with BioNTech is an important validation from a global leading biotech company of our proprietary technologies to discover and characterize highly specific TCRs and empower resulting TCR-T cells to fight solid tumors. This partnership provides Medigene with meaningful financial resources to fuel our next generation development programs targeting potentially novel tumor-specific "dark matter" antigens, further tools to enhance T-cell-based immunotherapies, as well as additional potential strategic deals with future milestone payments and royalties."

BioNTech will acquire Medigene's next generation preclinical TCR program, which combines TCR-4 of Medigene's MDG10XX program targeting PRAME with Medigene's proprietary PD1-41BB switch receptor technology. BioNTech will also obtain the exclusive option to acquire additional existing TCRs in Medigene's discovery pipeline and will receive licenses to the company's PD1-41BB switch receptor and precision pairing library. This has the potential to augment TCR cell therapy efficacy and can be applied to all BioNTech cell therapy programs.

Under the terms of the agreement, Medigene will receive EUR 26 million upfront, as well as research funding for the period of the collaboration. BioNTech will be responsible for global development and hold exclusive worldwide commercialization rights on all TCR therapies resulting from this research collaboration. Medigene will be eligible to receive development, regulatory and commercial milestone payments up to a triple digit million EUR amount per program in addition to tiered deferred option payments on global net sales for products based on TCRs arising from the collaboration and royalties on products utilizing at least one of the licensed technologies.

### 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, bi-specific checkpoint immuno-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, Bayer Animal Health, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma and Pfizer.

For more information, please visit [www.BioNTech.de](http://www.BioNTech.de).

### About Medigene

Medigene AG (FSE: MDG1, ISIN DE000A1X3W00, Prime Standard) is a publicly listed biotechnology company headquartered in Planegg/Martinsried near Munich, Germany. With its scientific expertise, Medigene is working on the development of innovative immunotherapies to enhance T cell activity against solid cancers in fields of high unmet medical need. Medigene's pipeline includes preclinical as well as clinical programs in development.

Medigene's strategy is to develop its own therapies towards clinical proof-of-concept. In addition, the Company offers selected partners the opportunity to discover and develop therapies on the basis of its proprietary technology platforms. In return for such partnerships, Medigene expects to receive upfront and milestone payments as well as research and development funding and royalties on future product sales.

For more information, please visit <https://www.medigene.com>

### **About Medigene's TCR-T cells**

T cells are at the center of Medigene's therapeutic approaches. With the aid of Medigene's immunotherapies the patient's own defense mechanisms are activated, and T cells harnessed in the battle against cancer. Medigene's therapies arm the patient's own T cells with tumor-specific T cell receptors (TCRs). The resulting TCR-T cells should thereby be able to detect and efficiently kill cancer cells.

This approach to immunotherapy aims to overcome the patient's tolerance to cancer cells and tumor-induced immunosuppression by activating the patient's T cells outside the body, genetically modifying them with tumor-specific TCRs and finally multiplying them. In this way, large numbers of specific T cells are made available to patients to fight the cancer within a short period of time.

### **About Medigene's PD1-41BB switch receptor**

Checkpoint inhibition via PD1-PDL1 pathway: Solid tumor cells are known to be sensitive to killing by activated T cells. Tumor cells can escape this killing activity by expressing inhibitory molecules, so-called 'checkpoint proteins', such as Programmed Death Ligand 1 (PD-L1) on their surface. When this occurs, activated T cells which express PD-1, the natural receptor for PD-L1, are inactivated. The expression of PD-L1 by tumors represents an adaptive immune resistance mechanism that can lead to tumor survival and growth.

The 4-1BB co-stimulatory signaling pathway: Effective T cell immune responses to antigens typically require costimulatory signals to be received alongside the primary antigenic stimulation via the T cell receptor (TCR). The intracellular signaling domains of the 4-1BB protein offer a well-characterized pathway to positively enhance T cell responses.

Medigene's PD1-41BB switch receptor takes advantage of the binding of PD-1 on the T cells to PD-L1 on tumors. In the switch receptor, the inhibitory signaling domain of PD-1 has been substituted with the activating signaling domain of 4-1BB. As a result, the switch receptor then delivers an activating signal to the TCR-T cells (not the usual inhibitory signal of PD-1). This enables the PD1-41BB-modified TCR-T cells to proliferate strongly in the presence of PD-L1-positive tumor cells and to mediate greater killing of tumor cells upon repeated exposure. Additionally, signals mediated through the switch receptor also enhance metabolic fitness of TCR-T cells, enabling better function in conditions of low levels of glucose or high levels of the immunosuppressive factor TGF $\beta$ , two conditions that are characteristic of strongly hostile tumor microenvironments.

### **About Medigene's precision pairing library**

T cell receptors (TCRs) consist of an alpha and a beta chain, which together act as a receptor on the cell surface of T cells. Medigene's therapies aim to equip the patient's own T cells with tumor-specific TCRs. The resulting TCR-T cells should thereby be able to detect and efficiently kill cancer cells. The precision pairing library allows selection of specific modifications in each chain of a TCR so that the alpha and beta chains preferentially pair with each other, with the result that improved TCR surface expression and/or functionality is achieved.

### **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 Medigene; the ability of Medigene's TCR discovery platform to develop multi-specific immunotherapies, including cell therapies; and the ability of BioNTech to commercialize these immunotherapies, if successfully developed. Any forward-looking statements in this press release are based on BioNTech 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 the section entitled "Risk Factors" in BioNTech's Annual Report on Form 20-F for the Year Ended December 31, 2020, filed with the SEC on March 30, 2021, which is available on the SEC's website at [www.sec.gov](http://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.

### **Medigene Forward-looking Statements**

This press release contains forward-looking statements representing the opinion of Medigene as of the date of this release. The actual results achieved by Medigene may differ significantly from the forward-looking statements made herein. Medigene is not bound to update any of these forward-looking statements. Medigene® is a registered trademark of Medigene AG. This trademark may be owned or licensed in select locations only.

### **Contacts**

#### **BioNTech**

#### Media Relations

Jasmina Alatovic  
+49 (0)6131 9084 1513  
[Media@biontech.de](mailto:Media@biontech.de)

#### Investor Relations

Sylke Maas, Ph.D.  
+49 (0)6131 9084 1074  
[Investors@biontech.de](mailto:Investors@biontech.de)

#### **Medigene**

Dr. Anna Niedl  
+49 89 2000 3333 01  
[investor@medigene.com](mailto:investor@medigene.com)

#### **LifeSci Advisors**

Sandya von der Weid  
+41 78 680 05 38  
[svonderweid@lifesciadvisors.com](mailto:svonderweid@lifesciadvisors.com)