BIONTECH SE

Rights Offering for up to 7,505,596 Ordinary Shares Including Ordinary Shares Represented by American Depositary Shares

This Prospectus Supplement No. 2 supplements information contained in our prospectus, dated July 23, 2020, relating to the offering to holders of our ordinary shares and American Depositary Shares, or ADSs, representing our ordinary shares, of rights to subscribe for up to an aggregate of 7,505,596 new ordinary shares and new ADSs representing our ordinary shares.

This prospectus supplement is being filed to update, amend and supplement the information previously included in the prospectus with the information set forth in our Reports on Form 6-K filed with the Securities and Exchange Commission on July 31, 2020, which are set forth below. This prospectus supplement should be read in conjunction with the prospectus dated July 23, 2020. To the extent there is a discrepancy between the information contained in this prospectus supplement and the information in the prospectus, the information contained herein supersedes and replaces such conflicting information.

You should carefully consider whether or not to exercise your subscription rights before the expiration of the rights offering at one minute after 11:59 p.m. (Mainz, Germany time) on August 14, 2020 (for ordinary share rights) or 12:01 a.m. (New York City time) on August 14, 2020 (for ADS rights). In addition, we plan to announce second quarter results on or about August 11, 2020. All exercises of rights to subscribe for new ADSs are irrevocable. Neither we, our supervisory board, the dealer-managers nor the subscription agents are making a recommendation regarding your exercise of the subscription rights.

Investing in our ordinary shares and ADSs representing our ordinary shares involves a high degree of risk. See "Risk Factors" beginning on page 22 of the prospectus, together with all of the other information contained in the prospectus and in our filings with the Securities and Exchange Commission that we have incorporated by reference in the prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this Prospectus Supplement No. 2 is July 31, 2020.

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

FOR THE MONTH OF JULY 2020

COMMISSION FILE NUMBER 001-39081

BioNTech SE

(Translation of registrant's name into English)

An der Goldgrube 12 D-55131 Mainz Germany +49 6131-9084-0 (Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F: Form 20-F \boxtimes Form 40-F \square

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

DOCUMENTS INCLUDED AS PART OF THIS FORM 6-K

On July 31, 2020, BioNTech SE (the "Company"), issued a press release announcing a strategic collaboration with Regeneron for a clinical trial combining BioNTech's BNT111 FixVac product candidate and Libtayo[®] (cemiplimab), a fully human anti-PD-1 therapy, for the treatment of melanoma. The press release is attached hereto as Exhibit 99.1.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BioNTech SE

By: <u>/s/ Dr. Sierk Poetting</u> Name: Dr. Sierk Poetting Title: Chief Financial Officer

Date: July 31, 2020

EXHIBIT INDEX

Exhibit Description of Exhibit

99.1 Press Release dated July 31, 2020 - BioNTech Announces Strategic Collaboration with Regeneron to Advance FixVac and Libtayo[®] (cemiplimab) Combination in Melanoma.



BioNTech Announces Strategic Collaboration with Regeneron to Advance FixVac and Libtayo[®] (cemiplimab) Combination in Melanoma

- BioNTech and Regeneron plan to jointly conduct a randomized Phase 2 study combining BNT111 FixVac and Libtayo for the treatment of melanoma that has progressed after prior PD-1 blockade
- Combines two immunotherapies with complementary mechanisms of action with the aim to accelerate the path to market approval in melanoma if the trial is successful
- Development costs for the clinical trial to be shared equally with each company retaining full commercial rights to their respective product candidates

MAINZ, Germany, July 31, 2020 (GLOBE NEWSWIRE) — <u>BioNTech SE</u> (Nasdaq: BNTX, "BioNTech" or "the Company") today announced a strategic collaboration with Regeneron for a clinical trial combining BioNTech's BNT111 FixVac product candidate and Libtayo® (cemiplimab), a fully human anti-PD-1 therapy, for the treatment of melanoma. The companies plan to jointly conduct a randomized Phase 2 study in patients with anti-PD1-refractory/relapsed, unresectable Stage III or IV cutaneous melanoma. Melanoma is the deadliest skin cancer and estimated to kill more than 63,000 people around the world this year.¹

