# EXHIBIT 6

# Q2 2020 Earnings Call

## Company Participants

- Ozlem Tureci, Chief Medical Officer
- Ryan Richardson, Chief Strategy Officer, Managing Director & Member of Management Board
- Sean Marett, Chief Business Officer, Chief Commercial Officer & Member of Management Board
- Sierk Poetting, Chief Financial Officer, Chief Operating Officer & Member of Management Board
- Sylke Maas, Vice President, Investor Relations and Business Strategy
- Ugur Sahin, Co-Founder, Chief Executive Officer & Member of Management Board

## Other Participants

- Analyst
- Arlinda Lee
- Daina Graybosch
- Matthew Holt
- Navin Jacob
- Olga Smolentseva
- Suzanne van Voorthuizen
- Zhiqiang Shu

## Presentation

### Operator

Thank you for standing by and welcome to the BioNTech Second Quarter 2020 Operational Progress and Financial Results Call. At this time, all participants are in a listen-only mode. There will a presentation followed by a question-and-answer session. I must advise you this call is being recorded today, Tuesday, the 11th of August 2020. And I would now like to hand the call over to the Vice President, Investor Relations and Business Strategy, Sylke Maas. Please go ahead.

### Sylke Maas {BIO 20912536 <GO>}

Thank you for joining us today for BioNTech's Second Quarter 2020 Update Call. Before we start, we encourage you to view the slides for this webcast as well as operational and financial results press release issued this morning, both of which are accessible on our website, in the Investors section.

As shown on slide two, during today's presentation, we will be making several forward-looking statements. These forward-looking statements include but are not limited to the timing of enrollment, initiation, completion and reporting of data from our clinical trials, the potential registrational nature of certain clinical trials, the impacts of the COVID pandemic on our business and financial outlook. The timing for any potential emergency use authorizations or approvals for BNT162; the potential safety and efficacy of BNT162, 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.

Actual results could differ from those we currently anticipate. You are, therefore, cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this conference call and webcast. Speaking and available for questions today will be Ugur Sahin, Chief Executive Officer; Ozlem Tureci, Chief Medical Officer; and Sean Marett, Chief Business and Commercial Officer; Sierk Poetting, Chief Financial and Operating Officer; and Ryan Richardson, Chief Strategy Officer.

I now hand the call over to Ugur Sahin, BioNTech's CEO.

## **Ugur Sahin** {BIO 18869003 <GO>}

Thank you, Sylke. It's a pleasure to welcome you to our second quarter 2020 conference call. The last few months have been a game-changing time for BioNTech. The groundbreaking potential of our technologies, as well as our ability to quickly respond to new challenges and execute fast has been on full display. One key highlight is the initiation of the pivotal Phase 2b/3 trial of our lead BNT162 COVID-19 vaccine candidate within six months of starting the Lightspeed vaccine discovery preclinical and clinical research program.

In parallel to the COVID-19 program, we have continued to advance our oncology pipeline and broadened our base of strategic collaborations. I'm happy about the accomplishments we have made in the second quarter, and would like to thank our entire team and also our partners for their tireless efforts and outstanding commitment.

Slide five summarizes some of our key highlights since our last quarterly update. We reached a number of important milestones over the past few months. We continue to advance our clinical-stage pipeline. We now have 12 immunotherapies in clinical testing across three drug classes that includes eight messenger RNA therapeutic programs, three antibody programs and one small molecule immunomodulatory program.

In July, we and Pfizer selected BNT162b2 as our lead COVID-19 vaccine candidate and initiated a pivotal stage 2b/3 trial. We have made progress in granting up our manufacturing capacities to support global supply. We have signed commercial supply agreement with multiple countries around the world for more than 250 million doses in 2020 and 2021. This also includes an option to purchase up to 500 million additional doses; all this is subject to regulatory approval.

In parallel to our effort to bring COVID-19 vaccine to the market as quickly as possible, we also continued to advance our oncology pipeline. Ozlem will provide the key updates made on the call, including for our iNeST program, BNT122 or our BNT111 FixVac melanoma program. Here we announced a new cooperation with Regeneron to combine BNT111 with Libtayo an anti-PD-1 in a randomized Phase 2 trial, which we believe could have a registrational potential.

Moreover, we significantly strengthened our balance sheet, bringing in commitments of approximately $1.1 billion in gross proceeds from non-dilutive upfront cash payments and equity and debt financing commitments. These accomplishments have strengthened our ability to advance our pipeline on multiple fronts and deliver on our longer-term vision to bring novel immunotherapies to patients across a range of diseases.

Moving to slide six; I would like to touch on the importance of our strategic collaboration. This is important because these collaborations continue to play a crucial role in how we are building our business. Our partnership extend our execution capabilities and global reach, and in some cases, provide us the access to external technologies such as Genmab's DuoBody technology, which are highly complementary to our own.

The first half of 2020, we expanded our existing partnerships with Pfizer to jointly develop our COVID-19 vaccine program. In addition, we have established a new collaboration with Regeneron in the oncology field. The important aspect here is that we have retained significant economics on our programs through these collaborations. Sean will provide some further details on the Pfizer collaboration later in our prepared remarks. In the case of Regeneron deal, it is important to note that each party keeps 100% of the rights to its own product. That means that BioNTech has kept full product commercialization rights for BNT111 melanoma FixVac.

On slide seven, you'll see an updated version of our multi-platform, immuno-oncology strategy. The cornerstone of this strategy is to leverage our immunotherapy expertise with new therapeutic approaches to target cancer, and modulate immune responsive simultaneously. We believe, the approach can produce multiple blockbuster product opportunities, but also will enable the development of powerful combination treatment approaches, which combine complementary mechanisms of actions.

Despite the challenges associated with the COVID-19 pandemic, we have continued to execute our immuno-oncology strategy on multiple fronts. We are on track to initiate multiple late-stage trials for FixVac and iNeST product candidates. We are anticipating the first data update for our next generation checkpoint immunomodulator BNT311, a bi-specific antibody targeting anti-PD-L1/anti-4-1BB late this year.

Furthermore, since our last earnings call, we have initiated a Phase 1/2 trial for our TLR7 agonist small molecule immunomodulatory program and expect to initiate first-in-human trials for two novel cell therapy approaches in the coming months, including BNT211, an first CAR-T cell therapy and for BNT221, our neoantigen T cell therapy. As we have done in the past, we will continue to be data driven in how we assess each product opportunity we take into clinical testing.

I will now turn it over to Ozlem to provide an update on our programs.

## Ozlem Tureci {BIO 20629996 <GO>}

Thank you, Ugur. In the interest of time, I'm going to focus my remarks to the four programs highlighted on slide nine. These include BNT111, our FixVac melanoma; BNT122, our iNeST program; BNT311, our anti-PD-L1/anti-4-1BB antibody; and BNT411, our TLR7 agonist. For further details on the status of other programs, please refer to our full quarterly update, which will be released -- which was released this morning.

