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BioNTech Fourth Quarter and Full-Year 2019 Results

Tuesday, 31st March 2020

Welcome

Sylke Maas

Vice President, Investor Relations and Business Strategy, BioNTech

Thank you for joining us today for BioNTech's fourth quarter and full year 2019 update call. Before we start, we encourage you to view the slides for this webcast, as well as the financial results press release issued this morning, both of which are accessible on our website in the investor section. Slides two and three provide legal disclosures related to the pending acquisition of Neon Therapeutics.

As shown on slide four, during today's presentation, we will be making several forward-looking statements. These forward-looking statements include but are not limited to, the timing for enrolment and completion and reporting of data from our clinical trials and preclinical programs, the potentially registrational nature of certain of our clinical trials, expectations regarding the timing for completion and potential benefits of the Neon acquisition, the impact of the COVID-19 pandemic on our business and our financial outlook. 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; Özlem Türeci, our Chief Medical Officer, Sean Marett, Chief Business and Commercial Officer; Ryan Richardson, Chief Strategy Officer; and Sierk Poetting, Chief Financial and Operating Officer.

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

Agenda and Results Overview

Prof Dr Ugur Sahin

Chief Executive Officer, BioNTech

Agenda

Thank you, Sylke. It's a pleasure to welcome you all to our fourth quarter and full year 2019 conference call. I will start with a few introductory remarks, followed by an update on our significant efforts to address the COVID-19 pandemic that is having a severe impact around the globe. I will invite Ryan Richardson to provide a brief update on the pending Neon Therapeutics acquisition, announced in January of this year and Özlem Türeci will provide some pipeline updates. Sierk Poetting will then review our financial results. I will then make a few closing remarks on the outlook for 2020 before opening up the call for questions.

Progress in 2019–2020

To start on slide five, over the past year we have taken a number of important steps toward our vision of building a global, next generation immunotherapy company. We have built a broad suite of novel therapeutic platforms to exploit the full potential of the immune system. We are advancing, along with our pharmaceutical collaborators, a broad pipeline of first-in-class immunotherapies for the treatment of cancer.

We have built a growing number of programs targeting infectious diseases. Most importantly, one of these programs is our recently announced mRNA vaccine program, aimed at prevention of COVID-19, which we initiated earlier this year as part of our Project Lightspeed in response to the global coronavirus pandemic. Our COVID-19 vaccine program is based on our deep experience in the cancer vaccine field and growing footprint in infectious diseases. To address this epidemic, we are applying the full spectrum of our capabilities: our broad mRNA vaccine platform, our integrated GMP manufacturing infrastructure and our broad base of global world-class collaborators. I will come back to COVID-19 in a few minutes and provide an update on the status of our programme.

Executing on our vision

Turning to slide six, our accomplishments in 2019 and so far in 2020, demonstrate our ability to execute on our vision. 2019 was a transformational year for BioNTech. We have continued this strong momentum into 2020 against a challenging market backdrop. I want to quickly highlight a few of these key achievements.

Consistent with our stated objectives, we have increased the number of product candidates in clinical testing from seven to ten since the completion of our IPO in October of last year and have announced our intention to initiate multiple late-stage studies over the next 12 months.

We have also increased our pharma partnerships through the recent expansion of our Pfizer collaboration and the announcement of our first Asian partnership: a strategic alliance with Fosun Pharma.

Early in January this year, we announced the signing of a merger agreement and our offer to acquire Neon Therapeutics which, if Neon's shareholders vote in favour of the merger and the other conditions to closing are met, we expect to bring us some exciting new pipeline candidates in the cell therapy space. These are complementary technologies and the US R&D hub will support the growing number of studies we are conducting in the US.

We also completed two successful financings: our series B round and of course, the Nasdaq IPO, which together brought in gross proceeds of $374 million to the company.

Lastly, we made good progress in our multi-year investment program to expand our in-house messenger RNA and cell therapy manufacturing capacity. Manufacturing remains a key strategic priority for us as we advance our pipeline of product candidates toward the market.

COVID-19

I will now turn to slide seven and discuss COVID-19, the growing global health threat that has dominated the world's attention over the past weeks. Earlier this month, we announced that we are developing a vaccine which aims to induce immunity and prevent COVID-19. We initiated Project Lightspeed because we feel we have the duty to fully utilise our technology and immunotherapy expertise to help to address this pandemic emergency created by the global spread of this dangerous pathogen.

