

**Scientific Update by Sanofi Pasteur Representatives to Member State Experts
Nominated by the Steering Board + [REDACTED]**

17 December 2020

15:00 – 16:00 CET

Subject: COVID-19 Adjuvanted Pandemic Vaccine Clinical Development Update

The Chair opened the meeting and welcomed all participants, the representatives of Sanofi Pasteur and the experts nominated by the Steering Board + [REDACTED] and [REDACTED].

The slides were presented as per the post-read slides, explaining the [REDACTED].

In the Q&A session, [REDACTED] enquired whether the [REDACTED]

Sanofi Pasteur [REDACTED]
[REDACTED] There is no need to change the [REDACTED], only the [REDACTED] would need adjustment.

Regarding the preclinical data, [REDACTED] asked whether Sanofi Pasteur would evaluate the impact of the [REDACTED] on the [REDACTED] profile of the [REDACTED] response in more detail and whether immunisations done in the mouse model were with or without [REDACTED]. In the [REDACTED] model, a question was asked as to whether [REDACTED] was assessed.

Sanofi Pasteur replied [REDACTED]
profiles. They had looked at multiple [REDACTED] in terms of [REDACTED] data and [REDACTED], including [REDACTED]

[REDACTED] further enquired how [REDACTED] assay was performed – which stimulus and whether [REDACTED] responses were assessed in a flow-based assay.

Sanofi Pasteur replied that [REDACTED].

[REDACTED] asked how Sanofi Pasteur intends to handle SAEs (serious adverse events) in case of increasing dose levels.

Sanofi Pasteur explained that by increasing dose levels, they had not seen any SAEs, but they did see higher reactogenicity. They established that this was due to [REDACTED] – once [REDACTED] Once the [REDACTED] is optimised, the latter would improve the purity and potency of the [REDACTED] and should hence address both the immunogenicity and the reactogenicity of the vaccine.

[REDACTED] enquired whether Sanofi Pasteur would agree that in comparison with other vaccines, the clinical data presents more [REDACTED] or whether assays, for example the [REDACTED], [REDACTED].

Sanofi Pasteur answered that their GSK colleagues reported that they observed exactly what they were expecting to see from [REDACTED]. Assays are not directly comparable but a balanced immune response from [REDACTED] was established. With the support from [REDACTED] Sanofi Pasteur and GSK would be looking into correlates of protection as of [REDACTED].

[REDACTED] asked whether Sanofi Pasteur is considering that the high reactogenicity is due to a high content of host cell proteins or rather from the expression vector. She further asked how this would be improved with a better formulation or rather in the manufacturing process.

Sanofi Pasteur explained that due to scalability different purity profiles were established. [REDACTED]

[REDACTED]. For example, in the [REDACTED] trial, a much better purity profile can be reached. [REDACTED]

[REDACTED] suggested that Sanofi Pasteur plans for a [REDACTED]

Sanofi Pasteur expressed appreciation for the fact that the development of the vaccine is a race against time and that more and more placebo controlled trials are being carried out. [REDACTED]

[REDACTED] indicated that it may be difficult to demonstrate [REDACTED]

A [REDACTED] trial requires [REDACTED]

She further thanked for the presentation.

[REDACTED] enquired whether publications could be shared.

The Chair thanked all participants for their active involvement and Sanofi Pasteur for the detailed update and closed the meeting.

Participants

Sanofi Pasteur

[REDACTED], Sanofi Pasteur
[REDACTED], Sanofi Pasteur
[REDACTED], [REDACTED], Sanofi Pasteur

Member States:

[REDACTED] (AT)
[REDACTED] (AT)
[REDACTED] (BE)
[REDACTED] (CY)
[REDACTED] (CZ)
[REDACTED] (CZ)
[REDACTED] (DE)
[REDACTED] (DK)
[REDACTED] (EE)
[REDACTED] (ES)
[REDACTED] (ES)
[REDACTED] (FI)
[REDACTED] (FR)
[REDACTED] (FR)
[REDACTED] (HR)
[REDACTED] (HR)
[REDACTED] (HR)
[REDACTED] (HU)
[REDACTED] (HU)
[REDACTED] (HU)
[REDACTED] (IC)

[REDACTED] (IE)
[REDACTED] (IE)
[REDACTED] (IT)
[REDACTED] (IT)
[REDACTED] (LT)
[REDACTED] (LU)
[REDACTED] (LV)
[REDACTED] (MT)
[REDACTED] (NL)
[REDACTED] (NL)
[REDACTED] NL)
[REDACTED] (PL)
[REDACTED] (PT)
[REDACTED] (PT)
[REDACTED] (PT)
[REDACTED] (PT)
[REDACTED] (NO)
[REDACTED] (SE)

European Commission:

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