Scientific Presentation by AstraZeneca Representatives to Experts from EU27 Nominated by the Steering Board

5 August 2020

2:00 - 3:00pm CET

Subject: AZD1222 Oxford University-AstraZeneca Partnership

The Chair welcomed participants and introduced the representatives of AstraZeneca.

The representatives of AstraZeneca delivered the presentation as per the post-read slides.

In the Q&A session, [redacted] The Chair asked whether the vaccine is a two-dose regimen.

AstraZeneca confirmed that two doses would maximise the chance of getting an efficacious read-out in the studies run. As the correlates of immune protection are not yet fully understood, two doses would be the starting point and a reassessment can take place further down the road.

[redacted] enquired about immunogenicity by age and how to best understand it.

AstraZeneca replied that information on the older population is a component of the Phase III study in the UK and that they would also be looking at T-cell responses. [redacted] more patient data would be coming through on age range and on the regimen (two doses vs. one dose). Furthermore, correlations across assays are important as well as correlates of immune protection generated. The Moderna vaccine generates more neutralising antibodies than the Oxford vaccine, hence scientifically it is very difficult to compare IC50 with IC100. Convalescent plasma samples from hospitalised patients are the only available benchmark. Overall, AstraZeneca is pleased with the antibody and T-cell response generated.

[redacted]

[redacted] asked when Member States can start immunising their populations.

AstraZeneca replied that they are expecting efficacy data from October onwards and that those who have plans in place can start immunising their populations soon thereafter.

[redacted] highlighted that according to the Lancet article[1], duration of immunity studies would be performed in vaccinees after one year. [redacted] asked whether interim studies are planned on this subject.

On the query of [redacted] on declining immunogenicity levels, AstraZeneca replied that they have been following animal data for two years and are aspiring to collect evidence over time. They are hopeful for 12 months immunogenicity but this could also extend to 24 months. The current assumptions indicate 12-18 months immunogenicity.

[redacted] and [redacted] enquired about the low upper age limit and the envisaged upper age limit in Phase III, as well as SAEs (serious adverse events).

AstraZeneca replied that for Phase III, the intended upper age limit is over 75 years of age, going all the way up without limit. On SAEs and pharmacovigilance, AstraZeneca explained that they intend to follow patients for up to two years. One cannot predict SAEs but the company would be looking out for them.

[redacted] asked about evidence for cytotoxic T-cell responses, within the T-cell compartment. In other words, if other T-cell assays have been performed apart from IFN-γ ELISPOT assays.

AstraZeneca confirmed that this is the case.

A question was asked on anti-vector anti-bodies.

AstraZeneca replied that one can immunise several times and still maintain a reaction, as in one study previously vaccinated individuals were also included. Over the life-cycle of the vaccine, they would be able to look at others, including in conjunction with an mRNA vaccine.

[redacted] asked whether AstraZeneca maintained the expectation to submit the request for marketing authorisation approval (MAA) by September 2020. She also enquired about the data presented to support the request for MAA.

[redacted]

The Chair asked a question on storage requirements.

AstraZeneca replied that the 10-dose vials are to be stored at 2-8°C. The vaccine is intended for all adults over 18 years of age.

[redacted]

[redacted]

[1] "Safety and immunogenicity of the ChAdOx1 nCoV-19 vaccine against SARS-CoV-2: a preliminary report of a phase 1/2, single-blind, randomised controlled trial": https://www.sciencedirect.com/science/article/pii/S0140673620316044

[redacted] enquired about the intended approximate percentage of participants with co-morbidities in Phase III.

AstraZeneca replied that they included adults with stable chronic conditions and later they would also be looking at patients with more significant comorbidities.

[redacted] further asked whether additional studies in non-human primate (NHP) modelling are ongoing and whether these could be made more predictive for protection in humans.

AstraZeneca replied that no further studies are planned.

[redacted] enquired whether any efficacy or safety data for patients seropositive at baseline for adenoviruses is planned.

[redacted] asked about distribution in each Member State.

AstraZeneca replied that both points are still open and under discussion. Refrigerated conditions will be required.

[redacted] asked whether any effect of antibodies that it enhances infection in vitro or in vivo was observed.

AstraZeneca replied that they had not seen any antibody-dependent enhancement (ADE). Th1 read-outs were balanced, no evidence of ADE, same as for all manufacturers.

[redacted] asked whether there is already communication by the company with the MSs that will be chosen for official batch release testing.

[redacted]

[redacted] asked about potential concerns around [redacted]

[redacted]

The Chair further asked whether they are planning for a pediatric version.

AstraZeneca replied that indeed they are planning a pediatric version [redacted]

The Chair thanked AstraZeneca for the vivid presentation and participants for their involvement and closed the meeting.

Participants

AstraZeneca:

[redacted]

Member States:

[redacted] (AT), co-Chair

[redacted] (AT)

[redacted] (AT)

[redacted] (AT)

[redacted] (BE)

[redacted] (BE)

[redacted] (BG)

[redacted] (BG)

[redacted] (CY)

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[redacted] (PT)

[redacted] (RO)

[redacted] ***(SI)***

[redacted] (SI)

[redacted] (SI)

[redacted] (SK)

[redacted] (SK)

[redacted] (SK)

European Commission :

Sandra Gallina (EC, Chair)

[redacted] (EC)

[redacted] (EC)

[redacted] (EC)

[redacted] (EC)

[redacted] (EC)

[redacted] (EC, Minutes)