



BioNTech Announces Publication of Preclinical Data for First-in-Kind CAR-T Cell Therapy Approach Targeting Solid Tumors in Science

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- Publication of preclinical proof-of-concept data for BNT211 reports Claudin 6 (CLDN6) as a novel target for CAR-T cell therapy of solid tumors and introduces CARVac, a first-in-kind RNA vaccine approach promoting the amplification and persistence of CAR-T cells *in vivo*
- Combination of CAR-T cell therapy with CARVac highlights the value of cross-platform synergies to address key development challenges in the treatment of cancer
- Applicability of CARVac to various CAR-T cell therapeutic targets offers broad potential to improve therapeutic efficacy of CAR-T cell therapies across a range of solid and liquid tumors
- First-in-human Phase 1/2 clinical trial for BNT211 in multiple solid tumors including ovarian, testicular, uterine and lung cancer intended to start in 2020

MAINZ, Germany, Jan. 02, 2020 (GLOBE NEWSWIRE) -- BioNTech SE (NASDAQ: BNTX, "BioNTech" or "the Company"), announced today a publication in [Science](#) on the company's novel CAR-T therapeutic approach for solid tumors which utilizes a **C**AR-T Cell **A**mplifying **R**NA **V**accine, or CARVac. The report entitled "*An RNA vaccine drives expansion and efficacy of claudin-CAR-T cells against solid tumors*" provides preclinical proof-of-concept data for BioNTech's first CAR-T product candidate BNT211, an autologous CAR-T cell therapy targeting the oncofetal antigen Claudin 6 (CLDN6), and outlines CARVac as a broadly applicable RNA vaccine approach to improve therapeutic efficacy of CAR-T cell therapies.

Although CAR-T cell therapy has shown significant clinical efficacy in blood cancers, it still faces major challenges in solid tumors, including a limited number of identified cancer-specific solid tumor targets, inefficient infiltration of CAR-T cells into solid tumors and insufficient CAR-T cell persistence. BioNTech aims to overcome these hurdles by targeting CLDN6, a novel tumor specific antigen expressed in multiple solid tumors, in combination with an RNA vaccine promoting the amplification, persistence and efficacy of CAR-T cells *in vivo*.

In the published study, a second generation CLDN6-CAR-T therapy with a 4-1BB costimulatory domain (BNT211) was evaluated both *in vitro* in tumor cell lines and *in vivo* in mice with human ovarian cancer transplants. In mice, CLDN6-CAR-T cell therapy demonstrated complete tumor regression of transplanted large human tumors within two weeks after treatment initiation. Furthermore, the combination with CARVac achieved an improved engraftment, proliferation and expansion of CAR-T cells *in vivo* resulting in tumor regression even at sub-therapeutic CAR-T doses. CARVac was also successfully applied for CAR-T cells targeting the pan-cancer antigen CLDN18.2 and CD19, the target of approved CAR-T cell therapies. The combination of CAR-T cell therapy with CARVac underlines the value of cross-platform synergies to address key development challenges in the treatment of cancer.

BioNTech intends to initiate a first-in-human Phase 1/2 clinical trial for BNT211 this year in solid tumors, including ovarian, testicular, uterine and lung cancer. Manufacturing to support clinical trials of BNT211 will be conducted in-house at BioNTech's state-of-the-art GMP certified cell therapy manufacturing facility in Idar-Oberstein, Germany, which has been in operation since 1999. BioNTech initiated a multi-year capacity expansion at the facility in 2018 which it expects to complete in 2020.

About BioNTech

BioNTech was founded in 2008 on the understanding that every cancer patient's tumor is unique and therefore each patient's treatment should be individualized. Its cutting-edge pipeline includes individualized mRNA-based product candidates, innovative chimeric antigen receptor T cells, novel checkpoint immunomodulators, targeted cancer antibodies and small molecules. BioNTech has established relationships with seven pharmaceutical collaborators, including Eli Lilly and Company, Genmab, Sanofi, Bayer Animal Health, Genentech, a member of the Roche Group, Genevant and Pfizer, and has published over 150 peer-reviewed publications on its scientific approach.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended including, but not limited to, statements concerning development of BNT211. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. 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. You should review the risks and uncertainties described under the heading "Risk Factors" and those described in BioNTech's Prospectus filed with the U.S. Securities and Exchange Commission (SEC) on October 11, 2019 and in subsequent filings made by BioNTech with the SEC, which are available on the SEC's website at <https://www.sec.gov/>. Except as required by law, BioNTech disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on BioNTech's current expectations and speak only as of the date hereof.

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