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Peter

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Wednesday, August 25, 2021 9:03 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: FW: [EXTERNAL] RE: Janssen COVID Vaccine - recent conversations with HHS - upcoming public statements

Dear Peter,

Over the last couple of days, Janssen has bombarded us with emails regarding their booster dose studies. Karin van Baelen emailed me, Ruta Walawalkar emailed Sudhakar and also, Karin informed me that Mathai Mammen has spoken to you August 23. I have discussed the requests (copied below) Jansen made with DVRPA leadership and my response to Karin van Baelen is stated in red:

Janssen is requesting for an opportunity to have a discussion with the Agency on a potential data package that could support a booster submission as an EUA Amendment.

- Proposed supportive material: To expedite this engagement, Janssen proposes to submit a slide presentation with data and questions to the Agency to support the meeting and forego submission of a formal briefing document. Would this be agreeable?
  No, please submit a formal briefing document for our review that contains updated immunogenicity data from COV1001 and COV2001. We are also interested in the data from COV3009 (2-dose efficacy) as these data will further inform the need for a booster dose with your vaccine.

- Proposed timeline: Additional immunogenicity data from COV1001 and COV2001 will become available in the next weeks (August-September 2021). Furthermore, the readouts for the end of the double-blind phase of our pivotal Phase 3 studies COV3001 (1-dose efficacy) and COV3009 (2-dose efficacy) are expected in the same timeframe and will further support discussion on potential booster strategies. Janssen suggests to have the meeting once these data have become available (exact date to be determined).
  We agree that a meeting can take place once these data are available.

Peter, I want to make sure (in case you talked to Mathai) that our messages are aligned.

I am also very concerned that companies (such as Pfizer and Janssen) are trying to put pressure on OVRR by way of PR. We need to be given time to consider their data and cannot be pushed by these companies and, for that matter the Administration, who try to impose timeless that make no sense (e.g., Sep 20).

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Also, I need to let you know that OVRR, for homologous booster studies, will apply the same criteria as for the heterologous booster studies (i.e., as per our guidance regarding VOCs). I also discussed this approach with colleagues at EMA and HC and there is agreement. It appears that at least Pfizer's data will not be aligned with this approach and the "n" they have is grossly insufficient. Obviously, we have to review the data but we have taken a peak and have serious concerns.

Lastly, and this is my personal opinion, data we have seen so far from various companies (Pfizer, Janssen, Moderna) appear to suggest that boosters are not needed.
Marion

From: Van Baelen, Karin [JRDBE] <KVBAELEN@its.jnj.com>
Sent: Tuesday, August 24, 2021 4:16 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: [EXTERNAL] RE: Janssen COVID Vaccine - recent conversations with HHS - upcoming public statements

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Dear Marion,

As promised, I am sharing the manuscript that was submitted today and the press release. We plan to issue it on the newswire at 6:45 am ET tomorrow morning (Wed, August 25). Thanks for keeping this confidential until posted.

We are sharing the same information with the RPM.
I am looking forward to our discussion.

Kind regards
Karin

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: dinsdag 24 augustus 2021 1:38
To: Van Baelen, Karin [JRDBE] <KVBAELEN@its.jnj.com>
Subject: RE: [EXTERNAL] Janssen COVID Vaccine - recent conversations with HHS - upcoming public statements

Dear Karin,
Thank you for the update. I will discuss with my team and will be in touch. Give me a couple of days, please.