So let's start on slide 10 with BNT111, our melanoma FixVac program. As a reminder, BNT111 is composed of four non-mutated melanoma antigens. NY-ESO-1; MAGE-A3; tyrosinase and a novel antigen from our own libraries TPTE. In July, we published interim Phase 1 data in Nature from our ongoing Lipo-MERIT trial. The Lipo-MERIT trial is a multi-center, open label dose escalation study to evaluate safety and tolerability of vaccinated patients with Stage IIIbc and Stage IV melanoma.

Efficacy was evaluated in a subset of 42 checkpoint-inhibitor experienced patients with a data cutoff in July 2019. As I reported earlier, at the data extraction date, three patients out of 25 in the FixVac monotherapy group experienced a partial response. Seven patients showed stable disease and one patient showed a complete metabolic remission of metastatic lesions. Of the 17 patients treated with the combination of FixVac of BNT111 and an anti-PD-1, six patients showed a partial response.

Of note, at our target dose for the Phase 2 trial of 100 micrograms, we observed that five of 10 patients had a partial response to FixVac in combination with anti-PD-1 therapy. The publication in nature summarized on slide 11 highlighted extensive biomarker and immunological data. These support the mechanism of action and the observed clinical activity of FixVac alone and in combination with anti-PD-1.

Importantly, treatment with BNT111 resulted in the expansion and activation of circulating tumor antigen specific T-cells with memory function that exhibited strong cytotoxic activity against tumor cells. These vaccine-induced T-cells displayed a Th1 phenotype. In 20 patients tested by post IVS interferon-gamma ELISpot, all showed immune response against at least one of the used tumor-associated antigens. Most patients demonstrated CD4 or concurrent CD4 and CD8 T-cell responses.

In 50 patients tested by ex vivo interferon-gamma ELISpot, which only captures high magnitude responses, more than 75% of patients showed immune responses against at least one tumor-associated antigen, most of which were high magnitude CD8 positive T cells. T-cells ramped up within four to eight weeks to single digit or low-double digit percentages of total circulating CD8 positive T-cells. Under monthly maintenance treatment, the levels of T-cells continued to slowly increase or remain stable up to over one year.

Safety was assessed in 89 patients. Overall, FixVac treatment was well tolerated with no dose-limiting toxicity observed. Most common adverse events were mild-to-moderate,

transient flu-like symptoms, such as pyrexia and chills. As Ugur mentioned earlier, we recently announced a strategic collaboration with Regeneron and plan to pursue an accelerated development program for the combination of FixVac and Regeneron anti-PD-1 agent Libtayo in the second line treatment setting for advanced melanoma patients that have progressed after prior PD-1 blockade.

Under the terms of agreement, we and Regeneron have agreed to share development costs equally. If approved, each party will retain full commercial rights for their respective product and would record revenues related to its own product. We plan to initiate a randomized Phase 2 trial in the fourth quarter of 2020 and expect to provide more details on the study in the third quarter 2020.

Now moving to slide 12 to BNT122, our individualized neoantigen specific immunotherapy or iNeST platform program, which is partnered with Roche Genentech. The data updates for the Phase 1a monotherapy and 1b combination with Tecentriq basket trials in multiple solid tumors was reported in June as part of AACR virtual annual meeting, too. This is the first time that we have shown safety and immunogenicity data across different tumor types outside of melanoma.

The patient populations in these cohorts were heavily pretreated many with refractory and recurrent disease with a high proportion of low PD-L1 expresser. Treatment with BNT122 alone and in combination with Tecentriq was well tolerated with the majority of adverse events being Grade 1 or Grade 2 and there were no dose limiting toxicities. In the majority of patients treated with BNT122 alone and in combination with Tecentriq, ex-vivo T-cell responses against multiple neoantigens were detected. We also detected BNT122-induced T-cells in infiltrates of patient tumors.

In the Phase 1a immunotherapy portion of the trial, 26 patients underwent at least one tumor assessment, one patient (inaudible) with gastric cancer and metastatic liver lesions had a durable complete response and remains on study after 1.5 years and the rest patients had stable disease. In the Phase 1b combination portion of the trial, in 108 patients that underwent at least one tumor assessment, one patient had a complete response, eight patients had partial responses, and 53 patients had stable disease.

We continue to believe that iNeST is well suited to earlier lines of therapy across a range of solid tumors. We have depicted our ongoing Phase 2 trial in first line melanoma and our planned adjuvant [ph] clinical trial for iNeST. On slide 13, we expect to provide an enrollment update from the randomized Phase 2 trial of BNT122 plus pembrolizumab in first line melanoma in the second half of 2020 and an interim data update is anticipated in the second half of 2021.

We are going to start two Phase 2 studies in the adjuvant setting. One is in an IO sensitive cancer type, namely evaluating the efficacy and safety of iNeST plus Tecentriq compared with Tecentriq alone in patients with early and adjuvant stage non-small-cell lung cancer. The second study is in an IO insensitive cancer type namely a multisite open-label Phase 2 randomized trial to compare the efficacy of iNeST versus watchful waiting in patients with circulating tumor DNA positive Stage 2 high-risk and Stage 3 colon cancer.

Now moving to slide 14 to the two DuoBody programs, we have partnered with Genmab. On slide 15, you'll see one of them, BNT311, the anti-PD-L1-anti-4-1BB bi-specific antibody that combine constitutive TPI blockade and conditional costimulatory activity. A mechanism of action which led to enhanced proliferation of antigen-specific activated T-cells in the presence of PD-L1 positive cells in preclinical studies.

Based on the preclinical data we have generated, we believe, this molecule could represent a powerful new checkpoint immune modulator with seropositive potential across a range of solid tumors. We expect to provide the first human data in the second half of 2020. This update will include dose escalations data from the Phase 1/2 trial in multiple target tumors. We believe it has broad potential in a range of solid tumors, including those where checkpoint therapy is currently established, but also in more difficult tumors where first generation checkpoint inhibitors have not been as successful.

Finally now turning to slide 16; we recently initiated clinical testing for BNT411 from our toll-like receptor binding program. This molecule is engineered for high potency and has high selectivity for the TLR7 receptor at the therapeutically active dose range. We expect this molecule to activate both the adaptive and innate immune system, in particular, in combination with cytotoxic therapies and checkpoint inhibitors.

Preclinical studies suggest a Type 1 interferon-dominated release of cytokines and chemokines and potent stimulation of antigen-specific CD8 T-cells, but also B cells details, and innate immune cells such as NK cells and macrophages. In early July 2020, the first patient was dosed in the Phase 1/2a first-in-human open-label dose escalation trial with expansion cohorts to evaluate the safety, pharmacokinetics, pharmacodynamics, and preliminary efficacy.

BNT411 will be posted as the monotherapy in patients with solid tumors and in combination with Tecentriq, carboplatin and etoposide in patients with chemotherapy-naive extensive-stage small cell lung cancer. Now these were the highlights from our oncology programs. I now provide an update on our COVID-19 vaccine program.