For our COVID-19 programme, we are leveraging our proprietary messenger RNA platforms for infectious diseases, our fully-owned GMP manufacturing infrastructure for mRNA vaccine production and our global clinical development capabilities. We have partnered with Pfizer for worldwide development of the vaccine and have also established a strategic alliance with Fosun to develop the vaccine in China. We have been in close contact with regulatory and scientific authorities around the world and in ongoing discussions with research organisations. We anticipate initiating clinical testing in late April, subject to regulatory approval. We expect to conduct a global a global development program spanning Europe, the United States and China.

Our mRNA vaccine for COVID-19 exploits a highly-potent lipid nanoparticulate, or LNP, messenger RNA vaccine product. We believe that mRNA vaccines are ideally suited for this challenge: mRNA vaccines have been shown to be highly immunogenic and induce neutralising antibodies, as well as T-cell responses. mRNA is a naturally-occurring molecule with well-characterised safety properties. Furthermore, mRNA vaccines are well-defined biopharmaceuticals with high purity and are animal-material free. We believe mRNA vaccines may offer several advantages over traditional vaccine approaches, including an ability to precisely design and manufacture them rapidly in a large quantity.

Sean, do you want to say a few words about our recently-announced collaborations for our COVID-19 vaccine?

COVID-19 Pfizer Collaboration

Sean Marett

Chief Business and Commercial Officer, BioNTech

Thanks Ugur. For COVID-19, we are collaborating with one of the world's largest pharmaceutical companies, Pfizer and one of the leading healthcare groups in China, Fosun Pharma. Just a few weeks ago, we signed a letter of intent with Pfizer regarding development of BNT162 outside China and expect to provide more details of the financial terms behind our collaboration soon. As we already have a successful collaboration with Pfizer for infectious diseases, aimed at developing influenza vaccines, we have been able to immediately start work to rapidly advance BNT162 toward clinical testing for the prevention of COVID-19. We are currently utilising multiple research and development sites from both BioNTech and Pfizer and look forward to providing further updates on this fast-moving collaboration in the future.

We also recently announced our strategic alliance with Fosun Pharma, our first strategic collaboration in Asia, to jointly develop BNT162 in China. Together with Fosun Pharma, we intend to conduct clinical trials in China, leveraging our mRNA vaccine technology and manufacturing and Fosun's extensive clinical development, regulatory and commercial capabilities in the country. Under the agreement, both companies will collaborate to conduct clinical trials in China. Fosun Pharma has the rights to commercialise the vaccine in China and will pay BioNTech up to $135 million that is €120 million, in upfront and potential future investment and milestone payments. The two companies will share future gross profits from the sale of the vaccine in China.

Operational Impact of COVID-19

Prof Dr Ugur Sahin

Chief Executive Officer, BioNTech

Thanks Sean. Before I move on, I would like to note that we are currently monitoring the situation in regards to the potential impact of COVID-19 on our operations. Özlem and Sierk will provide additional detail later in the call but there has been impact to some of our previously-communicated trial timelines, in particular to planned study starts for 2020. We will continue to monitor this situation and provide updates as appropriate.

I will now ask Ryan to provide a brief update on our announced offer to acquire Neon Therapeutics. First however, I wanted to highlight Ryan's appointment as Chief Strategy Officer. He has significantly contributed to multiple key corporate development initiatives, including the acquisition of Neon and he was instrumental in successfully taking BioNTech public in a challenging market environment. I want to thank him for his accomplishments so far and look forward to his continued efforts in helping to execute our global growth strategy. Ryan?

Neon Therapeutics Acquisition Update

Ryan Richardson

Chief Strategy Officer, BioNTech

Thank you, Ugur. Turning to slide eight, in January, we announced entry into a definitive merger agreement under which BioNTech would acquire Neon in an all-stock transaction. The transaction remains subject to a vote of Neon's shareholders, which we expect to take place during the second quarter. For those unfamiliar with Neon, it's a biotechnology company based in Cambridge, Massachusetts developing novel neoantigen-based T-cell therapies.

From a strategic standpoint, this acquisition is a strong fit on multiple levels. For one, it will bring us some exciting preclinical programmes, including NEO-PTC-01, a personalised neoantigen-targeted T-cell therapy candidate, consisting of multiple T-cell populations that target the most therapeutically-relevant neoantigens from each patient's tumour. It also brings NEO-STC-01, a T-cell therapy candidate targeting shared RAS neoantigens.

In addition, Neon has assembled libraries of high-quality TCRs against various shared neoantigens across common HLAs, which we believe will complement our own technology toolkit. Neon's pipeline is underpinned by several complementary platform technologies including RECON, its machine-learning bioinformatics platform, and also NEO-STIM, its proprietary process to directly prime, activate and expand neoantigen-targeting T cells ex vivo.

