CureVac Conference Call, October 12, 2021

Focus Shift to Second-Generation mRNA Technology

Presenters

Dr. Franz-Werner Haas	Chief Executive Officer CureVac
Pierre Kemula	Chief Financial Officer CureVac
Rino Rappuoli	Head of Vaccines R&D GSK
Dr. Sarah Fakih	Vice President Corporate Communications & Investor Relations CureVac

SARAH Thank you. Good morning, good afternoon and welcome to our conference call. My name is Sarah Fakih, and I am the Vice President of Corporate Communications and Investor Relations at CureVac.

Please let me introduce today's speakers.
On the call with me from CureVac are Franz-Werner Haas, the Chief Executive Officer of CureVac, Pierre Kemula, our Chief Financial Officer and Klaus Edvardsen, Chief Development Officer of CureVac.
From GSK we are joined today by Rino Rappuoli, Head of Vaccines R&D.

Please note that this call is being webcast live and will be archived on the Events and Presentations section under Investor Relations on our website.

Before we begin, a few Forward-Looking Statements: The discussion and responses to your questions on this call reflect management's view as of today, Tuesday, October 12th, 2021.

We will be making statements and providing responses to your questions that state our intentions, beliefs, expectations or predictions of the future. These constitute forward-looking statements for the purpose of the Safe Harbor provisions. These statements involve risks and uncertainties that could cause actual results to differ materially from those projected.

CureVac disclaims any intention or obligation to revise any forward-looking statements. For more information, please refer to our filings with the U.S. Securities and Exchange Commission.

I will now turn the call over to Franz.

FRANZ Thank you Sarah. Ladies and gentlemen, a warm welcome to this conference call from all of us here at CureVac and welcome Rino Rappuoli, who we are happy to have participate on our call today from the GSK vaccines headquarters in Belgium.

The global fight against SARS-CoV-2 continues, however the situation has changed considerably. Since the fight against COVID-19 began, licensed efficacious first-generation vaccines have become available, which have successfully helped to manage the initial peak demand to rapidly prime-vaccinate unprecedentedly large populations. While the pandemic is still ongoing, the benefits of these vaccination efforts are easy to observe.

Globally, COVID-19 cases and deaths reported weekly by the WHO continue to decline after reaching an interim peak earlier this year as a result of the rapid spread of the delta variant.
Today, a downward trend in weekly COVID-19 cases can be observed, continuously dropping from a mid-August peak of more than 4.5 million new cases per week and about 68,000 deaths to about 3.1 million new cases and just over 54,000 deaths at the beginning of October.

Absent the emergence of a new variant able to evade vaccine-generated immunity a gradual transition from acute pandemic to endemic SARS-CoV-2 is expected to occur in vaccinated regions in 2022.

Managing a pandemic response is incredibly difficult. However, emerging from a pandemic is just as challenging. As we continue to move away from an overarching state of crisis, we are approaching a state where the virus and emerging variants are still a very real danger but cease to be the predominant public health threat.

But what will the endemic COVID-19 state look like? And how can the technologies that have enabled potent pandemic vaccines safeguard the long-term protection of people?

A gradual change in urgency and vaccine demand is expected to lead to the need for more differentiated vaccines targeting endemic COVID-19, which differ from the first-generation pandemic vaccines in that they provide:

- flexible and long-term protection against current and new variants in one vaccine via multivalent vaccines,
- broad protection against several different infectious diseases in one vaccine via combination vaccines,
- improved convenience of administration via single-use formats, and
- efficient, scalable and cost-effective vaccine manufacturing and delivery.

At CureVac, we remain fully committed to providing a safe and efficacious vaccine – this goal has not changed. However, we recognize that the requirements to effectively address the virus and potential future variants will require differentiated solutions going forward.

Current regulatory review timelines for CVnCoV suggest that due to the complexity of data the earliest decision on an approval for CVnCoV would be expected to come in the second quarter of 2022.

In this context, we have made the strategic decision to withdraw our first-generation vaccine candidate, CVnCoV, from the current regulatory review with the European Medicines Agency to fully focus on a suite of improved second-generation vaccine candidates we are developing in collaboration with GSK.

While we acknowledge that we cannot be part of the first wave of pandemic vaccines anymore with CVnCoV, together with our partner, we fully intend to be at the forefront of delivering improved second-generation vaccines.

