CureVac Conference Call, July 1, 2021

Final Analysis of Phase 2b/3 Clinical Trial of First-Generation COVID-19 Vaccine Candidate, CVnCoV

Presenters

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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 are Franz-Werner Haas, the Chief Executive Officer of CureVac and Ulrike Gnad-Vogt our interim Chief Development Officer. Mariola Fotin-Mleczek, CureVac's Chief Technology Officer and Pierre Kemula, Chief Financial Officer, will be available for the Q&A session after the presentation.

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, Thursday, July 1st, 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.

Over the past six months, we have been conducting a pivotal Phase 2b/3 efficacy trial – called the HERALD study – with our first-generation COVID-19 vaccine candidate, CVnCoV.

Conducted in 10 countries and across 2 continents in Europe and Latin America, the HERALD study is so far unmatched by similar trials in terms of geographic diversity and, even more important, in terms of the increasingly challenging variant-rich environment the vaccine faced.

In this highly dynamic variant environment and across this broad geography, CVnCoV met the statistical success criteria on the basis of 228 adjudicated cases, including an additional 68 cases compared to the pre-defined 160 cases for final analysis as per trial protocol.

Efficacy was calculated to be 53% in the age group of 18 to 60 on the basis of 228 adjudicated cases that met the criteria for analysis inclusion.

This was calculated against any severity of disease and across a total of 15 different virus variants, which in sum featured 86 percent Variants of Concern and Variants of Interest and two additional variants beyond the 13 detected in the second interim analysis.

In the same age group and across the same broad range of 15 different variants, protection against moderate to severe disease was calculated at 77 percent.

Full protection was provided against hospitalization or death, with 6 cases occurring in the placebo arm and none in the vaccine arm.

Efficacy across all age groups amounted to 48 percent - and please let me repeat – this was across any severity of disease and in the face of 15 different variants that were detected within the adjudicated cases.

The age group above 60 included 21 cases or approximately 9 percent of the adjudicated cases. In this predefined age group, as per protocol, the data available from these 21 cases did not enable a statistically significant determination of efficacy.

We believe CVnCoV is to date the only vaccine which has been able to show robust protection against moderate to severe disease as well as hospitalization or death while being challenged with a confirmed spectrum of 15 different virus variants in a placebo-controlled pivotal study.

We also believe this data establishes CVnCoV as an effective vaccine that has the potential to make an important contribution to the continuing fight against COVID-19.

Now, let me hand the call over to Ulrike, our interim Chief Development Officer, to walk you through the details of the study setup, the case accrual process and the efficacy analyses within the final analysis.

ULRIKE Thank you Franz. Please let me start by briefly reminding you on slide 5 of the highly international scope and the age distribution within the HERALD study.

Conducted in four countries in Europe and six countries in Latin America, HERALD constitutes a multi-variant study with high geographic and ethnic diversity.

Of the approximately 40,000 trial participants about 25 percent were recruited in Europe, while about 75 percent were recruited in Latin America – a region which today accounts for approximately 32 percent of COVID-19-related deaths worldwide.

These approximately 40,000 study participants were distributed in 2 predefined age groups. Roughly 5,000 participants, or 13 percent, were above the age of 60, while the majority of about 35,000 participants, or 87 percent, were between the age of 18 and 60. The mean age of study participants was about 43 years.

I am now on slide 6 to give you an overview of the COVID-19 case accrual process within the HERALD study, according to the study's primary endpoint. This is defined as the occurrence of first episodes of confirmed cases of COVID-19 of any severity.

Per study protocol, COVID-19 cases are eligible to be included in the vaccine efficacy calculation if they occur at least 15 days after the second vaccination – the earliest time at which the vaccine is considered to be fully protective.

PCR-confirmed COVID-19 cases that occur at least 15 days after the second vaccination additionally undergo a stringent adjudication process, including the exclusion of those confirmed COVID-19 participants who test positively for a prior COVID-19 infection.

Since the second interim analysis, communicated on June 16th on the basis of 134 adjudicated cases, 94 additional cases have been accrued and adjudicated, resulting in a total of 228 cases used for the final efficacy analysis.