The acquisition will enable us to significantly expand our presence and capabilities in the United States, which remains a strategic priority for us.

Under the terms of the agreement, Neon would become a wholly-owned subsidiary of BioNTech upon closing. As previously indicated, subject to a favourable vote of Neon shareholders, we expect the transaction to close during the second quarter of 2020. We look forward to closing the acquisition and beginning the integration process.

I will now hand over to Özlem to discuss key updates in our development programmes.

Key Development Updates

Dr Özlem Türeci

Chief Medical Officer, BioNTech

Delays to clinical trials due to coronavirus pandemic

Thank you Ryan. Today I am going to provide key updates for our pipeline since our last call in November. I will start with some detail on the effects of the coronavirus pandemic on the timing of our clinical trials. The short message is that we do expect some impact to the timelines we have previously communicated. As shown on slide nine, while our review of the impact is ongoing, we are developing and implementing a three-point plan to manage the still-evolving disruptions that the pandemic is creating.

First, we still intend to initiate phase two trials for BNT111, BNT113 and the iNeST program as originally planned. We assume that the anticipated start dates of end-of-year 2020 provide time for stabilisation of the clinical trial environment.

We believe that the trials of BNT111 and BNT113, these are our FixVac products for melanoma and for HPV-positive cancers, have the potential to be registrational studies. Therefore, continuing the activities to progress towards initiation of these trials is a key priority for the company.

Second, we will manage our ongoing phase one exploratory and dose escalation trials to support timely completion. We have seen evidence of slowed enrolment in our trials, given restrictions at clinical sites and travel restrictions for patients. We expect BNT111 and BNT114, the TNBC and melanoma FixVac trials, to be less affected given that these trials are near completion of enrolment. The recently-initiated programmes, such as BNT112, which is prostate cancer FixVac, are more likely to be affected by these delays.

Third, we expect that there will be delays to some of our first-in-human studies planned to commence this year. For now, we maintain timing guidance for our CARVac programme, BNT211. Delayed start of first-in-human phase one, may occur for our RiboMab programme, BNT141 and BNT142; our RiboCytokine programmes, BNT151, BNT152 and BNT153; our TLR7 agonist programme, BNT411 and also for our

influenza programme and our rare disease programme. At this time, we estimate the delay for these trials at approximately 3–6 months.

Overall, as the coronavirus situation remains dynamic, we will continue to monitor the situation as it evolves. We will update investors as appropriate.

Key updates to our clinical pipeline

Now I'll discuss key updates to our clinical pipeline, as shown on the next slide, where we have ten products in 11 ongoing trials.

First, an update on BNT111, our FixVac candidate for the treatment of advanced melanoma. Data from our phase one trial in advanced melanoma is on track to be published soon. Further regulatory discussions have occurred regarding next steps and I will provide more details later.

BNT112 is our FixVac candidate for the treatment of prostate cancer. Dosing of patients in a phase one/2a study has been initiated. Eligible patients for dose titration have metastatic castration-resistant prostate cancer. In the expansion part, also patients with newly-diagnosed, high-risk, localised prostate cancer are eligible and will be treated with BNT112.

BNT114 is a programme that evaluates a range of novel antigens for the treatment of TNBC for immunogenicity in a phase one/two trial. Data was previously expected to be presented at CIMT annual meeting, scheduled for May. Given the postponement of the conference due to the COVID pandemic, BioNTech is evaluating the appropriate opportunity to present the data this year.

Moving on to our individualised neoantigen-specific immunotherapy, or iNeST, programme, earlier this year, at our JP Morgan presentation, we provided some additional clinical data from the phase one trial for BNT121, the precursor to RO719 845 7, or BNT122. This data update demonstrated stable disease in melanoma patients for up to 60 months post vaccination.

For BNT122, we disclosed, with Genentech, that two additional phase two clinical trials in the adjuvant setting are planned for initiation in 2020. The first adjuvant phase two study will evaluate the efficacy, safety, pharmacokinetics, immunogenicity and biomarkers of BNT122 plus atezolizumab, compared with atezolizumab alone, in patients with stage two/three non-small cell lung cancer who are positive for circulating tumour DNA following surgical resection and have received standard-of-care adjuvant platinum-doublet chemotherapy. The second indication has not been yet disclosed.

Regarding the iNeST phase two trial in first-line melanoma, we still plan to provide detailed interim data in 2021 and an enrolment update in H2 2020. We expect the interim data in 2021 to include top-line efficacy and safety data as of the interim date.

