Scientific Presentation by CureVac Representatives to Member State Experts Nominated by the Steering Board

28 August 2020

14:30 - 15:30 CET

Subject: CureVac's mRNA based vaccine candidate CVnCoV against SARS-CoV2

The Chair opened the meeting and welcomed all participants, including the participants from Norway who joined this format of meetings [redacted]. CureVac representatives gave the presentation as per the previously distributed slides, highlighting their differentiation from other mRNA companies in that 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 [redacted] and Belgium [redacted]. Doses: 2, 4, 6 or 8µg (with a boost at day 28). Phase IIa/b is planned for autumn with inclusion of a cohort of >60 years of age, with an international multicenter study. Vaccine production is fully managed by CureVac, partnerships envisaged *inter alia* for Fill/Finish. For further details, the reader is referred to the PPT presentation.

Q&A:

The Chair thanked for the presentation and opened the Q&A session.

In the Q&A session, [redacted] enquired whether the offer also included injection devices, in this case needles. CureVac answered that the two syringes to dilute the formulation are part of the pack but not the syringes for actual administration [redacted].

[redacted] enquired whether CureVac plans to build its own Fill/Finish capacities. CureVac answered that they envisage [redacted].

[redacted] invited the speakers to elaborate further on the composition of the convalescent panel and [redacted] the vaccine response [redacted], based on data to date. [redacted] further enquired whether the [redacted] patients were hospitalised or not. [redacted]

The sera originates from a hospital network [redacted]. Most of the sera come from symptomatic patients. The presentation draws on preliminary assay data from 2, 4, 6µg (the data

from 8µg assays is forthcoming). oreover, CureVac highlighted that results look for induction of T-cell responses, not just neutralising antibodies (NAbs). The T-cell data is expected in , with the second dose study starting in . The data in non-human primates (NHP) will be available in .

asked whether primate data would be part of the EMA submission. CureVac explained that the data would not be ready for the advice meeting in September but that the Protocol would be shared.

enquired whether CureVac had any data on mucosal immunity (i.e. efficacy for infection prevention versus disease severity reduction). CureVac answered that they expect data –
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asked how long the follow-up of subjects is planned for in what concerns the persistence of the immune response. CureVac answered that the follow-up is envisaged for after vaccination. Based on the rabies study, the stable response was monitored after vaccination. The duration of the immune response is expected to be .

The Chair asked CureVac to elaborate on when they expect the drug substance dosage to be final. CureVac replied that they would select the dose in . Initial indications point to an 8µg formulation, as safety data seems in order. CureVac informed that the 12µg formulation is considered a back-up for which the capacity needs to be in place. The 8µg dosage shows initial good results. The 12µg is a conservative fallback but so far significant differences between the elderly and the younger vaccinees have not been observed.

The Chair asked how likely the 8µg single dose would be. CureVac answered that the study in Latin America to select the appropriate dose has started
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asked whether challenge trials in NHP were performed and whether disease enhancement was investigated. CureVac answered that

[redacted] studies are ongoing to shed more light on these elements.

The Chair thanked CureVac for their insightful presentation and all experts for their interest and active participation and closed the meeting.

Participants

CureVac:

[redacted] Managing [redacted]
[redacted], [redacted] Supervisory Board
[redacted], [redacted] Technology Officer
[redacted], [redacted] Pre-Clinical
[redacted], [redacted] Infectious Diseases
[redacted] Vice-President

Member States:

[redacted] (AT)
[redacted] (AT)
[redacted] (AT)
[redacted] (BE)
[redacted] (BE)
[redacted] (BG)
[redacted] (CZ)
[redacted] (CZ)
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[redacted] (DK)
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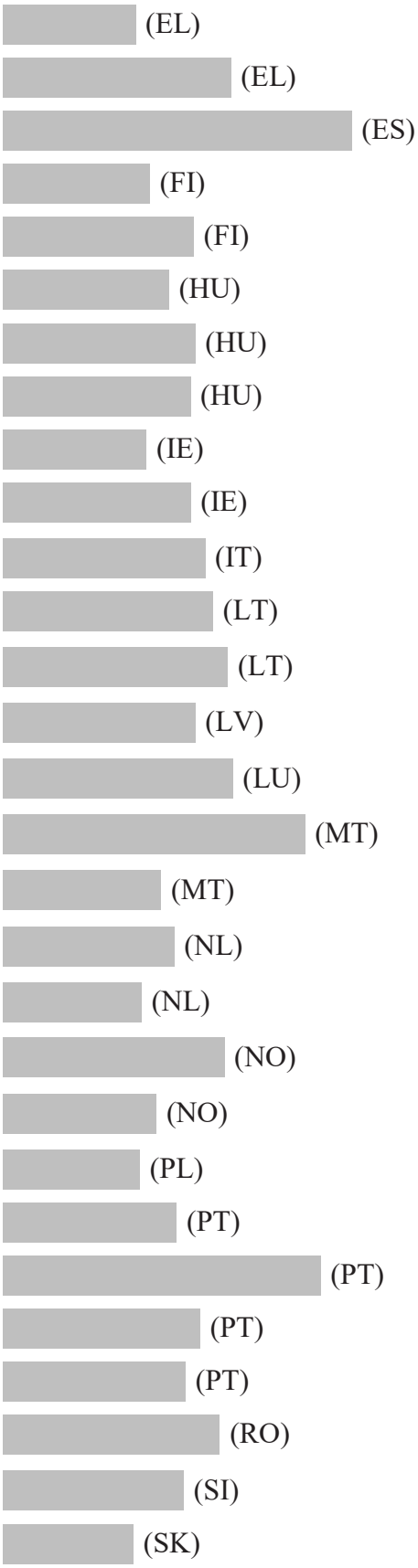
[redacted] (EE)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European Commission:

[redacted] (EC, Chair)

[redacted] (EC)

[redacted] (EC)

[redacted] (EC)

[redacted] (EC)

[redacted] (EC, Minutes)