CureVac Conference Call, January 6, 2023

CureVac Announces Positive Data on Joint COVID-19 and Flu mRNA Vaccine Development Programs

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Presenters

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SARAH FAKIH

Thank you. Good morning, good afternoon and welcome to our conference call. My name is Sarah Fakih, and I'm 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, our Chief Executive Officer and Ulrike Gnad -Vogt, our Interim Chief Development Officer. Please note that this call is being webcast live and will be archived on the Events and Presentation section under Investor Relations on our website.

Before we begin, a few forward-looking statements. The discussion and responses to your question on this call reflect management's view as of today, Friday, January 6, 2022. 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 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-WERNER HAAS

Thank you, Sarah. Ladies and gentlemen, a warm welcome to this conference call and a very Happy New Year from all of us here at CureVac.

As highlighted during our Q3 earnings call in November last year, 2022 was a highly productive year for CureVac. We have, fundamentally, transformed our organization and grown our operation bandwidth. Most importantly, we have broadened our proprietary technology platform and extended our robust product development pipeline, two core competencies that were accompanied by the robust expansion of our large GMP manufacturing capacities. At the core of this transformation, we have initiated and executed on our broad clinical development programs in COVID-19 and seasonal flu, in collaboration with our partner, GSK. Both programs are based on CureVac's proprietary second-generation mRNA backbone, designed and developed to achieve improved mRNA translation, as well as stronger and earlier immune responses at low doses. These two programs are driven by a broad and unrestricted technology approach covering unmodified and modified mRNA, as well as monovalent and multivalent formats. Our goal is to select the best performing candidates for the next stage of clinical development in both indications.

The positive clinical data demonstrated to date and described in today's press release, as well as presented within this webcast, have enabled us to make this selection. It is important to stress that the earlier results from the Phase I studies are not derived from a former interim analysis. They are preliminary, based on a limited number of participants prior to database lock and not yet complete, which means they remain subject to change. Nevertheless, we consider these preliminary data, to date, meaningful enough to draw three main conclusions with regard to the potential of our technology platform.

First, the preliminary data clearly validate CureVac's mRNA technology platform, led by our second-generation mRNA backbone. Our platform has demonstrated its potential to provide vaccine candidates that, as of today, appear to be in line with currently licensed vaccines for COVID-19 and flu, in terms of reactogenicity and immunogenicity.

Second, the broad and unrestricted technology approach we took with our second-generation backbone candidates enabled us to select modified mRNA as the best performing technology for prophylactic vaccines in both indications. Correspondingly, we will enter the next stages of clinical development with modified candidates in COVID-19, as well as in flu.

Third, clinical development of product candidates in both indications will continue in 2023, this year, with bespoke candidates designed with current state-of-the-art vaccine format and tailored to public health needs.

In COVID-19, we expect to advance candidates that encode relevant variants in a mono and/or bivalent format to match the current standard of care. In flu, we expect to advance a multivalent candidate.

As our modified candidates will form the basis of our continued clinical developments, we will focus on these data, during this webcast. On Slide 5, let me briefly remind you of the four Phase I dose escalation trials that are the basis for the vaccine development programs that we are, jointly, conducting with GSK. For COVID-19, on the left, the tested candidates include CV0501, a monovalent, modified candidate encoding the Omicron Variant BA.1 and CV2CoV, a monovalent and modified candidate encoding the original or wild-type virus. For flu, on the right, we are testing FLU-SV-mRNA, a monovalent modified candidate expressing the H1N1 hemagglutinin antigen, a subtype of influenza A and CVSQIV, a multivalent and modified candidate addressing relevant antigens of four different influenza strains.

All four candidates are being tested in a one-shot booster setup.

I will now hand over to Ulrike to walk you through selected preliminary data on reactogenicity and immunogenicity profiles for the modified vaccine candidates.

ULRIKE GNAD-VOGT

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

On Slide 6, I would like to start with an overview of the preliminary reactogenicity data available from our jointly developed COVID-19 program. The illustrated data represents elicited drug events in younger adults, within seven days after the booster vaccination. As Franz has already said, our studies are characterized by broad and unrestricted technology approach covering unmodified and modified mRNA. In the figure on the left, you can see the comparison of our second-generation and modified construct, CV2CoV, with our second-generation modified construct, CV05051, at a 12-microgram dose level.

Please note that this qualitative comparison is based on two separate studies. The comparison shows that the change from unmodified to modified mRNA results in pronounced differences leading to substantially lower reactogenicity for CV0501 at this dose.

