Scientific Presentation by CureVac Representatives to Member State Experts Nominated by the Joint Negotiation Team and [redacted]

28 September 2020

10:00 – 11:00am CET

Subject: CureVac's mRNA based vaccine candidate CVnCoV against SARS-CoV2 – Pre-Clinical and available Phase I Data Update

The Chair opened the meeting and welcomed all participants, including the representatives of CureVac who provided an update, one month on from the scientific presentation delivered to nominated experts from EU27 and Norway. CureVac representatives gave the presentation as per the post-read slides. [redacted]. CureVac CVnCoV vaccine is the vaccine with unmodified mRNA, transported into cells by lipid nanoparticles. The antigen is the full length SARS-CoV-2 Spike protein. In terms of clinical development, Phase I was launched in June 2020 in Germany (3 sites) and Belgium (1 site), over 240 participants. Partially blinded, placebo-controlled, dose-escalation study in Tuebingen, Hannover, Munich and Gent, enrolling healthy adults 18-60 years of age. Doses: 2, 4, 6 or 8, 12µg (with a boost at day29) with 48 vaccinees and 8 placebo recipients per group (less for groups >8µg). The 16µg assay was being initiated on 28 September 2020. Exploration envisaged to continue at 20µg. Participants will be followed for at least one year after the last vaccination.

CureVac announced that a reanalysis of all the samples so far is ongoing to avoid the assay variability due to different operators. [redacted] Whilst there were few instances of swelling, redness, fatigue, headache and myalgia, a cascade of increasing rates of events occurred with increasing dosages.

With regards to animal data, the hamster model was presented. The dose response to 2, 4, 6 or 8µg was measured. High virus neutralising antibodies that reach the positive control were observed that were able to decrease viral levels in the lower respiratory tract from day56 to day60. Whilst CureVac observed full protection in the lungs, in the upper respiratory tract partial protection was observed. The endpoints were protection against disease, against infection and reduction of transmission. The histopathology of the lung studies are still ongoing.

In terms of stability data for storage conditions, CureVac representatives [redacted] at 4°C instead of the previously announced 3 months, whilst long-term storage is in cold chain at -80°C. Full stability data should become available by November 2020.

Vaccine production is fully managed by CureVac, partnerships envisaged *inter alia* for Fill/Finish.

With regards to timelines, [redacted]. Phase IIa/b is planned for autumn [redacted]. Phase IIb/III trials should start by [redacted].

[redacted]
Phase II trials were starting in Panama and in Peru.

For further details, the reader is referred to the [redacted] presentation.

Q&A:

The Chair thanked for the presentation and opened the Q&A session. Certain questions were asked during the presentation but they are recorded for the purposes of these Draft Minutes as being a part of the Q&A session.

The Chair asked whether assays with 16 and 20µg mRNA would continue as planned. CureVac confirmed that the intention behind these assays [redacted].

[redacted] expressed a [redacted]

CureVac further explained they have plans to expand their panel of convalescent subjects.

[redacted] queried the usefulness of the hamster model and asked whether there were any plans to set up a transmission model since protection is much stronger if transmission is prevented. [redacted] further enquired on the state of play of NHP data. CureVac replied that the transmission model would be built [redacted] and that first draft NHP data (imaging read-outs for the lung pathology) is expected in the first half of October, thanks to the cooperation with Public Health England.

[redacted] congratulated CureVac for the considerable progress made in the last few weeks. [redacted] enquired how CureVac interprets the data [redacted]

. CureVac replied that With regards to the age grouping, CureVac explained that .

enquired whether T-cell immunogenicity data would feed into selection criteria for the dose, especially if a higher dose is to be considered. CureVac replied that they indeed aim to complete the full analysis in the next weeks and to compare with to have a good picture. The dose selection will be based on the entire dataset, but also on the reanalysis.

The Chair supported the drive for an optimised dataset and enquired whether there is any threshold for which the dose would not be sufficient. CureVac explained that the dose selection would depend entirely on the data, . The 12µg group is of a key interest and as compared to other vaccine candidates, even 16µg mRNA is a low dosage.

enquired whether Phase I data would be published soon. CureVac replied that also pre-clinical results would be seeing the public domain soon.

asked whether CureVac would be prepared to use paracetamol when going up in doses. CureVac replied affirmatively that participants are not prohibited from using anti-inflammatories. This dimension can be built into the analysis ex-post.

enquired what would be the T-cell assay for the clinical samples – peptide pools or Th1 versus Th2. CureVac replied that they can discriminate between CD4 and CD8 induction in blood.

asked whether CureVac can concentrate on specific antibodies and differentiate RBD specific antibodies. CureVac explained that .

enquired about sterilising immunities and whether the vaccine aims at achieving high risk group efficacy or herd immunity (i.e. where younger subjects can be vaccinated as well). CureVac replied that the primary endpoint is stopping the disease, followed by prevention of infection. Symptom-based swabbing will be applied.

asked whether a one-dose regimen is still an option or whether a boost is needed. CureVac elaborated that a two-dose regimen is the best solution, with a strong observed expansion after the first dose. The T-cell response specifically benefits from a vaccination boost. In the low dose cohort, a third cohort will be included to show the boost effect of the response – in the seropositive group, a good primed response can be observed.

[redacted]

The Chair enquired whether [redacted] are for the CureVac vaccine candidate or for vaccines in general. [redacted]

[redacted]

The Chair expressed appreciation for the overview on the manufacturing aspects which seemed to be on track.

[redacted]

The Chair thanked CureVac for their engagement and insightful presentation and all experts for their fruitful and constructive participation and closed the meeting.

Participants

CureVac:

[redacted] Managing [redacted]

[redacted] Supervisory Board

[redacted] Technology Officer

[redacted] Infectious Diseases

[redacted] COVID-19 Programme Lead

Member States:

[redacted] (AT)

[redacted] (AT)

[redacted] (AT)

[redacted] (DE)

[redacted] (DE)

[redacted] (ES)
[redacted] (ES)
[redacted] (FR)
[redacted] (FR)
[redacted] (FR)
[redacted] (IT)
[redacted] (IT)
[redacted] (NL)
[redacted] (NL)
[redacted] (PL)
[redacted] (SE)

European Commission:

[redacted] (EC, Chair)
[redacted] (EC)
[redacted] (EC)
[redacted] (EC)
[redacted] (EC)
[redacted] (EC)
[redacted] (EC)
[redacted] (EC)
[redacted] (EC, Minutes)