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Sent: jeudi 24 septembre 2020 11:44
To: BUCHER Anne (SANTE)
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Subject: Johnson & Johnson COVID-19 vaccine development update; launch of Phase 3 clinical trials
Categories: A voir [REDACTED]



Johnson & Johnson begins Phase 3 clinical trials of single-dose COVID-19 vaccine candidate, emphasizing representation of populations that have been disproportionately impacted by the pandemic.

Esteemed Director General,

I sincerely hope this letter finds you and your loved ones healthy and well.

As I appreciate your crucial role in working to advance the well-being of European citizens, I would like to provide you with updated information regarding Johnson & Johnson's efforts to develop a **safe and effective vaccine against COVID-19**:

The launch of our **large-scale, pivotal, multi-country Phase 3 trial (ENSEMBLE)** for our COVID-19 vaccine candidate, JNJ-78436735 which is being developed by our Janssen Pharmaceutical Companies.

We are sharing this with you to ensure you have complete information directly from us.

The initiation of the ENSEMBLE trial follows **positive interim results from our Phase 1/2a clinical study**, which demonstrated that the safety profile and immunogenicity after a **single vaccination** with JNJ-78436735 were supportive of further development. Based on these results and in discussions with regulators, ENSEMBLE will enrol up to **60,000 volunteers across three continents** and will study the safety and efficacy of a single vaccine dose versus placebo in preventing COVID-19.

The Phase 3 study aims to enroll participants in Argentina, Brazil, Chile, Colombia, Mexico, Peru, South Africa and the

United States. In order to evaluate the effectiveness of Janssen's COVID-19 vaccine, countries and clinical trial sites which have a high incidence of COVID-19 and the ability to achieve a rapid study initiation have been selected.

We will develop and test its COVID-19 vaccine candidate in accordance with high ethical standards and sound scientific principles. We are also committed to transparency and sharing information related to the Phase 3 study, including details of our study protocol.

As the world's largest healthcare company, Johnson & Johnson has continued scaling up its manufacturing capacity and remains on track to meet the goal of providing a [REDACTED]. We are committed to bringing an affordable vaccine to the public on a not-for-profit basis for emergency pandemic use and anticipate the first batches of a COVID-19 vaccine to be available for emergency use authorization [REDACTED].

The Janssen COVID-19 vaccine candidate leverages our [AdVac® technology platform](#), which was also used to develop and manufacture Janssen's recently approved Ebola vaccine and construct our Zika, RSV, and HIV vaccine candidates. The AdVac® platform has been used to vaccinate more than [REDACTED] people to date across Janssen's investigational vaccine programs. Additionally, with this platform, the vaccine remains stable at 2-8° C for three months, making it compatible with standard vaccine distribution channels.

In terms of global access, Johnson & Johnson is in ongoing discussions with many stakeholders, including national governments and global organizations, as part of its efforts to meet its commitment to make the vaccine candidate accessible globally, provided the vaccine is demonstrated to be safe and effective. We will be sharing additional updates in due course on global availability of the vaccine.

Built on a legacy of purpose-driven actions and a commitment to diversity and inclusion, the Company aims to achieve representation of populations that have been disproportionately impacted by the pandemic in the implementation of its COVID-19 Phase 3 trial programme.

For more information, please don't hesitate to reach out to us.

As always, our team remains available to answer any questions you may have and we remain relentlessly committed to working together for a healthy Europe.