Now moving to slide 18, which recaps how far we have come in the race to develop a COVID-19 vaccine. We began work on multiple vaccine candidates in late January following use of the coronavirus outbreak in China. Approximately six months later, we initiated a pivotal Phase 2b/3 trial aimed at supporting an approval of our vaccine in the U.S. Our goal with Pfizer is to be in a position to file for approval or emergency authorization from the FDA as early as the fourth quarter of 2020, if the trial hits our enrollment targets and is deemed to be successful. I will come back to the Phase 2b/3 trial design in a few minutes.

On slide 19 you see the four vaccine variance we have taken into clinical testing. These variants vary based on the type of mRNA construct used and the antigen target, two of variance target for RBD domain and the other two the full-length spike protein. Both our b1 and b2 candidates have received FDA fast-track status. In late July, we along with Pfizer selected BNT162b2 to as our lead candidate for Phase 2b/3 trail.

BNT162b2 encodes for a modified version of a full-spike protein and utilizes our nucleosidemodified RNA construct. The decision to advance the BNT162b2 was made after an extensive review of a preclinical and available clinical data and in consultation with the FDA. For the Phase 2b/3 trial, the 30 microgram dose level in a two-dose regimen was chosen.

Now moving to slide 20; BNT162b2 vaccinated participants displayed a favorable breadth of epitopes recognized in T-cell responses specific to the SARS-CoV-2 antigen. The candidate also demonstrated concurrent induction of both high-magnitude CD4 and CD8 T-cell responses. These T-cell responses were observed against both the RBD and the remainder of the spike glycoprotein. We believe that immune recognition of more spike T-cell epitopes may have the potential to generate more consistent responses across diverse populations and in older adults.

Preliminary data for BNT162b2 suggested a favorable reactogenicity profile. Systemic events were generally mild to moderate and transient, lasting one to two days. Events included fever, fatigue, and chills. There has not been any serious adverse events observed in our BNT162 program. Data collection from the Phase 1/2 trial for all four vaccine candidates is continuing. We plan to submit data on BNT162b2 for peer review and potential publication in the next few weeks. We also intend to also post the manuscripts on the preprint server at that time.

Moving to slide 21; I'd like to spend a few minutes to outline the design of our ongoing Phase 2b/3 trials. The study is expected to enroll up to 30,000 participants age 18 to 85 years, starting in the U.S., and expanding to include approximately 120 sites globally. The trial regions will include areas with significant anticipated SARS-CoV-2 transmission. The Phase 2b/3 trial is a one-to-one vaccine candidate to placebo randomized observer blinded study to obtain the safety, immune response and efficacy data needed for regulatory review.

The primary endpoint is prevention of COVID-19 in participants without evidence of SARS-CoV-2 infection before vaccination, as well as prevention of COVID-19 in participants regardless of SARS-CoV-2 infection before vaccination. The primary efficacy analysis will be an event-driven analysis based on the number of participants with symptomatic COVID-19 disease. We reduced polymerase chain reaction to confirm infection of SARS-CoV-2 since antibody tests to confirm previous exposure. One of the secondary endpoints includes prevention of severe COVID-19 disease. The trial design allows for interim analysis and un-blinded reviews by an independent external data monitoring committee. Assuming clinical success, we along with Pfizer may potentially seek regulatory review in Q4, as early as October 2020.

With that, I will now hand over to Sean to provide an overview on our commercial updates.

**Sean Marett** {BIO 5299154 <GO>}

Thank you, Ozlem. I will start by recapping our commercial arrangements for BNT162 with Pfizer and Fosun. Depicted on slide 22, our collaboration with Pfizer involves co-development of a portfolio of COVID-19 vaccine candidates on a worldwide basis, excluding China. Upon approval, we would jointly commercialize the vaccine with Pfizer.

As part of our preparation for commercialization, BioNTech is taking steps to establish a limited commercial infrastructure in a selected set of countries, while leveraging Pfizer's commercial infrastructure and capabilities in the rest of the world, excluding China, as I just noted. In terms of financials, our collaboration with Pfizer is based on a 50-50 partnership. Both companies share development expenses and gross profits worldwide on a 50-50 basis, regardless of which company distributes the vaccine in a given country.

Furthermore, capital expenditures are funded by each party independently. In addition to the combined upfront payment and equity investment of $185 million, which BioNTech received in April, BioNTech is eligible to receive further development in sales milestones of up to $563 million. If reached, these milestones will come in addition to BioNTech's 50% share of gross profits generated. Our Fosun collaboration in China is also a co-development agreement.

However, Fosun funds the majority of development expenses incurred in China and would take on commercialization responsibilities if the vaccine is approved. In addition to the combined upfront payment and the equity investment totaling $51 million, which was received in April, BioNTech is eligible to receive further development and sales milestones up to $84 million. BioNTech would also share gross profits on the sale of the vaccine in China.

I will now turn to slide 23 to provide an overview of our recently-announced commercial supply agreements. From the beginning, we have been very clear about our intention to make our vaccines available for global supply to address the pandemic. And we are investing at risk to scale up our manufacturing to enable us to do so. BioNTech and Pfizer have a target to manufacture up to 100 million doses by the end of 2020, and approximately 1.3 billion doses by the end of 2021.

This estimate presumes a continued ramp-up in production at our Idar-Oberstein and Mainz facilities in Germany, which are currently producing vaccines for clinical supply. We're also working with Pfizer to activate and ramp-up vaccine production at several Pfizer sites in the United States and one in Europe. While it is still early, we have announced commercial supply agreements with the governments of multiple countries for more than 250 million doses with an option for an additional 500 million doses.

Furthermore, we are currently in a number of discussions with governments around the world in relation to further commercial supply. All agreements are subject to clinical success and regulatory approval of the vaccine.

I will now hand over to Sierk it to provide an update on our financials.

**Sierk Poetting** {BIO 21288849 <GO>}

Thank you, Sean. Now, I would like to summarize our financial results for the quarter that are shown on slide 25. Our total revenue, which primarily consists of revenue from our collaboration agreements, was EUR41.8 million for the second quarter 2020 compared to EUR25.8 million for the second quarter 2019. For the period of six months ended June 30, 2020, our total revenue was EUR69.4 million compared to EUR51.9 million for the comparative prior-year period.

The revenue from collaboration agreements overall increased due to the recognition of revenue from our new collaboration agreement signed with Pfizer and Fosun Pharma as part of our BNT162 vaccine program against COVID-19. The revenues from other sales transactions increased due to increased orders and include sales of diagnostic products, peptides, retroviral vectors for clinical supply and development and manufacturing services sold to third-party customers.