Let me now go into further detail of this decision on the next slide.

On slide 4 I would like to further walk you through the factors that have informed our decision to terminate the CVnCoV development program.

In light of the anticipated vaccine demand in 2022, we have drawn a number of conclusions, which have led us to the strategic decision to withdraw CVnCoV from the regulatory review process.

We acknowledge that CVnCoV will not be able to still have an impact on the current pandemic. Going into 2022, with CVnCoV as a first-generation pandemic vaccine, we will likely not be able to meet the anticipated demand for more differentiated vaccines in an endemic COVID-19 world. And this is why we will now focus our efforts and resources on the second-generation vaccines.

The context of the pandemic evolving into endemic COVID-19 and the corresponding change in vaccine demand structure and urgency, meaning a diminished medical need for first-generation vaccines in the second half of 2022, was a major factor in our decision process.
This includes a decreased demand for organizations such as COVAX. Due to the expectation to have reached vaccination coverage objectives by mid-2022, they have indicated to us that there is limited interest in distributing CVnCoV in the second half of next year.

Most importantly, our decision weighed the expected development status of the broad second-generation vaccine program that we currently develop together with our strategic partner GSK.

Toward mid-2022 we expect first candidates from the second-generation program to have progressed to an advanced stage of clinical development.

The first representative of the program, CV2CoV, recently demonstrated the strong potential of our improved second-generation mRNA technology. In preclinical studies, CV2CoV was able to show a better and more balanced activation of immune responses compared to first-generation CVnCoV, demonstrating faster onset of immune response, higher antibody titers and stronger memory B and T cell activation. CV2CoV also showed higher neutralizing capacity across relevant variants, including the Delta variant.

Together with GSK we will now put our undivided focus and resources on the clinical development and manufacturing activities for the second-generation vaccine program to accelerate market readiness of second-generation solutions for an endemic vaccine demand.

CureVac is a pioneering company that has been establishing mRNA as a potential medical modality for more than 20 years, and it has much to contribute to the continuing effort against COVID-19 and other infectious diseases.

I would now like to hand over the call to Pierre, who will briefly address the financial implications of our decision.

PIERRE Thank you Franz and good morning, good afternoon to everyone on the call.

I am now on slide 5 to give you a first overview of financial considerations in view of today's announcement. Before we go into further detail, please let me note that while we would like to answer all your questions today, many aspects are currently being worked on simultaneously.

It is therefore not possible to provide exact figures at this stage, as continuing arrangements with third-parties - such as partners and suppliers - will be further refined in the coming weeks and months, and we hope to provide more clarity within this timeframe.

Over the last year and a half, we have protected our significant investment in the clinical development of CVnCoV and mitigated associated financial risk through payments received from collaborations, grants, and upfront payments.

As a direct consequence of the potential approval shift of CVnCoV well into 2022, the existing Advanced Purchase Agreement with the European Commission, which was based on employing CVnCoV to address the acute pandemic need, will cease. This is in line with the diminished medical need and hence commercial demand for pandemic first-generation vaccines in 2022 that Franz has just highlighted.

In the development of CVnCoV, it was very important for us as a company to limit the risk and our financial exposure. We are thankful to several governments and authorities to have shared the risk with us. Two major elements have financially protected the company.

In the Advanced Purchase Agreement with the European Commission, we secured an upfront payment of 450 million euros. This represented a significant part of the financial buffer aimed to minimize the risk around our efforts in accelerating vaccine research and buildup of production capacity. Additionally, and importantly, we have spent more than 450 million euros developing CVnCoV and, pursuant to the terms of the agreement, do not expect to make any repayments to the EU.

This upfront payment was strengthened by an overall 252-million-euro grant by the German Federal Ministry of Education and Research. Thereof, we believe we will be able to claim up to 196 million euros and we have so far claimed approximately 140 million euros.

Due to our withdrawal of CVnCoV from regulatory review, we will not be able to claim more than 196 million euros.

The total of approximately 650 million euros provide an important basis to manage the development and financial risks around CVnCoV. We have been able to balance the amounts received with our financial obligations.

These financial commitments include our European manufacturing network to expand our mRNA manufacturing and formulation capacity. In September of this year, we responded to the change in demand for first-generation vaccines as a result of the first wave of large-scale vaccination – and the associated demand projections for CVnCoV – by terminating collaborations with two network partners to adjust our peak production capacity.