Of these 228 COVID-19 cases, 207 cases were detected in participants in the age group of 18 to 60, representing an increase of 88 cases compared to the second interim analysis. 21 cases were detected in participants above the age of 60, representing an increase of 6 cases compared to the second interim analysis.

As occurrence of COVID-19 cases needs to be seen in the context of the rapid spread of new virus variants, 204 of the 228 adjudicated cases were sequenced to identify the variant causing each infection. A total of 24 cases could not be sequenced due to insufficient sample material.

The next slide is a frequently used slide in our presentations that illustrates the currently estimated variant spread in the two study geographies, Latin America and Europe.

New virus variants have emerged and spread steadily since the end of 2020 and have all but displaced the original virus strain. As Franz has already highlighted, the dynamic variant background must be considered for the interpretation of the CVnCoV efficacy results.

Variants of Concern initially included mainly three lineages, namely:

- the Alpha strain, first detected in the UK,
- the Beta strain, first detected in South Africa, and
- the Gamma strain, first detected in Brazil.

This group was recently extended to include the Delta strain, first detected in India. Over the past 3 to 4 months, the Delta strain has rapidly spread around the globe and is today estimated to show an approximate 13 percent prevalence in Latin America and an approximate 26 percent prevalence in Europe.

Also, new Variants of Interest have been added to the watch list, based on genomic properties or other evidence that imply a potential impact on transmissibility, severity and/or immunity. This includes the Lambda strain, first detected in Peru and the B.1.621 strain first detected in Colombia.

Because of the continuing spread and emergence of new variants, we have conducted comprehensive sequencing analysis to better understand the dynamics of the virus in our trial.

Over the next two slides, I will go into the details of the unique variant distribution we have detected in the HERALD study.

Within the HERALD study, 204 cases, or approximately 89 percent of the 228 adjudicated cases that were used for the final efficacy analysis, were sequenced. As said before, 24 cases could not be sequenced due to insufficient sample material.

The strain distribution resulting from these sequencing analyses is illustrated on slide 8 and provides important context around the CVnCoV efficacy results calculated at final analysis – against any severity of disease, according to the primary study objective.

Of the 204 sequenced adjudicated cases, Variants of Concern, including the Alpha, Gamma and Delta strain, represent approximately 51 percent.

Variants of interest contributed approximately 35 percent, including the Lambda or C.37 strain, originating from Peru, and the B.1.621 strain originating from Colombia.

The Lambda variant was previously reported to be responsible for more than 80 percent of COVID-19 cases in Peru, and evidence has become available for high rates of transmission in multiple countries in Latin America.

The strain is known to feature two critical mutations in the receptor binding motif of the Spike protein. As the receptor binding motif is a primary target for neutralizing antibodies, this might potentially allow this variant to evade immunity.

Overall, the final efficacy calculation reflects performance against a total of 15 different variants, majority of them known to have mutations conferring increased transmissibility or immune resistance.

As shown in the geographic breakdown of the total number of sequenced cases, the diversity of variants originates primarily in Latin America, which provided the majority of newly adjudicated cases and contributed overall 155 cases to the 204 sequenced cases.

In Europe, the 49 cases we observed are strongly dominated by the Alpha strain in accordance with the general virus distribution there.

The variant overview provided on slide 9 further extends the pool of sequenced COVID-19 cases recorded in the HERALD study to look at a combined pool of adjudicated and non-adjudicated cases, in order to provide a more detailed picture of the variant dynamics within the study.

This overview is based on a total of 588 COVID-19 cases, which were accrued and sequenced within the HERALD study irrespective of the formal COVID-19 case adjudication process. This group includes the 204 adjudicated cases as well as 384 non-adjudicated cases, which occurred before the 15 day post-second vaccination cut-off and therefore did not qualify for adjudication.

While the latter group of cases therefore did not contribute to the efficacy calculation, they help to provide a more accurate and extended picture of the circulating virus variants within the study.

Overall, 29 different COVID-19 variants were identified, which cover:

- all currently designated Variants of Concern, including the Alpha, Beta, Delta, Epsilon and Gamma strain;
- Variants of Interest, including the Lambda, Iota, Zeta and B.1.621 strain;
- the B.1.1.519 strain with high prevalence in Mexico and
- three lineages related to the original virus.