Research and development expenses were EUR95.2 million for the second quarter 2020 compared to EUR53.4 million for the second quarter 2019. For the six month ended June 30, 2020, total research and development expenses were EUR160.3 million compared to EUR110.6 million for the comparative prior-year period. The increase was mainly due to an increase in headcount leading to higher wages, benefits and social security expenses, as well as an increase in expenses for purchased research and development services, especially with respect to our BNT162 program.

In addition, from the date of acquisition, our new U.S.-based subsidiary BioNTech US Inc, contributed EUR5.3 million to our research and development expenses. General and administrative expenses were EUR18.8 million for the second quarter 2020 compared to EUR14.6 million for the second quarter 2019. For the six month ended June 30, 2020, total, general and administrative expenses were EUR34.6 million compared to EUR23.9 million for the comparative prior-year period. This increase was mainly influenced by higher expenses for purchase management consulting and legal services, as well as an increase in headcount leading to higher wages, benefits and total security expenses.

In addition, from the date of acquisition, our new U.S. based subsidiary BioNTech US Inc, contributed EUR1.6 million to our general and administrative expenses. Net loss was EUR88.3 million for the second quarter 2020 compared to EUR50.1 million for the second quarter 2019. For the six month ended June 30, 2020, total net loss was EUR141.7 million compared to EUR90.8 million for the comparative prior-year period.

Turning to the balance sheet on slide 26, BioNTech ended the second quarter 2020 with cash and cash equivalents of EUR573 million, or $641.6 million. Additionally, we raised EUR680.7 million or $762.2 million in gross proceeds from a private equity placement and our follow-on underwritten offering after the end of the second quarter. Considering these gross proceeds, the expected pro-forma cash and cash equivalents balance at June 30, 2020 amounts to EUR1.25 billion or $1.4 billion.

Further, we announced a debt financing of up to EUR100 million or $112 million from the European Investment Bank in June 2020. All financing transactions are subject to closing conditions that were not fulfilled before June 30, 2020 and did not have an accounting impact within the second quarter 2020. As a result of increased spending related to BNT162, we now expect net cash used in operating activities and for purchases of property and equipment to be between EUR450 million and EUR600 million for the full-year 2020.

We anticipate that existing cash and cash equivalents, the net proceeds from the recent underwritten offering and the expected net proceeds from the private investment announced in June 2020 will enable us to fund our operating expenses and capital requirements through at least the next 24 months. With that, I will return the call back to Ryan for concluding remarks.

## **Ryan Richardson** {BIO 20337628 <GO>}

Thank you, Sierk. Slide 27 outlines the key milestones were focused on delivering as we look to the remainder of 2020. The first relates to our COVID-19 vaccine program, where the next major milestone is the Phase 2b/3 trial we are conducting with Pfizer. As Ozlem mentioned, we expect to be in a position to seek regulatory review as early as October 2020.

In the meantime, we expect to publish Phase 1 safety and immunogenicity data for BNT162b2 in the next few weeks. We also intend to publish preclinical data over the same time period. In addition, we anticipate three first-in-human data updates for our oncology programs over the course of the year, including for BNT114, BNT131 and our DuoBody program BNT311. Data from our BNT114 FixVac Phase 1 study in triple negative breast cancer has been accepted for an oral presentation at ESMO in mid-September.

The Phase 1 study is a three-arm trial as a monotherapy and in combination with iNeST evaluating safety and immunogenicity. The data to be presented will include a preliminary analysis of immune responses in TNBC patients treated with iNeST. For BNT131, our mRNA intratumoral immunotherapy program, partnered with Sanofi, we expect the data update for our Phase 1/2 trial in solid tumors in the second half of 2020. The study is a first-in-human, multicenter, open-label Phase 1 dose escalation and expansion trial to evaluate safety, pharmacokinetics, pharmacodynamics and antitumor activity of BNT131, both as a monotherapy and in combination with cemiplimab in patients with certain advanced solid tumors.

The data to be presented will include safety, tolerability and pharmacodynamic biomarker data. While updates for these programs will focus on safety and immunogenicity, we expect that our preliminary update for BNT311 our bi-specific antibody will also include top-line response data from our ongoing Phase 1/2 trial. And finally, we plan to initiate up to six additional studies from oncology pipeline over the remainder of 2020.

These include randomized Phase 2 trials for FixVac in melanoma and HPV16+ head and neck cancers, and for iNeST in adjuvant NSCLC and adjuvant CRC cancers. We also

anticipate initiating first-in-human trials for our cell therapy programs starting with our Claudin 6 CAR-T cell therapy, the first program to incorporate our CAR-T amplifying mRNA vaccine or CARVac approach.

And with that, I'll hand it back over to Ugur for concluding remarks.

### Ugur Sahin {BIO 18869003 <GO>}

Thank you, Ryan. I'm proud of what we have accomplished over the first half of 2020 and believe a tremendous opportunity lies before us. We thank our shareholders and partners for their trust and support. Let us open up the call for questions now.

## Questions And Answers

### Operator

(Question And Answer)

Thank you. Ladies and gentlemen, we will now begin the question-and-answer session. (Operator Instructions). Your first question comes from the line of Tazeen Ahmad from Bank of America. Please ask your question.

### Q - Analyst

Hi, good morning. This is Bill Maughan on for Tazeen. So two from me. First of all, how do you think about distributing the initial doses that are going to be manufactured later this year of the vaccine -- of the potential COVID vaccine assuming approval? So the initial doses manufactured later this year and early next year given that the first manufacturing batches won't immediately cover all supply agreements.

And then secondly when you have to repay the Pfizer upfront investment out of profit sharing, can you help quantify what Pfizer has already put up in terms of operating investment and what the pace of paying that back would be out of profit share and milestones? Thank you.

### A - Ryan Richardson {BIO 20337628 <GO>}

Yes, I'll start with the first question. This is Ryan on the distribution side and then turn it over to Sierk to comment on the second. So, I think we're in the fortunate position to have considerable demand or interest in the vaccine as you can see from the supply deals that we've announced so far. Some of those deals do call for doses to be supplied in 2020, others in 2021. We've indicated that by '20 -- end of 2020 we'd expect to have up to 100 million doses and then expect to be able to increase our capacity pretty significantly as we head into 2021.

So I think we can't get into specifics at this point, but I think it's safe to say that we will -- already with the distribution agreements that we've announced, we feel confident that the

doses that we can produce, we'll be able to distribute across the countries that are included in those agreements.

I don't know, Sierk, do you want to comment on the second question?

## A - Sierk Poetting {BIO 21288849 <GO>}

Yes, happy to. Actually so in Q2, this was the first reconciliation that we did with Pfizer and this quarter we reconciled $20 million as the total net cost on the BioNTech side, actually this was the 50% of cost-share for BioNTech in this quarter. So compared with the total program, still a small amount because it was ramping up in April and May and June so far. So, $20 million was recognized as cost so far as our share.

## Q - Analyst

Okay. And I guess, how do you get to that $20 million given the large numbers that Pfizer has kind of put out in terms of what they are investing in their manufacturing?