We continue to monitor and match demand and capacity, specifically with the shift towards a large second-generation program including multiple vaccine candidates.

We also made significant early investments to inventory large quantities of raw materials to manufacture CVnCoV.

In order to reduce raw material write-offs and manage commitments to our raw material suppliers, we are now primarily assessing the possibility of using our materials for the production of second-generation vaccine candidates, while also evaluating resale opportunities to support any supply shortages at other vaccine manufacturers.

Lastly, we have made Property, Plant and Equipment investments for the buildup of production lines at the production facilities of our European manufacturing network.
These investments will now be used for the manufacturing of our second-generation vaccine candidates.

Some production lines will be applied in our large scale in-house GMP IV plant, which we expect to come online end-2022, early 2023. Some production lines will be transferred to GSK for clinical material supply. We will ensure that we maximize the use of production lines and, alternatively, favor a resell of some materials and equipment.

While we expect there will be write-offs following our decision to withdraw CVnCoV, we will maximize our efforts to leverage existing commitments related to CVnCov for our second generation COVID-19 vaccine candidates.

With this let me hand back the call to Franz.

Franz Thank you Pierre. I am now on slide 6 to give you an overview of our current status and plans for manufacturing capacities in view of our decision.

As Pierre has already highlighted, last month, we responded to the change in demand for pandemic first-generation vaccines and streamlined our manufacturing capacities to ensure that we can rapidly and flexibly deliver potential second-generation vaccines in line with the endemic COVID-19 vaccine demand going into 2022.

For this purpose, we have already started to switch the manufacturing setup at GMP III and the European network facilities to the production of clinical material of second-generation constructs.

This includes the implementation of processes for flexible adaption to new variant-specific constructs as well as processes for the production of modified mRNA constructs, which will be explored as part of our second-generation development program.

For CV2CoV, the first representative of our broad second-generation program, we have already produced clinical trial material in our in-house plants, GMP I and II. We aim to kick-off the second-generation clinical development program with CV2CoV within the next months.

As Pierre said, to expand our internal manufacturing capabilities and be more independent within our overall production process, we further expect our internal commercial scale manufacturing plant, GMP IV.

Together with GSK, we strive to shape the manufacturing processes and organization to efficiently deliver on future public health needs.

I will now hand over the call to Klaus, our Chief Development Officer.

KLAUS Thank you Franz. On slide 7 I would now like provide you with an overview of our collaboration with GSK, in which we jointly develop a suite of potentially improved second-generation vaccine candidates for COVID-19 but also for a broad range of other infectious diseases. We have recently strengthened our collaboration through an extension to the agreement, in which both companies commit to a large number of dedicated experts and additional resources to further accelerate the development program.

Please let me remind you that our second-generation vaccines are based on an improved mRNA setup, which differs from the setup of CVnCoV and which was generated on the basis of our learnings over the past year.

Targeted optimizations focus on improved mRNA translation for increased and extended protein expression as well as improved and faster immune responses at low doses.

We believe, these characteristics will be key to develop vaccine candidates focusing on specific features designed to address the demand for differentiated vaccines in an endemic COVID-19 world. These include:

- addressing current and emerging variants in one multivalent vaccine,
- broadening protection against several different diseases in one combination vaccine, and
- improving convenience of administration via single-use vaccination formats.

To select and advance the best candidates, we also plan to work together on a technology extension into modified mRNA in parallel to the development of unmodified mRNA constructs.

We expect the withdrawal of CVnCoV to enable us to fully focus on accelerating the second-generation program based on the learnings and infrastructures built up during the development of CVnCoV.

With CV2CoV, we have already pre-clinically advanced the first representative of the second-generation COVID-19 program, which is expected to initiate the clinical development program within the next months.

Let me briefly go into the recently published preclinical data of CV2CoV, demonstrating the strong potential of our second-generation mRNA setup.

The data shown on slide 8 form part of a larger preclinical dataset in non-human primates, which was generated in collaboration with the Harvard Medical School. The manuscript is currently available from the bioarchive pre-print server and has been submitted to a high-ranking peer review journal.

The data is based on animals immunized with CV2CoV or CVnCoV, according to the vaccination schedule applied in humans, which includes two vaccinations with a 12 microgram dose, four weeks apart.