Now turning to our intratumoural immunotherapy program, partnered with Sanofi: a data update from the ongoing phase one/two trial of BNT131 in solid tumours remains on track for later this year.

I am also pleased to report that our next-generation checkpoint immunomodulatory programme, partnered with Genmab, is moving rapidly. Top-line data from phase one/two trial, BNT311, in multiple solid tumours is now expected in the second half of this year, ahead of our previous expectations for a data readout in the first half of 2021.

And finally, progress has been made in our clinical program for BNT321. The first patient has been dosed in the resumed phase one/two study evaluating the safety and recommended phase two dose of BNT321 in patients with pancreatic and other CA19-9-positive malignancies.

Preclinical pipeline

I will now move to slide 11 and provide some quick updates on our preclinical pipeline.

First, for our FixVac portfolio, BNT116 has been added to our product portfolio and is currently in preclinical development for non-small cell lung cancer.

As I mentioned earlier, BNT211, our CAR-T programme targeting solid tumours, is on track to go in the clinic in summer this year. This programme combines our CAR-T therapeutic approach with our mRNA vaccination and uses our proprietary, tumour-selective target, claudin-6.

For our TLR7 agonist, BNT411, the IND was allowed in Q4 2019. We expect phase one initiation later this year.

Lastly, Project Lightspeed: as Ugur mentioned earlier, we expect to dose the first patient in our clinical program testing BNT162, our COVID-19 vaccine candidate, in April this year.

BNT111 and BNT122

Now, on slide 12, I want to give some additional detail on two of our most advanced immuno-oncology programmes: BNT111 and BNT122. For BNT111, our melanoma FixVac, we expect data from our phase one trial in advanced melanoma to be published in a medical journal in late H1 2020. As I mentioned earlier, we have had further discussions with regulatory authorities regarding next steps and the design of a registrational trial. Based on those discussions, we believe there may be potential to conduct a registrational phase two trial instead of a phase three trial. We are not providing full trial design details at this time but we can say that we expect the arms to include BNT111 in combination with a checkpoint inhibitor and controls. The study population will be patients who are checkpoint inhibitor experienced. We expect to provide a further update on the expected trial design in Q3 2020.

For BNT122, a data update for the phase one/two trial in multiple solid tumours was planned at the AACR Annual Meeting, which, due to the COVID-19 pandemic, has been rescheduled for August 2020. Our data is embargoed until this presentation date.

We are very pleased that iNeST was included during the recent Genentech Research and Early Development, or gRED, event. For those that may have missed the presentation, Genentech highlighted iNeST's potential to provide a personalised cancer vaccine for a broad range of cancer patients.

I will now hand the call over to Sierk to discuss our current financial results for the fourth quarter and full year 2019.

Financial Results

Sierk Poetting

Chief Financial and Operating Officer, BioNTech

Mitigating the impact of the coronavirus pandemic

Thank you, Özlem. Before presenting the financial results, I would like to provide you information on our measures that we put in place in order to mitigate the potential impact of the coronavirus pandemic on our operations.

In response to the coronavirus outbreak, we continue to monitor the potential impact to our supply chain and manufacturing operations, which includes mRNA manufacturing for FixVac and iNeST platform products, as well as our CAR-T manufacturing site. So far, our manufacturing operations are unaffected and still running at full capacity.

In terms of our personnel, we have instituted measures to ensure their safety for precautionary reasons. We are closely monitoring any employee that has potentially been in contact with affected individuals or in affected areas and we are limiting access to BioNTech facilities as appropriate.

Financial results summary

Now, I would like to summarise our financial results that are shown on slide 13.

Cash and cash equivalents as of 31st December 2019 were €519.1 million. As we indicated earlier in the year, we expect net cash used in operating activities and other investments to total approximately €300 million for the full year of 2020. At this time, we are maintaining that guidance.

Total revenue, consisting primarily of revenue from collaborative agreements, was €28 million for the fourth quarter of 2019, compared to €63.8 million for the prior-year period. The decrease was primarily due to decreased revenues from our collaboration with Sanofi. Total revenue, consisting primarily of revenue from collaborative agreements, was €108.6 million for the full year of 2019, compared to €127.6 million for the prior year. The decrease was primarily due to decreased revenues from our collaboration with Sanofi. The decrease in revenue from Sanofi is primarily driven by a revenue of €33.2 million for a one-time reimbursement of certain sublicensing costs that was fully recognised in the year 2018.