## A - Sierk Poetting {BIO 21288849 <GO>}

Yes. So, there's only a certain type of cost there. So, not everything is shared 50, 50, so investments are -- investments into capacity is everybody's own cost and what shared is basically the development cost and scale up. So this is shared, and this is -- the $20 million is our part of the share. And so far it's covered from our upfront that we'd received when signing the contract.

## Q - Analyst

Okay. Thank you.

## A - Sierk Poetting {BIO 21288849 <GO>}

Sure.

## Operator

And your next question comes from the line of Cory Kasimov from JPMorgan. Please ask your question.

## Q - Matthew Holt {BIO 18274461 <GO>}

Hey, guys. Thanks for taking my question. This is Matthew on for Cory. So I guess just wondering for BNT162 if you can talk a little bit about how you maintain the integrity of a Phase 3 blinded trial when a large proportion of the BNT162 patients are expected to get fevers and other systemic AEs and what your view is on whether this could impact the ultimate outcome of the trial?

## A - Ugur Sahin {BIO 18869003 <GO>}

Yes. So thanks for the question. First of all, as we indicated in the press release when we announced the selection of BNT162b2, we indicated that b2 is significantly better tolerated than the b1. So actually only a little fraction of vaccinated individuals have fever and with regard to the other symptoms, you might have seen that even placebo vaccinated subjects have a number of background symptoms. So, we believe that we have a very good overall situation to avoid any type of bias negated by the understanding of the participant that he might or she might get the vaccine and not the placebo.



## Q - Matthew Holt {BIO 18274461 <GO>}

Okay, great. And then just wondering if you can walk us through your assumptions or essentially what needs to happen for the Phase 3 program to get data and a potential regulatory filing in October. And just I guess maybe if you can help quantify how dependent this is on either enrollment or infection rates or what might be the key factor in the time line?

## A - Ugur Sahin {BIO 18869003 <GO>}

Yes. So this is efficacy trial, that means at the end of the day, we are comparing the number of infected -- infections in the placebo whereas in the treatment group. We are online evaluating the blinded session, the safety data. The trial is proceeding very well. It's even recruiting faster than anticipated. And the overall concept is to wait until we have a given predefined number of events -- of infections event and then do a first evaluation, if there is significant difference between vaccine and placebo group.

The number -- the event number, so we will have several options, yes, to evaluate different event numbers and based on that -- based on the lower event numbers, you might be able to file already in October. If the lower event numbers do not support filing, we will have the opportunity to file four or six weeks later based, of course, on the assumption that the trial is positive.



## Q - Matthew Holt {BIO 18274461 <GO>}

Great. Thanks for taking my questions.

## A - Ugur Sahin {BIO 18869003 <GO>}

Yes, you're welcome.

## Operator

Your next question comes from the line of Arlinda Lee from Canaccord. Please ask your question.

## Q - Arlinda Lee {BIO 16422938 <GO>}

Thanks. Congrats on all the progress. I had a couple of questions on 162. One, can you provide an update on the enrollment of the pivotal trial? And two, I heard that some of the net costs for the trials have already -- you guided that, that was earlier in the development front. I'm wondering what you think that cost might be for the remainder of the year.

And then also on your oncology pipeline, I mean just more broadly, I guess, the rapidity and efficiency with which you guys have taken 162 into the clinic, I think highlights you guys' platform and I'm wondering what your appetite might be for additional collaborations, and if you've been getting inbound interest. Thank you.

### A - Ugur Sahin {BIO 18869003 <GO>}

So maybe we start with the first question. I had difficulties to acoustically understand the second and the third question. So the recruitment, sort of my understanding is that, the first question was related how fast the recruitment happens for the pivotal trial. So we anticipate to recruit up to 30,000 subjects until mid of October and we are at the moment -- I can't tell you exact numbers. But trial is recruiting better than what was modeled. Yes. So we are on track and even ahead.

The second question, can you repeat the second question a little bit louder?

### Q - Arlinda Lee {BIO 16422938 <GO>}

Yes. I'm just trying to, I guess, figure out on the cost sharing, how much you might accrue by year end.

### A - Ugur Sahin {BIO 18869003 <GO>}

This is the question for Sierk.

### A - Sierk Poetting {BIO 21288849 <GO>}

Yes, I can take this one. Yes so, as I mentioned before, so the net cost -- the net share in this quarter for BioNTech was $20 million and this was majorly driven by clinical costs, but also some preclinical research that was shared. So let's call it about a half or something was clinical cost, but remember May and June was only the Phase 1 trial, so basically patients were probably more expensive -- or sorry, subjects were more expensive, but also not as many. So I think, you can do the math and upgrade it to like it would be a lot more expensive in Q3 and with the Q3 numbers, we will also host like a better update, but it will be, yes, triple-digit million dollar amounts, I think.

### A - Ryan Richardson {BIO 20337628 <GO>}

I mean, maybe just to add to that one point which is, we had previously guided, Arlinda, to EUR300 million of spend for the year and I think it's safe to say that we were tracking on that ex the Neon acquisition and the impact of COVID. So we've guided to EUR450 million to EUR600 million of net cash spend by the end of this year. So that delta there also gives you a sense for what the incremental amount could be.

### Q - Arlinda Lee {BIO 16422938 <GO>}

Great. Thank you. And then I guess, the third question was, basically given you guys one or two kind of the platform, I'm kind of curious about whether you've gotten inbound interest and what your appetite might be for additional strategic collaborations.

**A - Ugur Sahin** {BIO 18869003 <GO>}

Maybe I can take the question. Yes, of course, this project of course validates our ability to respond quickly to challenges and opportunities. It validates our technology. It validates the safety of our approach and of course, it creates a lot of interest in future projects and we are in discussion with our partners for additional opportunities coming up in 2021.

**Q - Arlinda Lee** {BIO 16422938 <GO>}

Thank you.

**Operator**

Your next question comes from the line of Zhiqiang Shu from Berenberg. Please ask your question.

**Q - Zhiqiang Shu** {BIO 21945096 <GO>}

Hi, thank you. Good morning, everyone. Congrats on the progress. So, a few questions here on 162. I'd like to understand a little bit more on the old adults, the signals that you've seen in Phase 1 and 2. And maybe can you can qualitatively describe whether that's consistent with what people think the immune response there in this population is a lot lower than younger adults. And then whether the results from b2 would be -- b2 of again old adults would be included in the manuscript that you alluded in the few -- that will be available in a few weeks?



**A - Ugur Sahin** {BIO 18869003 <GO>}

Yes, so the first part of the question is older adults vaccine responses. So the size, I know, there are no publications yet on any group about vaccine responses in elderly adults, but as you, as everyone can guess and immune response in elderly adults is weaker, yes. And was likely for any vaccine platform, weaker. The reasons -- the reasons for that are twofold, it is the weaker innate immune response in elderly people and the second is the reduced number of naive T-cells and naive B-cells in elderly's. What we have observed is that, that a dose which is fully effective to induce a strong antibody and T-cell response in younger population is too low. In the elderly population, that's the reason why we increased the dose for our candidate b2 and with the increase of the dose, we are well in the range of a fully expective immune response or what is expected to be a fully effective immune response. And of course, yes, the data will be published with the next upcoming manuscript.

