



# BioNTech and Pfizer announce regulatory approval from German authority Paul-Ehrlich-Institut to commence first clinical trial of COVID-19 vaccine candidates

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*First COVID-19-related clinical trial to start in Germany Initial dose escalation phase to target dose range of 1µg to 100µg Clinical supply from BioNTech's GMP-certified mRNA production facilities in Europe Four vaccine candidates to enter clinical development*

MAINZ, Germany and NEW YORK , April 22, 2020 (GLOBE NEWSWIRE) -- BioNTech SE (Nasdaq: BNTX, "BioNTech" or "the Company") and Pfizer Inc. (NYSE: PFE), have announced today that the German regulatory authority, the Paul-Ehrlich-Institut, has approved the Phase 1/2 clinical trial for BioNTech's BNT162 vaccine program to prevent COVID-19 infection. BioNTech and Pfizer are jointly developing BNT162. The trial is the first clinical trial of a COVID-19 vaccine candidate to start in Germany , and is part of a global development program. Pfizer and BioNTech will also conduct trials for BNT162 in the United States upon regulatory approval, which is expected shortly.

The four vaccine candidates are the first candidates from BioNTech's COVID-19-focused project "Lightspeed", each representing different mRNA formats and target antigens. Two of the four vaccine candidates include a nucleoside modified mRNA (modRNA), one includes a uridine containing mRNA (uRNA), and the fourth vaccine candidate utilizes self-amplifying mRNA (saRNA). Each mRNA format is combined with a lipid nanoparticle (LNP) formulation. The larger spike sequence is included in two of the vaccine candidates, and the smaller optimized receptor binding domain (RBD) from the spike protein is included in the other two candidates. The RBD-based candidates contain the piece of the spike that

is thought to be most important for eliciting antibodies that can inactivate the virus.

The dose escalation portion of the Phase 1/2 trial will include approximately 200 healthy subjects between the ages of 18 to 55 and will target a dose range of 1 µg to 100 µg aiming to determine the optimal dose for further studies as well as evaluate the safety and immunogenicity of the vaccine. The study will also evaluate the effects of repeated immunization for three of the four vaccine candidates which utilize uRNA or modRNA. Subjects with a higher risk for a severe COVID-19 infection will be included in the second part of the study.

“We are pleased to have completed pre-clinical studies in Germany and will soon initiate this first-in-human trial ahead of our expectations. The speed with which we were able to move from the start of the program to trial initiation speaks to the high level of engagement from everyone involved,” says **CEO and Co-founder of BioNTech , Ugur Sahin .**

“Pfizer and BioNTech’s partnership has mobilized our collective resources with extraordinary speed in the face of this worldwide challenge,” said **Albert Bourla , Pfizer Chairman and CEO .** “Now that the work in Germany can commence, we are looking forward to and actively preparing for the potential start of this unique and robust clinical study program in the United States in the near future.”

During the clinical development stage, BioNTech will provide its partners clinical supply of the vaccine from its GMP-certified mRNA manufacturing facilities in Europe .

BioNTech is also collaborating with Fosun Pharma to develop BNT162 in China , where the companies expect to conduct trials.

**BioNTech Conference Call and Webcast** BioNTech will host a conference call and webcast Thursday, April 23, 2020 at 08:00 a.m. EDT ( 2:00 p.m. CEST ). The slide presentation and audio of the webcast will be available via the following link:  
<https://edge.media-server.com/mmc/p/b9xow5kn>

To participate in the conference call, please dial the following numbers 15-20 minutes prior to the start of the webcast and provide the Conference ID: 8534807

United States international: +1 (646) 741 3167    United States domestic (toll-free): +1 (877) 870 9135    Germany : +49 (0) 692 2222 625    Standard International : +44 (0) 2071 928338

The slide presentation and audio of the webcast will be available on BioNTech's website <https://biontech.de/> in the "Events & Presentations" page of the Investor Relations section. A replay of the webcast will be available shortly after the conclusion of the call and archived in the same section of the BioNTech's website.

**About BioNTech** Biopharmaceutical New Technologies ( BioNTech ) 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 immunomodulators, 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 Eli Lilly and Company, Genmab, Sanofi, Bayer Animal Health , Genentech , a member of the Roche Group, Genevant, Fosun Pharma, and Pfizer.

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

**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 efforts to combat COVID-19; the planned next steps in BioNTech's project Lightspeed ; the timing to initiate clinical trials of BNT162 in Germany ; collaborations between BioNTech and Pfizer , and BioNTech and Fosun Pharma, to develop a potential COVID-19 vaccine; the expected timing of clinical trials of BNT 162 in the United States and China ; and the ability of BioNTech to supply the quantities of BNT162 to support clinical development. 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. These risks and uncertainties include, but are not limited to: competition to create a vaccine for Covid-19 and potential difficulties. For a discussion of these and other risks and uncertainties, see BioNTech's Annual Report on Form 20-F filed with the SEC on March 31, 2020 , which has been filed with the SEC and 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.

**About Pfizer Inc. : Breakthroughs That Change Patients' Lives** At Pfizer , we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at [www.Pfizer.com](http://www.Pfizer.com) . In addition, to learn more, please visit us on [www.Pfizer.com](http://www.Pfizer.com) and follow us on Twitter at @Pfizer and @Pfizer News , LinkedIn , YouTube and like us on Facebook at [Facebook.com/Pfizer](https://www.facebook.com/Pfizer) .

**Pfizer Disclosure Notice** The information contained in this release is as of April 22, 2020 . Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about Pfizer's efforts to combat COVID-19, BioNTech's mRNA vaccine program, BNT162, a collaboration between BioNTech and Pfizer to develop a potential COVID-19 vaccine and the expected timing of clinical trials, including their potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from the clinical studies; whether and when any biologics license applications may be filed in any jurisdictions for any potential vaccine candidates under the collaboration; whether and when any such applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether any such vaccine candidates will be

commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of any such vaccine candidates, including development of products or therapies by other companies; manufacturing capabilities or capacity; uncertainties regarding the ability to obtain recommendations from vaccine technical committees and other public health authorities regarding any such vaccine candidates and uncertainties regarding the commercial impact of any such recommendations; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at <http://www.sec.gov/> and [www.Pfizer.com](http://www.Pfizer.com) .

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