Research and development expenses were €65.4 million for the fourth quarter of 2019, compared to €51.8 million for the prior-year period. The increase was primarily due to an increase in headcount and higher expenses regarding our collaboration projects. Research and development expenses were €226.5 million for the full year of 2019, compared to €143 million for the prior year. The increase was primarily due to an increase in headcount, the full-year impact of our ESOP programme and higher spending for purchased services and laboratory supplies for the projects.

General and administrative expenses were €11.1 million for the fourth quarter of 2019, compared to €10.1 million for the prior-year period. General and administrative expenses were €45.5 million for the full year of 2019, compared to €26.3 million for the prior year. The increase was primarily due to an increase in headcount, the full-year impact of our ESOP programme and a charge in connection with certain withholding tax payments for intellectual property licences that was recorded in the year 2019.

Net loss was €58.2 million for the fourth quarter of 2019, compared to net loss of €1.5 million for the prior-year period. Net loss was €179.2 million for the full year of 2019, compared to net loss of €48.3 million for the prior year.

Shares outstanding as of 31st December 2019 were approximately 226.8 million.

With that, I will return the call back to Ugur for concluding remarks.

Concluding Remarks

Prof Dr Ugur Sahin

Chief Executive Officer, BioNTech

Thank you, Sierk. Following a strong and productive 2019, there are several important milestones ahead of us in 2020, as shown on slide 14.

These include six trial updates, including publishing BNT111, FixVac melanoma phase one data in a peer-reviewed journal. We look forward to the initiation of a trial for our BNT111 FixVac melanoma candidate, which we believe has registrational potential. We also expect the initiation of two additional iNeST trials in adjuvant-stage cancers this year. By the end of next month, we expect the initiation of the clinical testing for our COVID-19 vaccine candidate BNT 162. I would like to point out that we expect to start a phase one/two trial using CARVac BNT211 in claudin-6-positive solid tumours and we want to start a phase one trial for our TLR7 programme, BNT411, in solid tumours. Lastly, we will work to integrate our US Hub in Cambridge, Massachusetts, following the expected closing of the Neon acquisition in the second quarter 2020.

We look forward to updating investors and other stakeholders throughout 2020. We thank our shareholders for their trust and support. We will now take any questions you may have.

Q&A

Cory Kasimov (JP Morgan): Hey, good morning guys and thank you for taking my questions. A couple of them for you. I guess to start, your COVID-19 programme BNT162 is – what are the gating factors to getting this product into the clinic, and can you maybe discuss at a high level how your vaccine approach might be differentiated?

Prof Dr Ugur Sahin: Yes, thanks for the question. So, the development of our COVID vaccine is based on our in-house platforms. We have three messenger RNA platforms which are currently exploited for development of COVID vaccines exploiting different epitopes. So, it's the modified messenger RNA platform, then the uridine mRNA-based platform which we are using currently for treatment of cancer patients and the self-amplifying RNA platform. The sequence of development events is based on pre-clinical evaluation of signals and on GMP manufacturing of the material, GMP toxicology and discussions about the clinical trial design with the regulatory authorities in Germany, China and with the FDA and the related ethics committees.

We are on track in the development of our vaccine approach and except a timely start of the first clinical trial in Germany in the second half of 2020. The differentiation factors of our vaccine platform is – it's – one intention is that we get – develop a vaccine which is not only safe, but it's enabled immune response with neutralising antibodies with the lowest possible dose.

Cory Kasimov: Okay, and then from a timeline point of view would you expect this to follow a similar path to other vaccines that have been publicly commented on?

Prof Dr Ugur Sahin: To which path of vaccines do you refer?

Cory Kasimov: Well, other COVID-19 vaccines that we've heard about from other companies that have been commented – that they've talked about and they've talked about timelines and talked about things like 12 to 18 months in a situation like this potentially get it from start to finish. Do you think that's a – kind of, a realistic expectation for your programme as well?

Prof Dr Ugur Sahin: So, maybe Özlem can –

Dr Özlem Türeci: Yes, I can take this one. These are plausible-sounding timelines. At the end of the day, this will – the timelines will depend on positions of regulatory authorities and based on which type of data such a vaccine would – would be made available to the larger population. So this will need to be really worked out in the ongoing discussions.

We and also the other companies you are referring to have also regulators and the data, which we can all present from our trials.

Cory Kasimov: Okay, makes sense. And then one non-COVID-19 question, if I may? Can you just give us a sense of where you are in terms of dose escalation for BNT311 and how much data we should maybe expect in the second half of this year?

Dr Özlem Türeci: That's a duobody. The duobody. We are – you refer to the PDL14-1BB duobody which we are developing –

Cory Kasimov: Exactly.