BNT111 is the most advanced of five clinical stage FixVac product candidates within BioNTech's broader development pipeline. It is an mRNA cancer immunotherapy targeting four antigens frequently expressed in the tumors of patients with melanoma – NY-ESO-1, MAGE-A3, tyrosinase, and TPTE. BNT111 has demonstrated clinical anti-tumor activity as a monotherapy and in combination with checkpoint inhibitors in an ongoing Phase 1 trial in patients with advanced melanoma after prior checkpoint blockade.

"We believe our FixVac platform represents a powerful new drug class of mRNA immunotherapies against cancer. We look forward to working together with Regeneron to advance this product candidate into potentially registrational clinical trials," said **Ugur Sahin, CEO** and **Co-founder of BioNTech**.

The two companies plan to pursue a clinical trial for the combination in the second-line treatment setting for advanced melanoma. The companies plan to disclose more details related to the planned Phase 2 study in the third quarter of 2020, with the goal of initiating the trial in the fourth quarter of 2020.

"Despite recent treatment advances with anti-PD-1 therapies for patients with melanoma, most patients fail to obtain a durable benefit. The combination of Libtayo and BNT111 FixVac has the potential to augment the immune system's ability to effectively recognize melanoma in multiple ways and hopefully improve immune targeting to control the cancer," said Israel Lowy, M.D., Ph.D., Senior Vice President, Translational Science and Oncology, at Regeneron.

Under the terms of the agreement, development costs for the clinical trial will be shared equally and both companies will contribute their products for the trial. Each party will retain full commercial rights for its respective product and record revenues related to its own product.

Libtayo is being jointly developed by Regeneron and Sanofi.

1 WHO International Agency for Research on Cancer (2020): <u>https://gco.iarc.fr/tomorrow/graphic-isotype?</u>

type=1&type sex=0&mode=population&sex=0&populations=900&cancers=16&age group=value&apc male=0&apc female=0&single unit=10000&print=0

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, Genevant, Fosun Pharma, and Pfizer.

For more information, please visit 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 FixVac program candidate BNT111; BioNTech's collaboration with Regeneron; timing for commencement of a Phase 2 trial in collaboration with Regeneron; timing for release of additional information relating to this trial; and the registrational potential of any Phase 2 trial we may initiate. 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: discussions with regulatory agencies regarding timing and requirements for additional clinical trials; and the ability to produce favorable clinical results in future clinical trials combining BNT111 and Libtayo. 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. 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.

For more information, please contact

Media Relations

Jasmina Alatovic Senior Manager Global External Communications Tel: +49 (0)6131 9084 1513 or +49 (0)151 1978 1385 E-mail: Media@biontech.de

Investor Relations

Sylke Maas, Ph.D. VP Investor Relations & Business Strategy Tel: +49 (0)6131 9084 1074 E-Mail: Investors@biontech.de

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

FOR THE MONTH OF JULY 2020

COMMISSION FILE NUMBER 001-39081

BioNTech SE

(Translation of registrant's name into English)

An der Goldgrube 12 D-55131 Mainz Germany +49 6131-9084-0 (Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F: Form 20-F \boxtimes Form 40-F \square

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

DOCUMENTS INCLUDED AS PART OF THIS FORM 6-K

On July 31, 2020, BioNTech SE (the "Company") issued a press release, announcing that the Company and Pfizer signed an agreement with the Ministry of Health, Labor and Welfare (MHLW) in Japan to supply 120 million doses of BNT162 mRNA-based vaccine candidate against SARS-CoV2, subject to clinical success and regulatory approval, beginning in 2021. The press release is attached hereto as Exhibit 99.1.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BioNTech SE

By: <u>/s/ Dr. Sierk Poetting</u> Name: Dr. Sierk Poetting Title: Chief Financial Officer

Date: July 31, 2020

EXHIBIT INDEX

Exhibit Description of Exhibit

99.1 Press Release dated July 31, 2020 - Pfizer and BioNTech to supply Japan with 120 million doses of their BNT162 mRNA-based vaccine candidate.