**Q - Zhiqiang Shu** {BIO 21945096 <GO>}

Okay. And then do you have a plan to publish any results from other variants on C2?

**A - Ugur Sahin** {BIO 18869003 <GO>}

From other candidates?

**Q - Zhiqiang Shu** {BIO 21945096 <GO>}

Yes. From other variants that were on Phase 1 and 2 study?

### A - Ugur Sahin {BIO 18869003 <GO>}

Yes. We -- the other variants are in continued clinical evaluation with a somehow lower priorities. We expect to have a first publication related to another variant in October, and we will continue to share insights from this development program, which was not only just about selecting the first candidate but selecting the best candidate and also generating insights into the future generation of vaccines, which may come with lower doses, so where lower doses might result in the same type of immune response.

### Q - Zhiqiang Shu {BIO 21945096 <GO>}

Great. That's helpful. And then finally just quickly touching on the oncology program BNT111. I remember there is an adjuvant cohort in the Phase 1 study. The results haven't been communicated. Is there anything that you have seen in that adjuvant melanoma cohort?

### A - Ozlem Tureci {BIO 20629996 <GO>}

Thank you for that question. We are evaluating the adjuvant cohort as well and later this year, we will be able to report on that cohort as well.

### Q - Zhiqiang Shu {BIO 21945096 <GO>}

Okay. Great. Thank you very much and congrats on the progress.

### A - Ozlem Tureci {BIO 20629996 <GO>}

Thank you.

### A - Ugur Sahin {BIO 18869003 <GO>}

Thank you.

### Operator

Your next question comes from the line of Daina Graybosch from SVB. Please ask your question.

### Q - Daina Graybosch {BIO 20659414 <GO>}

Thank you very much. Maybe I'll start with two on BNT162 and then after that come back for one on iNeST. So, on BNT162 two questions, one, there's been a lot made over differences in CD8 immunogenicity response between different companies and vaccines. And I wonder if you could comment on, if there's anything in the BNT162 mRNA construct or lipid nanoparticle that could be driving your relatively higher CD8 response versus some of the others?

And then the second question is, we've seen some of the CD8 and CD4 T-cell response data for our patients who have COVID-19. And then a lot of those publications there's a lot of response, I guess, on nucleocapsid especially for patients with certain HLA types. And I wonder what you think about your vaccines and others not including antigens for the nucleocapsid and whether that will be necessary in lifecycle management for full protection for old people.



## A - Ugur Sahin {BIO 18869003 <GO>}

Okay. So thanks Daina for the questions. So first of all, yes, it's as, you know, our focus in messenger RNA vaccine development is optimizing not only antibody responses but particularly CD4 as well as CD8 responses. If you see the track record of the publications that we made in the last 10 years, we have included a number of independent optimizations to increase the translation of our messenger RNA in human dendritic cells. Which includes untranslated UTR regions, cap analogs and as well as the delivery of the vaccine. This CD8 response requires a direct expression of the antigen in dendritic cells.

So if you express the protein outside of the dendritic cells, the classical pathway for antigen presentation is uptake of the antigen by the exogenous presentation machinery of dendritic cells and presenting on class two which produced nice CD40 cell response. That's the reason why the spike on protein vaccines, and with vaccines which don't go into dendritic cells, you get CD40 cell responses, but the only way to get powerful CD8 responses is expression, strong expression with human dendritic cells, which we have proven for our platform and for the COVID-19 vaccine in detail, and I think this is the key differentiator for observing a stronger CD8 T-cell response.

The second part of the question was related -- what was the second question?



## Q - Daina Graybosch {BIO 20659414 <GO>}

The nucleocapsid and whether there's some efficiency by not including that?

## A - Ugur Sahin {BIO 18869003 <GO>}

Yes. I think if you ask the question what is the immunodominant antigen in an infection, this is not the same question with what antigen is particularly suitable to have a protective T-cell response. Yes, nucleoprotein is an immunodominant antigen, yes, but we know that the virus entry is mediated of course by the full virus and the spike protein is one of the key proteins in this virus and therefore having a protein and particularly with the supposed spike protein which is more than 1,200 amino acids and a large protein with 1,200 amino acids gives you multiple base of presentation of class 2 and class 1 epitopes on multiple MHC haplotypes. So, we believe that this spike protein is the near-perfect antigen.

We wanted clearly to avoid to add additional antigens into our vaccine because every additional antigen comes with an independent price, yes. and independent costs for potential diversification of the autoantibody repertoire. And therefore having a simple vaccine which is able to induce CD4 and CD8 T-cells in a broad population of people is

sufficient and we believe with this -- with the large spike protein we have an ideal candidate.

## Q - Daina Graybosch {BIO 20659414 <GO>}

That's very helpful. And then on iNeST looking back at the data that was presented at AACR, one or two questions. I wonder if we should read anything to the biomarkers that there were a few TCM cells versus TEM cells? And also whether the number of sort of immunogenic neoantigens at around 2.6 is high enough. And sort of with both of those biomarkers if you're worried about them and if you're doing anything to optimize them as you go forward.

## A - Ugur Sahin {BIO 18869003 <GO>}

Yes. And so the most important learnings from this bucket card is the feasibility of the approach for really multiple different indications for safety of the approach in different indications in combination also with atezo and the broad immunogenecity. The shortcomings of the part, of course, this is a bucket uncontrolled trial in patients with heavily pretreated and most of these patients had a progression-free survival time less than three months. So this is not an ideal population for vaccine. And therefore it's difficult to draw any conclusion with regard to potential clinical activity from this cohort. And this was the reason why we have already started in 2019, our randomized trial in melanoma, in certain melanoma which gives us with the PFS in the range of above nine months, gives us sufficient time to have a fully induced T-cells response, succeeded in the T-cells response.

And here, the key question is, if iNeST in combination with checkpoint locate in our first-line a highly mutated tumor type could induce an added benefit? So, this trial would help us to other indications with a similar type of profile. And the second learning not only from this iNeST type, but also from the melanoma trial that we had published in 2017 and followed up with updated data in 2020 is that tumors with lower tumor load might be the ideal setting for iNeST and that's the reason why we are going to start two clinical trials in ctDNA positive tumors, one is the non-small cell lung cancer program and the second one is the colorectal cancer trial.

And this is also based on a learning from the basket trial because in the colorectal cancer patient population that we have vaccinated, even though these were advanced patients, we observed really strong T-cell response, so that the number of mutation seems not be the limiting for application of iNeST in the population and that was encouraging enough to define it to two additional indications. So the next 12 months will be extremely informative for the iNeST project with data coming from the melanoma trial and with the randomized trials in lung cancer and colorectal cancer being active.