Dr Özlem Türeci: – in cooperation with our partner Genmab. We are pretty advanced in our dose escalation. So, have cleared a number of dose levels which were planned, and the data disclosure presentation would definitely include data referring to safety of the different doses, probably also the phase two dose.

Cory Kasimov: Okay, very helpful. Thank you for taking the questions.

Tazeen Ahmad (Bank of America Merrill Lynch): Hi, good morning. Thanks for taking my questions. With regards to your publication that you mentioned in your prepared remarks that's expected in the second half of the year on phase one data for melanoma, can you give us an idea of what level of detail you expect to have in that article and as it relates to a potential for a registrational study? What in your discussions with FDA gives you confidence that you would be able to potentially use the next study as registrational versus having to do a full phase three? Thank you.

Dr Özlem Türeci: For the first question referring to our publication, here the data we will publish is data which comes from our LipoMerit trial. So, the dose-escalation, dose-expansion trial with our melanoma FixVac is in a heterogeneous population of patients with advanced melanoma, and what we will publish, the focus here is primarily on the mode of action of the vaccine, which we show for the first time in humans, in particular, also the immune responses, their magnitude, their type and their kinetics, but also some safety and activity data.

Tazeen Ahmad: Okay, thank you. And as it relates to your discussions with FDA on the potential for a registrational study?

Prof Dr Ugur Sahin: Yes, so the discussion with the FDA was, of course, based on the design of the clinical trial. The statistical parameters required for showing the endpoints of the clinical trial and treatment and control arm and based on this discussion then we could further provide updates – specific updates about different arms and size of the arms later on. Based on the discussion with the FDA we are confident that if we can deliver – deliver the request for the study – of the study design, then the FDA would be in agreement with the registrational nature of the trial.

Tazeen Ahmad: And would that require an in-person meeting once you deliver the study design?

Dr Özlem Türeci: Sorry, can you repeat? What –

Tazeen Ahmad: Sure. Once you deliver the study design to the agency, would you then need to have an in-person meeting with the agency to determine if this can be registrational?

Dr Özlem Türeci: In general, the agency also enables non-in-person meetings, also phone conferences, so that would be – also in this case, be sufficient.

Tazeen Ahmad: Okay, thank you.

Shanshan Xu (Berenberg): Hey, good morning. Regarding the BNT162, that's the COVID-19 vaccine, among as – the end proteins, what could be your targets? And are you thinking about receptor-binding domains? And you also mentioned that you saw neutralising antibodies generated in the BNT162 pre-clinical study. Can you share with us which epitopes you observed for these neutralising antibodies? And do you think titre of neutralising antibodies can serve as a surrogate clinical advocacy endpoint in COVID-19 vaccine development? And I have one follow-up.

Prof Dr Ugur Sahin: Thank you, Shanshan for the interesting question. So, yes, we are evaluating different epitopes, including the full-length spike protein but also subdomains. We will provide details of our subdomain vaccines in the coming weeks and the immune responses that we observe against the full-length protein and the subdomain parts. We have established a number of assays studying immune responses in mice, including antibody responses, titre responses, neutralising antibody responses using pseudo-type and virus-based neutralisation assays. And based on the assays, we are confident to reduce the spectrum of candidates to a meaningful number to be tested in the clinical trial.

Shanshan Xu: Okay, thank you. And another question regarding RNA format and also the delivery formulation. So, modRNA, that's the modified RNA that is the mRNA format you used in your Zika vaccine.

To us, it is not highly immunogenic. Can you tell us what is the scientific rationale of using it in infectious disease vaccine?

And also for your delivery formulation, the lipid nanoparticle LNP, you saw that with this delivery technique it was modified to shift the immune response more towards Th2 cells, not Th1 cells. Can you share with us what modifications have been done on this LNP formulation to increase Th2 activation? Thank you very much.

Prof Dr Ugur Sahin: Yes, you're welcome. So, actually – actually we have a set of mechanistic data that the different platforms which we are using all produce different levels of Th1 responses. So, it is also the modified RNA – RNA platform together with a novel formulation that has a strong T follicular helper immune response and most importantly in the use of highly-neutralising antibody responses which are in our – in our – in our working hypothesis, are the most important – important immune response parameters required to control COVID-19.

We use the unmodified mRNA platform since it comes with TLR7 core stimulator reactivity to evaluate if the additional TLR7 agonistic activity can further reduce the dose and we are using a self-amplifying RNA-based approach to further elaborate whether, due to the self-replication based on the vaccine – vaccine amplification after delivery, we can further reduce the dose.