In accordance with the variant mix in the group of adjudicated cases, diversity was again more pronounced in Latin America compared to Europe, where the Alpha strain dominates.

I am now on slide 10 to discuss CVnCoV efficacy data from the final analysis.

In the context of 15 different virus variants and in the predefined age group of 18 to 60, CVnCoV exhibited a favorable efficacy of overall 53 percent against any severity of disease. This includes the occurrence of more than 80 percent of mild cases, which are characterized by the occurrence of at least one – and not necessarily respiratory – symptom in combination with a positive PCR test.

In the same age group, a 77 percent protection was achieved against moderate to severe disease and full protection was shown against hospitalization or death.

Preventing hospitalization or death with a robust and widely variant-tested vaccine is an important prerequisite to support the global fight against COVID-19 and the associated burden on healthcare systems.

In the predefined age group above 60, the available data did not enable a statistically significant determination of efficacy.

On slide 11 let me now go a bit more into detail of the efficacy trends we observed in view of selected variants with higher prevalence in the pool of adjudicated and sequenced cases.

As the HERALD study was not powered to provide a statistically robust efficacy readout per strain, case numbers for the separate variants are

too low to calculate statistically robust efficacies or conduct further correlations with specific disease severities.

We therefore present the efficacy data in this table together with the corresponding case numbers detected in the placebo and vaccine arm as well as the upper and lower limit of the confidence interval to allow for a better assessment of the statistical robustness of efficacy numbers.

We were able to assess efficacy trends in the age group of 18 to 60 for the 2 prevalent Variants of Concern, the Alpha and Gamma variant as well as 2 prevalent Variants of Interest, the Lambda and the Colombia strain.

Results shown in this table indicate robust and balanced protection against the separate variants spanning a range from 42 percent observed against the B.1.621 strain originating in Colombia to 67 percent observed against the Gamma variant.

Please remember that these efficacy results are calculated against any severity of disease.

I am now on slide 12 to remind you again of the safety and reactogenicity profile of CVnCoV on the basis of the first 2,000 participants recruited within the HERALD study.

The two 12 microgram vaccinations of CVnCoV are shown to be well tolerated. As previously reported for CVnCoV, and in line with other mRNA-based COVID-19 vaccines, the majority of events were mild to moderate and accumulated around fatigue, headache, muscle pain or myalgia, and chills, and only few fever events were recorded.

We were particularly pleased to see that there was no increase in the severity of side effects after the second vaccination compared to the first vaccination – both reactogenicity profiles are comparable.

The data is further stratified according to trial participants between the age of 18 to 60 and participants above the age of 60. As expected, side-effects are generally more pronounced but still in a well-tolerated range within the group of 18- to 60-year-old study participants compared to study participants above the age of 60.

Overall, this safety profile is fully in accordance with the safety profile reported for other mRNA-based vaccines and further confirms the safe applicability of CVnCoV.

Let me now hand back the call to Franz for a short summary of next steps and key messages.

FRANZ Thank you Ulrike.

Let me quickly summarize the key messages from the present final analysis and outline the next steps.

The readout of the final analysis of the HERALD study confirmed strong public health value of CVnCoV vaccination in the predefined age group of 18 to 60, providing 77 percent protection against moderate to severe disease and full protection against hospitalization or death.

These would be satisfactory numbers when tested against a handful of the currently circulating virus variants. Against the combined, simultaneous and unprecedented influence of 15 different variants, including mainly Variants of Concern and Variants of Interest, this is truly a major achievement.

We remain fully committed to supporting the effort to end the COVID-19 pandemic, which continues to cause many thousands of deaths each day. We intend to file for regulatory approval, leveraging CVnCoV demonstrated strengths against the continuous variant dynamics and in populations where it can provide a great benefit and serve the highest unmet need.

We are in a continued and constructive dialogue with the European Medicines Agency, and data submission processes are ongoing.

In the meantime, we will further execute on the manufacturing ramp-up and build-up of our broad European manufacturing network as well as the development of our strong second-generation COVID-19 vaccine candidate, which we are co-developing in partnership with GSK and which we intend to bring into the clinic within the next months.

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 do not hesitate to contact us should you have any further questions.

Thank you and goodbye.