## Q - Daina Graybosch {BIO 20659414 <GO>}

Great. Thank you very much.

## A - Ugur Sahin {BIO 18869003 <GO>}

You're welcome.

## Operator

Your next question comes from the line of Navin Jacob from UBS. Please ask your question.

## Q - Navin Jacob {BIO 20931208 <GO>}

Hi. Yes. Thank you for taking my question. Can you hear me, okay?

## A - Ozlem Tureci {BIO 20629996 <GO>}

Yes.

## Q - Navin Jacob {BIO 20931208 <GO>}

Perfect. Thanks. Great. If I can -- I had quite a few, if I may start with the BNT162. Firstly, congrats on all the progress. Maybe, I could just on the trial design, I just was hoping for some clarity on some of the statistical powering assumptions. What is the trial powered for, for what size -- for what effect size and if you could provide any clarity on the number of events at the first interim look versus the second interim look, please and then I have some follow-up questions?

## A - Ugur Sahin {BIO 18869003 <GO>}

So, these are maybe important questions. But at the moment, we are not able to share this information here. But what you can -- so what you can assume is that we have different interim readouts and these interim readouts of course come with different powers and with this different assumptions about the efficacy. So that's how the trial is in general structure, but I can't share the actual number.

## Q - Navin Jacob {BIO 20931208 <GO>}

Okay. And then maybe on the regulatory requirement either based on an interim look and depending on the number of events, what is -- is there -- are there different requirements associated with say an interim look with 150 events versus 100 events? And attached to that, what is the regulatory requirement from a safety standpoint, a minimum follow-up of at least six months? If you were to file in October for example, based on an interim, would you have enough follow-up data as far as duration of the safety that would allow for emergency use authorization?

## A - Ugur Sahin {BIO 18869003 <GO>}

Yes. So, the safety effect is addressed by two parameters. The one is the number of vaccinated subjects. Though, usually 3,000 subjects are sufficient to support a pandemic vaccine approval. The second is the follow-up time, and we are all aware that we have on the one side the need to get vaccine approved as fast as possible and make it available. For example, we are an emergency use authorization pathway, yes, and on the other side to continue to collect the safety data and that is exactly what is happening. So the subjects in this trial will be followed up for safety, safety parameters and we will get three months, say, to six months safety and we will continue also to monitor immune responses and the

stability of immune response in the subject to understand also the durability of the immune response.

## Q - Navin Jacob {BIO 20931208 <GO>}

And what exactly does emergency use authorization mean in the context of the vaccine? Does that mean it can be used if you have the doses? Could that be used in a broad population or will it be only used in high-risk population such as patients in the front-line healthcare workers so on and so forth?

And then two quick other questions. So you mentioned long-term immunity. Wondering what gives you confidence or what are you seeing that should allow us to have some confidence in long-term immunity or memory function?

And then for on the Fosun partnership, I -- it looks like you're moving forward with 16b1 if I'm correct with Fosun and not 16b2. Maybe that's just -- is just earlier in where you're developing it in China, so maybe that's one. But if you could just clarify that, that would be appreciated.

## A - Ugur Sahin {BIO 18869003 <GO>}

Okay, so let's start with the first question, who could benefit from the emergency use authorization. And of course, this is an issue of the governmental interest. So this is something where the U.S. government or the FDA had to decide for whom such a vaccine would be applicable. That's the same as in the Europe. It's a decision of every government to make the vaccine available and to be found to which population it should be made available.

The second question or the third question was about durability. So, we are collecting data with regard to durability of antibody response as well as evaluation of the durability of T-cell responses. So far, we have published data for up to 40 days -- 43 days and we will collect it for three months, six months, nine months, 12 months. We of course expect that the antibody titers will drop over time, that is what happens to antibody titers, which is vaccine in tandem. We have to see how fast this drop is and what is the baseline level where the drop stops, yes, and what kind of protection -- antibody-based protection still happens at this baseline level. So this is something which we will learn in the upcoming six months and continue to collect data.

I'm confident that having a vaccine which comes with a combined immune response, CD4, CD8, as well as antibody response based on the collaboration of this immune system arms, we will require lower amounts of each component since we will have a simplistic activity. But actually the community -- the whole scientific community and the industry has to learn what happens in the next two years, yes, how stable are these immune responses, what is required to protect from the infection.

If this is an issue -- if the drop of the immune response is an issue, I believe there's a messenger RNA vaccine we are in a good place to implement a booster immunization because this is one of the key strengths of messenger RNA vaccines, you can really use it

several times for boosting the immune response. It is not limited by any type of vector backbone immune response, which limits the activity of inducing and boosting antibody and T-cell response.

## Q - Navin Jacob {BIO 20931208 <GO>}

Thank you so much and just maybe two very quick questions on FixVac. The T-cell data in the Nature publication certainly look interesting, but it is a plasma data. Wondering if what it looks like in the two micro environment, which, as you know, literature suggests there's better correlation with anti-tumor activity with tumor in T-cells -- or T-cells in tumor? So -- and then wondering also when we're going to see the next data set with a later cut-off point from this Phase 1?

## A - Ugur Sahin {BIO 18869003 <GO>}

Yes. First of all, we have done in other studies, we analyzed tumor tissue and presence of T-cell receptors of -- vaccine-induced T-cell receptors, for example, in the iNeST trial but also for the FixVac and, yes, we confirm that T-cells that have been observed in the peripheral blood indeed infiltrate into the tumor and are detectable in the tumor.

So, this was not required to receive that in this special publication, which was more about the relationship between the strength and duration of the immune responses and the function of the immune response to cytotoxic assumption.

The next publication from this study will be sometime in 2021. I assume it's the second half of 2021 with regard to the population in this trial which is evaluated for relapse-free survival, so we had a patient population which -- who did not have tumors, metastatic tumor lesions but had surgery and afterwards received the therapy, and we will have relapse-free survival data here.

And actually the next upcoming publication would be the publication describing the Phase 2 data. And so we are -- as you know we are going to start a randomized Phase 3 study in melanoma FixVac end of the year and it will be a relatively small study which we'll record within the next 18 to 24 months. And I hope that this will be pivotal data required for registration of FixVac in second-line plus melanoma.

## Q - Navin Jacob {BIO 20931208 <GO>}

Got it. I'm sorry. Sorry, the question on Fosun. Are you moving forward with 16b -- 162b1 with them or 16b2?

## A - Ugur Sahin {BIO 18869003 <GO>}

No. Olzem, could you please answer?

## A - Ozlem Tureci {BIO 20629996 <GO>}

Yes. Sure. We are moving further with b2 globally, also in China and with Fosun. The reason why the b1 part of the study of our testing in China has started basically at the

same time when we make the b2 decision, is that we think that it has value to also compare in the Chinese population, meaning, in other population these two candidates of mod-RNA platform and we are now preparing the b2 entry in China.