Pfizer and BioNTech to Supply Japan With 120 Million Doses of Their BNT162 mRNA-Based Vaccine Candidate

- Supply of 120 million doses to be provided in the first half of 2021, subject to regulatory approval
- Agreement is part of Pfizer's and BioNTech's global commitment to help address the pandemic
- Pfizer and BioNTech began a Phase 2b/3 safety and efficacy trial and remain on track to seek regulatory review as early as October 2020, and manufacture globally up to 100 million doses by the end of 2020 and approximately 1.3 billion doses by the end of 2021

NEW YORK and MAINZ, GERMANY, July 31, 2020 — <u>Pfizer Inc.</u> (NYSE: PFE) and <u>BioNTech SE</u> (Nasdaq: BNTX) today announced an agreement with the Ministry of Health, Labour and Welfare (MHLW) in Japan to supply 120 million doses of their BNT162 mRNA-based vaccine candidate against SARS-CoV-2, subject to clinical success and regulatory approval, beginning in 2021.

Financial details of the agreement were not disclosed, but the terms were based on the timing of delivery and the volume of doses. As requested by the Government of Japan, deliveries of the vaccine candidate are planned for the first half of 2021.

"We are deeply honored to work with the Japanese government and to marshal our scientific and manufacturing resources towards our shared goal of bringing millions of doses of a potential COVID-19 vaccine to the Japanese people as quickly as possible," said Albert **Bourla, Chairman and CEO, Pfizer.** "In the face of this global health crisis, Pfizer's purpose – breakthroughs that change patients' lives – has taken on an even greater urgency. Under these difficult circumstances, we are proud to help support Japan in its steadfast determination to bring the world together at the 2020 Tokyo Olympics, in a celebration of solidarity, friendship and the power of sport as a global force for good. Our hope is that, subject to clinical and regulatory success, our potential vaccine will help make this happen."

"In bringing the world together at one place, for centuries, the Olympic Games have been a symbol of a global community. As a renewed version of that very spirit, the 2020 Tokyo Olympics may become a symbol for all of us for how all nations around the world can overcome a global pandemic threat together. We are proud and honored that our vaccine candidate may contribute to the efforts undertaken by the government of Japan to turn this vision into reality," said Ugur Sahin, M.D., CEO and Co-founder of BioNTech.

The BNT162 program is based on BioNTech's proprietary mRNA technology and supported by Pfizer's global vaccine development and manufacturing capabilities. The vaccine development program is evaluating at least four experimental vaccine candidates, each of which represents a unique combination of messenger RNA (mRNA) format and target antigen. The BNT162 vaccine candidates are undergoing clinical studies and are not currently approved for distribution anywhere in the world. Both collaborators are committed to developing these novel vaccines with pre-clinical and clinical data at the forefront of all their decision-making.

Recently, two of the companies' four investigational vaccine candidates – BNT162b1 and BNT162b2 – received Fast Track designation from the U.S. Food and Drug Administration (FDA). This designation was granted based on preliminary data from Phase 1/2 studies that are currently ongoing in the United States and Germany as well as animal immunogenicity studies.

On July 27, Pfizer and BioNTech announced that following extensive review of preclinical and clinical data from Phase 1/2 clinical trials, and in consultation with the FDA's Center for Biologics Evaluation and Research (CBER) and other global regulators, the companies selected the BNT162b2 vaccine candidate to move forward into a Phase 2/3 study. BNT162b2 encodes an optimized SARS-CoV-2 full length spike glycoprotein (S), which is the target of virus neutralizing antibodies. In the late-stage trial, the companies will study a 30µg dose level in a 2-dose-regimen among up to 30,000 participants aged 18 – 85 years. It is expected to include approximately 120 sites globally including in regions with significant expected SARS-CoV-2 transmission.

