From: [redacted] [JACDE] [redacted] @its.jnj.com>
Sent: 11 June 2020 23:11
To: GAUER Celine (SG-RECOVER)
Subject: Clarification on Term Sheet.

Categories: TO REGISTER

Dear Ms. Gauer,

Thanks again to you and your colleagues for the constructive meeting yesterday. We hope you agree that the data for our vaccine continues to look promising. Based on the available data until date, we believe that our COVID-19 vaccine will contribute significantly to addressing the current global health crisis. As [redacted] pointed out in his presentation, more critical data is expected over the coming weeks.

As discussed during our meeting we will work on a [redacted], but before moving forward we would like to clarify a few points to make sure we have a correct understanding of the proposed structure of our partnership, and highlight again a few points that will be critically important for Johnson & Johnson.

1. Advance Purchase Agreement ("APA")
    - Janssen and the EC would enter into an APA for Janssen's COVID-19 vaccine whereby the EC would represent all EU Member States.
    - EC would procure for the EU Member States under a Joint Purchasing Agreement, i.e. Janssen will not enter in separate agreements with individual Member States. Could you please confirm that this is an accurate assumption?
    - Under the APA:
        i. We would agree on a certain volume of vaccines (the "Volume") that would be purchased at an agreed price. Note: [redacted] not-for-profit price (NFP price). The EC will confirm the Volume later in the week.
        ii. The "Total Value" of the agreement would be the Volume multiplied by the NFP price.
        iii. EC would procure the Volume at the NFP price during an agreed period of time (the [redacted]), and Janssen would fulfill the purchase orders according to an agreed schedule.
        iv. EC would make a down-payment [redacted]
        v. [redacted]

2. Under these exceptional circumstances an appropriate regulatory framework will be required that allows for the use of the Vaccine prior to full/traditional approval. Based on our discussions we understand that EC will not enact new legislation that would allow for an Emergency Use Authorization (a mechanism that was put in place by the US Food and Drug Administration, FDA). You indicated that a Conditional Approval would be an appropriate mechanism. Given the importance of the matter, we will need to discuss this further with our regulatory experts to fully understand the impact both in terms of approval timelines and R&D budgets and would welcome any further discussions with the relevant EC experts as well.

3. Finally, we were not entirely clear on the EC's position on the matter of liability protection and compensation mechanisms. We would welcome a follow-up discussion on this topic with the appropriate representatives of the EC, to take you through our concerns and the suggested way forward to address this challenge. We are determined to making our vaccine available to the world in an expedited manner at a not for profit basis during the pandemic period and a resolution of this topic will be essential for us to move forward.

May I kindly ask that you confirm our correct understanding of the APA mechanism above and let us know at your earliest convenience when we could plan a call between legal experts.

Kind regards,