The two figures on the right further illustrate the full CV0501 dose escalation ranging from 12 to up to 200 micrograms in younger adults aged 18-64 years and older adults aged greater or equal to 65 years. The data demonstrate that for younger adults, CV0501 reactogenicity remains acceptable from 12-100 micrograms with only one systemic Grade 3 adverse event at 100 micrograms, which was reported as a headache. At the highest dose of 200 micrograms, two local Grade 3 adverse events occurred, both reported as redness at the injection site. In older adults, one systemic Grade 3 event occurred, reported as a headache in the 50-microgram dose group. The profile illustrate that the lower reactogenicity of modified mRNA allows access to a much broader dose range, compared to unmodified mRNA.

On Slide 7, let me move on the preliminary immunogenicity data with a focus on the modified second-generation mRNA backbone construct, CV0501. Shown here are the available geometric mean titers, or GMT, of neutralizing antibodies induced by CV0501 in younger adults as a function of those against the Omicron BA.1 variant, for which it encodes. The orange bars represent antibody titers before the booster vaccination, and the blue bars represent antibody titers either on day 15 or on day 29, after the booster vaccination. Due to a later start of recruitment for the older adult dose groups, our corresponding data readout are currently being finalized and will be available for the next COVID-19 program data reporting. GMTs were measured with a pseudo virus neutralization assay.

Across the displayed dose levels of 12, 25 and 50 micrograms on day 15 and at 12 micrograms on day 29, CV05051 induced a substantial antibody increase from pre- to post-boost titer. This antibody boost further quantifies for each dose group at a ratio of post to pre-boost titers. The so-called geometric mean increase, or GMI, is indicated above the orange and blue bars. It represents the most meaningful metric to assess the potential of CV0501 as a booster vaccine against the tested variant. Depending on the dose and day, the GMI range was between 6.8 and a 9-fold increase of antibody titers.

On Slide 8, you can see the corresponding graph. At those time points in the younger adult dose group looking at pre-and-post boost neutralizing antibody titers, elicited by CV00501 against SARS-CoV-2 wildtype. To the left of both figures, the data was extended to allow for a comparison with antibody levels elicited by our second-generation unmodified vaccine candidate CV2CoV, which encodes for the wild type. The CV2CoV titers at 12 micrograms were taken from its separate Phase 1 study. Although the data do not represent a direct head-to-head comparison within the same trial, antibody titers of both candidates were measured using the same assay to allow for a high-level qualitative comparison.

Despite encoding the Omicron variant, CV0501 was able to strongly boost neutralizing antibody titers against the wild type demonstrating substantial cross neutralization with titers about two times higher, compared to CV2CoV on day 15 and about 1.6 times higher on day 29. The fact that pre-and post-boost neutralizing antibody titers are markedly higher against the wild types than BA.1 across all dose groups can most likely be attributed to the generally higher prevalence of wild type pre immunity in the study population, which has been primed with licensed wild type vaccines. Boosting of a higher pre-immunity is expected to lead to generally higher neutralizing antibody titers.

The geometric mean increases showed that CV0501 induces booster activity against the wild type in the range of 3.3x to 5x, depending on dose and day. In summary, the preliminary reactogenicity and immunogenicity data available from our COVID-19 program supports the selection of the modified mRNA technology as the best performing technology. The second generation modified construct, CV0501, was shown to be well-tolerated within a much broader applicable dose range, compared to the unmodified second-generation mRNA backbone construct.

So far, a small number of Grade 3 adverse events occurred at 100 and 200 micrograms in younger adults and one Grade 3 event at 50 micrograms in older adults. All of them occurred well above immunogenic dose levels. In younger adults, CV0501 induced substantial antibody responses, even at the lowest dose of 12 micrograms with strong cross neutralization against the wild type. Overall, the use of modified mRNA in CV0501 enabled a better reactogenicity profile, which was accompanied by stronger immunogenicity.

Let us now move on to our flu vaccine development program.

Starting again with the available preliminary reactogenicity data, Slide 9 displays on the left, the reactogenicity profile of Flu-SV-mRNA, the monovalent construct encoding a hemagglutinin antigen using modified mRNA. Flu-SV-mRNA was tested in the dose range of 2 to 54 micrograms, which escalated to almost double the highest dose, compared to the unmodified CVSQIV candidate, which was tested between 3 to 28 micrograms. The Flu-SV-mRNA dose range takes into account that the candidate is a monovalent construct.