The difference between the time-dependent induction of neutralizing antibodies shown in this graph between the first and the second-generation is striking.

Antibody titers of CV2CoV are not only about ten times higher at peak level after six weeks but also show faster onset of neutralizing antibodies, already 2 weeks after the first vaccination.

Higher antibody titers for CV2CoV compared to CVnCoV were also observed in response to a large set of highly relevant COVID-19 variants, including the Delta variant.

The impact of variants on neutralizing antibody titers is illustrated in these two graphs next to the wild-type. A general reduction of antibody titers in response to the variants compared to the wild type is clearly visible, however, CV2CoV antibody titers range consistently higher than CVnCoV antibody titers.

In summary, the data demonstrate how an improved setup and targeted optimizations of the second-generation mRNA approach can substantially improve immunogenicity against multiple virus variants in non-human primates.

With this it is my pleasure to hand over to Rino Rappuoli, Head of Vaccines R&D at GSK.

RINO Thank you Klaus.

At GSK, we welcome the decision by CureVac to focus their efforts towards our collaboration on the development of the second-generation non-modified and modified mRNA technology - starting with our second-generation COVID-19 asset. I believe the fact that we are focusing on a common goal is going to speed up our ability to deliver vaccines in the short term.

In addition, as you certainly know, we highly value the RNA technology: We see mRNA as a very exciting platform technology and as a major opportunity for the future of vaccines. That is why we are investing in it significantly - focused on our collaboration with CureVac and also further building in-house end-to-end mRNA development and manufacturing capabilities.

Internally, we have a significant number of people dedicated to the RNA technology. With the announcement today, those people are going to work together hand to hand with the employees from CureVac on our collaboration. This collaboration will make our team much stronger. Initially, we will focus together on COVID-19 vaccine candidates.

Currently, we are starting to see that vaccines are basically calming down the COVID-19 situation. But, we believe that further vaccines will be needed in the future since there are still many people around the world that have not been vaccinated and because the virus keeps evolving.

Therefore, we need to develop new, advanced vaccines and with this technology, I am convinced that we can provide a solution for upcoming challenges.

As Klaus has already mentioned, we are confident in the second-generation mRNA technology as it is optimized for higher protein expression through specific changes in the 3’ and 5’ UTR, which help to drive mRNA stability and efficacy.

Furthermore, as you have already seen, the pre-clinical data we published recently show us that the second-generation technology has a significantly higher potential than CureVac’s first-generation, with up to 10x higher immunogenicity in animal models.

Therefore, we are excited about the second-generation module. We are going to use it as a set on a non-modified and modified basis. And we are currently obviously applying it to COVID-19 vaccines, but we will apply the same platform to many other diseases and vaccines that we have in our pipeline. This is why we see this collaboration as basis for a future pipeline in the field of RNA.

Moreover, we believe that we are going to grow much faster now that CureVac’s priorities and our priorities are fully aligned.

Underlying that fact, I will like to conclude saying that I am very much looking forward to advancing our second-generation COVID-19 asset. We would like to see it in the clinic in the next few months and starting from there, we will build up our pipeline for the future.

Thank you. Let me now hand back the call to Franz.

FRANZ Thank you Rino.

Let me quickly summarize the key messages from today's presentation.

- Changes in vaccine demand and urgency are starting to shift the requirements for a new generation of differentiated vaccines toward the endemic COVID-19 world.

- In the ongoing transition from acute pandemic to endemic, withdrawing CVnCoV from the regulatory review is a direct consequence of these expected changes in public health needs.

- We will focus our priorities and resources on delivering advanced second-generation vaccines for COVID-19 and beyond together with GSK, to address global post-pandemic medical needs.

- The first representative of the second-generation vaccine program, CV2CoV, has shown promising preclinical data and is expected to kick-off the overall second-generation clinical development within the next months.

- The expected technology improvements will contribute to our entire platform beyond COVID-19 and infectious diseases.

- We are convinced, the partnership with GSK in combination with CureVac's deep and diverse roots in mRNA technology, put us in an excellent position to play a prominent role in tackling future public health challenges.

With this, we conclude our presentation and would now like to open the webcast to your questions.

SARAH With this we would like to conclude this conference call. Thank you very much for your participation, stay safe and please don’t hesitate to contact us should you have any further questions.

Thank you and goodbye.