There is evidence in the pre-clinical setting. We have published data showing that this is the case for HIV, and this is the case for influenza vaccine and therefore also based on pre-clinical data that we have seen for COVID-19 which are encouraging, we decided also to evaluate this platform in a clinical trial.

Shanshan Xu: Perfect, thanks.

Navin Jacob (UBS): Hi, thanks for taking my question. A couple of questions. As it relates to targeting this spike protein, can you give us any kind of colour on how you're thinking about whether mutations around this spike protein could create selective pressure? And then with regards to that, how you're thinking about timelines, what data you need to see to ensure that that is not going to be an issue? And then along the same sort of lines, how are you thinking about antibody enhancement? Thank you.

Prof Dr Ugur Sahin: Thank you for the interesting question. First of all, there are new emerging publications showing the genetic profile of different COVID sequencing data and the positive conclusion from the studies is that COVID-19 genome is relatively stable. We have also done a deeper look particularly to the epitopes that we are targeting and we see minimal differences in COVID variants isolated in different regions of the planet, so that we are confident that escape of the spike protein is not an issue.

Navin Jacob: Perfect. Thank you so much.

Daina Graybosch (SVB Leerink): First a couple of questions on COVID-19 and I want to ask one about your oncology work. We've heard some people speculate that coronaviruses may need a T-cell immunogenistic response in addition to an antibody. You've talked mostly about an antibody response and I wonder if you can talk about a cellular response and how important that is in your preclinical work. And the second question is, there's a lot of speculation how durable immune responses are to coronaviruses broadly and in COVID-19 specifically. And can you help us understand how you're thinking durability of protection with your vaccine and your hypothesis on necessary boost schedules?

Prof Dr Ugur Sahin: Yes. First of all, all of our products induce in the combination with the formulation that we're using powerful CD-4 as well CD-8 T-cell response. So that's not an issue.

The second is durability of the immune response induced by the virus protection itself is something different than the durability of the immune response induced by a vaccine. So we are using here a vaccine with an inherent adjuvant effect. And we see with this type of vaccine, regardless of the epitopes that we are using, long-lasting immune responses. They have shown that for all of our platforms that we observe long-lasting

neutralizing antibody responses for more than one year with the different platforms and T-cell responses, long-lasting T-cell responses.

So we are not concerned with regard to the durability of the immune responses that we are generating by the vaccine. With regard to the durability of the immune responses that are generated by the COVID-19 infection, we have to see, because the data are emerging and long-term observational data are needed.

Daina Graybosch: Great. And then on oncology, you talked a lot about delays but we've heard reports of other challenges and conducting trials that are already enrolled, protocol violations like missed scans. And I think that's so important for your early Phase I trials and I wonder how you're monitoring that and if you're taking any mitigating action to make sure the data you get is what you need early so you understand problems in the data?

Dr Özlem Türeci: Sure. So you are perfectly right that indeed is one of the major activities, namely monitoring the situation, understanding the specific impacts on what is happening at the clinical sites, how regulatory authorities see for example potential deviations and how to mitigate those deviations we identify as potentially emerging patterns under the current situation, is one of the major actions taken here in our company. You may have heard that some regulatory authorities give guidance and particularly for deviations, how to document them for example, in order to ensure that they can then be addressed by regulators appropriately, given the situation the entire clinical trial landscape is in. But fully agreed this is one of the major aspects which are implemented into the way we are dealing now in this further emerging situation with the way we conduct our clinical trials and decide upon how the individual trials should be adapted or conducted.

Daina Graybosch: Very helpful. Thank you very much.

Akash Tewari (Wolfe Research): I have a few questions. So Roche made some comments that there are tweaks and optimisations that can be made to the iNeST programs. Any colour on what those tweaks are? And I think more broadly, where is the ideal setting for a personalised cancer vaccine and would that be in late-stage, more bulky solid tumours or perhaps in earlier settings?

Next, on your COVID vaccine, can you talk about your self-amplifying mRNA platform in the context of your vaccine? And given your current manufacturing capacity, what's the largest dose you think is commercially feasible to serve a broader population?

And then finally, there's been a lot of work recently that's shown the growing role of T-cells and tertiary lymphoid structures in the role of IO responses. What's your opinion on some of this emerging research in the context of your cancer vaccine platform and also your PDL1, 4,1BB bi-specific? Thanks.

Prof Dr Ugur Sahin: Starting with our personal vaccine approach. So we have of course ongoing trials with our third generation messenger RNA platforms running in collaboration with Genentech. Of course, we are further developing the platform and continuously evaluating improvements like for example improvements in antigen design, improvements in formulation, formulation optimisation, improvements in the number of epitopes that we are delivering, improvement in the extent of TNR stimulation, which is included with our vaccine. And we are in the next 12 months going to publish a number of collaborative studies with Genentech showing how next generation vaccine could look like.