Correspondingly, the applied doses reflect doses for a single mRNA construct, which would later be multiplied for a state-of-the-art multivalent flu vaccine. The total mRNA content of such a multivalent flu vaccine could, potentially, range up to 200 micrograms. The upper limit of the dose range is a complimentary ongoing study of the modified COVID-19 candidate, CV0501. Shown on the right is, again, the reactogenicity data for CV0501 to allow for comparison of dose construct using modified mRNA. We have refrained from comparing the Flu-SV-mRNA reactogenicity profile to the profile of our unmodified flu candidate, CVSQIV, in this webcast. In contrast to Flu-SV-mRNA, CVSQIV is a multivalent construct encoding a number of relevant targets covering for different flu strains. We previously reported early reactogenicity data of CVSQIV in the dose range of 3 to 28 micrograms. The data supported a benign profile across all tested doses. This trend has not changed.

Moving on to the available preliminary immunogenicity data for Flu-SV-mRNA on Slide 10, we are looking at the ratio of post-pre boost geometric mean hemagglutinin inhibition antibody titers to determine the geometric mean increase. Data is shown for younger adults in the range of 18-45 years. Within the study, immunogenicity of Flu-SV-mRNA was assessed in parallel to a licensed quadrivalent flu vaccine comparator, shown as the orange bar to the right. You can see that Flu-SV-mRNA achieved comparable antibody increases to the life of the vaccine, boosting HI geometric mean titers about 14 times beginning at the lowest dose of two micrograms. Due to a later start of recruitment for the older adult dose groups, the corresponding data readout are currently being finalized and will be available for the next flu program data reporting.

On Slide 11, you can see post vaccination hemagglutination inhibition antibody titers in younger adults in dose groups of 2 to 36 micrograms. Antibody titers were adjusted for prior infection, age and pre-boost titers. According to the geometric mean increases, the modified Flu-SV-mRNA achieved numerically higher GMT than the licensed comparator across all dose levels. At the dose level of 18 micrograms, GMT was more than 3x the GMT of the licensed comparator.

On Slide 12, I would like to complete discussion of the available immunogenicity data for flu in younger adults with a graph of the seroconversion rates. The consistently higher antibody titers across all doses results in seroconversion rates that are also substantially higher for our modified mRNA candidate.

In summary, the preliminary reactogenicity and immunogenicity data available from our flu program further support the modified mRNA technology as a select technology for ongoing clinical development. The monovalent Flu-SV-mRNA was generally well-tolerated across all tested dose groups and successfully boosted antibody titers against the matching flu strain. Preliminary immunogenicity data show that Flu-SV-mRNA antibody titers were in line with a licensed comparator vaccine, beginning at the lowest tested dose of two micrograms.

With this, let me hand back the call to Franz for a summary of today's key messages and an outline of what is next.

FRANZ-WERNER HAAS

Thank you, Ulrike. Let me quickly highlight the key takeaways from today's presentation.

- The preliminary data we have presented today provide a strong proof of our technology for our proprietary mRNA platform in prophylactic vaccines.
- This proof of technology needs to be seen in the context of a fundamental transformation of our organization in 2022, which has enabled significant expansion of our operational bandwidth.
- This covers our demonstrated core competencies in mRNA technology, as well as product development pipeline, complemented by our scalable manufacturing.

  With today's manufacturing setup and ongoing expansion into large-scale production with GMPIV, we will be able to supply clinical trials or commercial efforts, seamlessly, and mostly autonomously. Manufacturing will be a key success factor, moving forward.
- Together with GSK, we plan to advance candidates in COVID-19 and flu in 2023.
  - For COVID-19, candidates will encode relevant variants in mono and/or bivalent format to match the current standard of care. A Phase II study is expected to start later in 2023.
  - For clinical development in flu, we plan to advance a multivalent candidate, targeting all four flu strains recommended by the WHO. A Phase I/II study for multivalent vaccine candidate is expected to start around mid-2023.
- We also expect our second-generation mRNA backbone to drive forward our cutting-edge genomics and bioinformatics platform in the oncology area for which we have already announced the scheduled start of two clinical trials this year.
- In 2023, we thereby anticipate starting another four clinical trials to advance promising product candidates in prophylactic vaccines and to kick off clinical developments in oncology.
- We feel very energized by these positive preliminary data presented today. They demonstrate our commitment to the promise of mRNA and the potential of our proprietary technology platform. With strong focus and the ability to transform in 2023, CureVac worked hard and delivered its plans in 2022 to go forward.

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

Sarah Fakih

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.