Assuming clinical success, Pfizer and BioNTech are on track to seek regulatory review for BNT162b2 as early as October 2020 and, if regulatory authorization or approval is obtained, plan to supply up to 100 million doses worldwide by the end of 2020 and approximately 1.3 billion doses by the end of 2021.

In addition to engagements with governments, Pfizer and BioNTech have provided an expression of interest for possible supply to the COVAX Facility, a mechanism established by Gavi, the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations (CEPI) and World Health Organization (WHO) that aims to provide governments, including those in the emerging markets, with early access to a large portfolio of COVID-19 candidate vaccines using a range of technology platforms, produced by multiple manufacturers across the world.

About Pfizer: 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. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at <u>@Pfizer</u> and <u>@Pfizer News</u>, <u>LinkedIn</u>, <u>YouTube</u> and like us on Facebook at <u>Facebook.com/Pfizer</u>.

Pfizer Disclosure Notice

The information contained in this release is as of July 31, 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, the collaboration between BioNTech and Pfizer to develop a potential COVID-19 vaccine, an agreement with the government of Japan to supply BNT162 and other potential agreements, the BNT162 mRNA vaccine program, and modRNA candidates BNT162b2 and BNT162b1 (including qualitative assessments of available data, potential benefits, expectations for clinical trials and timing of regulatory submissions, anticipated manufacturing, supply and distribution), 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 risks associated with preliminary data, including the possibility of unfavorable new preclinical or clinical trial data and further analyses of existing preclinical or clinical trial data that may be inconsistent with the data used for selection of the BNT162b2 vaccine candidate and dose level for the Phase 2/3 study; the risk that clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; whether and when data from the BNT162 mRNA vaccine program will be published in scientific journal publications and, if so, when and with what modifications; whether regulatory authorities will be satisfied with the design of and results from these and future preclinical and clinical studies; whether and when any biologics license and/or emergency use authorization applications may be filed in any jurisdictions for BNT162b2 or any other potential vaccine candidates; 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 vaccine candidate's benefits outweigh its known risks and determination of the vaccine candidate's efficacy and, if approved, whether it 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 a vaccine, including development of products or therapies by other companies; manufacturing capabilities or capacity, including whether the estimated numbers of doses can be manufactured within the projected time periods indicated; whether and when additional supply agreements will be reached; uncertainties regarding the ability to obtain recommendations from vaccine technical committees and other public health authorities 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 <u>www.sec.gov</u> and <u>www.pfizer.com</u>.

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, Genevant, Fosun Pharma, and Pfizer.

For more information, please visit <u>www.BioNTech.de</u>

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 timing to initiate clinical trials of BNT162 and anticipated publication of data from these clinical trials; the timing for any potential emergency use authorizations or approvals; the potential to enter into additional supply agreements with other jurisdictions or the COVAX Facility; the potential safety and efficacy of BNT162; the collaboration between BioNTech and Pfizer to develop a potential COVID-19 vaccine; and the ability of BioNTech to supply the quantities of BNT162 to support clinical development and, if approved, market demand, including our production estimates for 2020 and 2021. 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; the ability to produce comparable clinical results in larger and more diverse clinical trials; the ability to effectively scale our productions capabilities; and other 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 is available on the SEC's website at <u>www.sec.gov</u>. 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.

Pfizer Contacts:

Media Relations

Amy Rose +1 (212) 733-7410 Amy.Rose@pfizer.com

Investor Relations

Chuck Triano +1 (212) 733-3901 Charles.E.Triano@Pfizer.com

BioNTech Contacts:

Media Relations

Jasmina Alatovic +49 (0)6131 9084 1513 or +49 (0)151 1978 1385 Media@biontech.de

Investor Relations Sylke Maas, Ph.D.

+49 (0)6131 9084 1074 Investors@biontech.de