With regard to the positioning of personalised cancer vaccine, we and Genentech believe that particularly tumours with a lower tumour load and particularly tumours with an adjuvant stage could be ideally suited for the vaccine in combination or even without checkpoint therapy. For diseases which are more in the advanced and later stage, it might be necessary to add additional combinations, IO transfer for example, cytokines to further improve the activity of a vaccine in this trial setting.

With regard to the saRNA, we have published a number of preclinical studies and one of the interesting insights in using saRNA is that saRNA can reduce the dose which is required to induce a strong antibody and

T-cell response, can reduce the dose up to 60 to 80 fold as compared to non-amplified vaccine. And this is of course an exciting opportunity to elaborate and to test in a setting where the manufacturing of a sufficient scale of vaccine could be a challenge. We are currently continuously increasing our manufacturing scale. We will update about the target scale for manufacturing in the coming weeks and months, but it is clearly our vision to test sufficient capacity to delivery to hundreds of millions individual doses of vaccine in a reasonable time period.

There was another question as related to the T-cell infiltration in human tumours. Yes, I think there is a series of publications showing that different type of infiltrates including infiltrates with dendritic cells and B-cells are associated with an improved prognosis and response to a checkpoint locator. And of course we are aware of these studies, for example for all of our iNeST studies we are evaluating the [inaudible] group of tumours and are able to see which type of infiltrate is associated with which type of immune response. And based on this type of information, we can of course exploit different types of immune-modularity treatments.

Akash Tewari: Thanks so much.

Arlinda Lee (Canaccord): Thanks for taking my question. First on the COVID vaccine, you mentioned that you were working with the German, Chinese and US governments. I'm wondering if you could provide some colour on your conversations and maybe your strategy on potentially manufacturing at risk.

Secondly, we have the chance to see some cancer care changes during COVID and I was wondering if you could comment on modifications to your clinical trials or enrolment criteria? And also, you're doing a lot of biomarker studies. I'm wondering if some of these assays can be done on archival samples and how that might be affected. Thank you.

Prof Dr Ugur Sahin: We are talking to regulatory authorities in China, Germany and the US, and part of the dialogue is, of course, harmonisation of the clinical trials designs in these different countries. And not only harmonisation, but also having complementary trials designs which allow to maximise the amount of information that can be generated. Interestingly, the situation in Europe and US now became the hotspot of the infection, and the infection rate in China is cooling down. So giving us different opportunities in different regions, effecting the different frequency of infection. This is also a good to have situation, because based on the situation we can generate safety and activity, efficacy and affectivity data in different regions of the world.

In regards to the biomarker strategy, of course, we need to evaluate antibody responses before vaccination and after vaccination and this is a straight-forward approach and an established industry for collecting samples, for analysing samples. We have already identified CROs supporting us here, so this will not be a challenge.

Ryan Richardson: Just maybe to add to that, in terms of the manufacturing at risk part of your question, I think it was our strategy from the beginning, to try and get a global consortium in place. And we leveraged our partnerships, both existing and also new, to do that. We are continuing to evaluate how best to scale up the manufacturing effort and fund it through those relationships with existing partners and also potential new sources of capital.

Arlinda Lee: Thank you, and maybe just following up on your oncology pipeline: the biopsy volumes are down, I'm just curious if the current criteria you have in place enables the use of archival tissue and how you're collecting biomarker data for your oncology trial, collecting and processing. And then maybe lastly, could you talk about your strategy for your Cytokine pipeline? Thank you.

Prof Dr Ugur Sahin: So the archival tissue for the development of the oncology trial…

Dr Özlem Türeci: I can take that one. It depends on really the drug we are investigating in those trials. In trials in which we want to see and collect trial specimen in order to see the effect of the drug and we need a baseline under treatment, sort of biopsy or blood sample, there is no flexibility to work with archival tissue or

samples, because this is really about seeing the impact of the drug. In studies we first want to test whether the patient has a certain marker which is stable and we work in fact with archival tissue from this patient. It really depends on which question needs to be answered and where the mixture of both fresh tissues and materials and archival materials.

Prof Dr Ugur Sahin: And if your question refers to the enrolment of patients into iNeST studies, yes, we can use and are using archival materials, which is paraffin dipped so there is no essential need to do fresh biopsies.

Thank you all for today's call and we look forward for meeting you in the future. Thank you.

[END OF TRANSCRIPT]

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