So the regulatory processes are the difference there. It's the more sequential approach, not the umbrella trial approach which works in that regulatory region. We think that generating class intrinsic data for mod-RNA as such and also benchmarking these to b1 and b2 mod-RNAs against each other in the Chinese population is of value for the entire program.



### Q - Navin Jacob {BIO 20931208 <GO>}

That's very clear. Thank you very much for this call. Very helpful details and congrats on the progress.

### A - Ozlem Tureci {BIO 20629996 <GO>}

Thank you.

### Operator

In the interest of time, we ask participants to limit their questions to two please. Your next question comes from the line of Suzanne van Voorthuizen from Kempen. Please ask your question.



### Q - Suzanne van Voorthuizen {BIO 19827693 <GO>}

Hi, good afternoon. I have a question on the COVID-19 vaccine. Looking back at the four different candidates that you went into Phase 1 with originally, I was just wondering for b1 and b2, these are mod-RNAs. It is our understanding that this format is more often used by BioNTech to de-immunize mRNA to make it especially useful for immune silent applications. So, can you elaborate a bit, are b1 and b2 also uridine modified? Or how are they modified to be more immunogenic?

### A - Ugur Sahin {BIO 18869003 <GO>}

Yes. So, the rationale for starting with four different vaccine was on the one hand to evaluate our three different vaccine platforms. This is that modified messenger RNA platform which were now used for the candidate b1 and b2 and here b1 and b2 were selected based on the experience of the field in the past with MERS and the SARS, where both antigens had been evaluated but never benchmarked side by side.

### A - Ozlem Tureci {BIO 20629996 <GO>}

(inaudible)

### A - Ugur Sahin {BIO 18869003 <GO>}

Yes, with the RBD and the spike. And our study shows that both candidates are viable candidates with b2 having some advantage in this case.

For the second platform, with the uridine based platform, which comes with the potential advantage of a higher reactogenicity, and thereby stronger activity at low doses. We started to evaluate the RBD variant and generated some data and the data shows that we have immunogenicity. But the immunogenicity that not matched the immunogenicity that we have observed with the nucleus-modified mRNA.

And the second was -- the first candidate was the saRNA based candidate and here we have in the preclinical models, evaluated RBD as well as full spike and determined that the full spike for the self-amplifying mRNA is significantly better. So the only the full spike is currently evaluated and here we expect immunogenicity data since the really dose escalation study started with extremely low doses, yes, we expect the first relevant immunogenicity data in the time frame at the end of September and we will share that with the community. So the third amplified messenger RNA comes with the potential promise of having a potent vaccine candidate which comes with doses at lower in the low microgram range.

### Q - Suzanne van Voorthuizen {BIO 19827693 <GO>}

Got it. And then maybe on the Phase 2, 3 trial, in terms of the primary endpoints, can you remind us of the bar that you have to achieve, was that a 50% reduction in infection rates? Do you need to hit both co-primary endpoints or one of the two to claim success?

### A - Ugur Sahin {BIO 18869003 <GO>}

Yes. It's very simple. We stick to the guidance of the FDA and that's the lowest one.

### Q - Suzanne van Voorthuizen {BIO 19827693 <GO>}

And are there co-primary endpoints, are they either/or, or are they and that you need to achieve to claim the success?

### A - Ozlem Tureci {BIO 20629996 <GO>}

These are either/or.

### Q - Suzanne van Voorthuizen {BIO 19827693 <GO>}

Okay, and maybe just one follow-up in this regard just to clarify for the filing. Is the primary endpoint data the hard requirements? Or maybe for an emergency use authorization? Will there be immunogenicity data analyzed with the interim analysis? Could it be that you can file on that if your primary endpoint data is trending in the right direction, for example, or is it a hard requirement?

### A - Ugur Sahin {BIO 18869003 <GO>}

So, this is an ongoing discussion with the FDA, but I think the FDA was crystal clear when it announced in July the requirements for authorization and if this is still the case, then we would expect that use of the vaccine is only allowed when there are efficacy data around it.

**Q - Suzanne van Voorthuizen** {BIO 19827693 <GO>}
Got it. Alright. Thanks a lot.

**A - Ugur Sahin** {BIO 18869003 <GO>}
Yes.

**Operator**

Your final question comes from the line of Olga Smolentseva from Bryan, Garnier. Please ask your question.

**Q - Olga Smolentseva** {BIO 20860074 <GO>}
Good afternoon, everyone and thank you for taking my questions. Firstly on BNT162, considering that recent publications suggested that different mutations since spike protein could provide deeper immunogenicity. Could you maybe give us a little bit more color on the sort of optimization of the full spark antigen in b2? What kind of mutations in spike protein it includes?

**A - Ugur Sahin** {BIO 18869003 <GO>}
Yes, so we -- this is publicly used b2 stabilized -- prefusion stabilized mutation of the spike protein which has been described to use a stronger antibody response as compared to the virus-type protein.



**Q - Olga Smolentseva** {BIO 20860074 <GO>}
Okay. That's great. Thanks. And maybe just a little bit on BNT221. So how should we think about target population here in terms of differentiation with the planned potential pivotal BNT111 program?

**A - Ozlem Tureci** {BIO 20629996 <GO>}
Sorry, I didn't get that. Is this BNT111 -- sorry, it's on BNT221 --

**A - Ryan Richardson** {BIO 20337628 <GO>}
The Neon program.

**Q - Olga Smolentseva** {BIO 20860074 <GO>}
Yes. The Neon program.

**A - Ozlem Tureci** {BIO 20629996 <GO>}
Okay. The Neon program. Do you mean the adoptive T-cell therapy program which is just about to start?

**Q - Olga Smolentseva** {BIO 20860074 <GO>}

Yes, yes. I'm just interested in the target population here because it seems to overlap with BNT111 and I'm just thinking how -- yes, sorry.

### A - Ugur Sahin {BIO 18869003 <GO>}

Yes. So the time which is going to start in Europe will be in relapsing melanoma -- metastatic melanoma patients and this is more or less a proof-of-concept study because the approach is really a legend. It is an approach of creating new antigen-specific T-cells directly from blood. So this is in principal a universal approach applicable to any type of tumor and the colleagues from BioNTech US have generated data also for other type of solid cancers. But melanoma is of course an excellent tumor type for first proof-of-concept study.

### Q - Olga Smolentseva {BIO 20860074 <GO>}

Okay, great. Thank you. And many congratulations on all the progress.

### A - Ugur Sahin {BIO 18869003 <GO>}

Yes. Thank you.

### A - Ozlem Tureci {BIO 20629996 <GO>}

Thank you.

### Operator

Thank you. I would now like to turn the conference back to Sylke Maas for closing remarks.

### A - Sylke Maas {BIO 20912536 <GO>}

Thank you for joining today's call. We look forward to speaking to you in future. Stay safe. Bye-bye.

### Operator

That does conclude our conference for today. Thank you for participating. You may all disconnect.