

From: [REDACTED]
Sent: 04 August 2020 16:05
To: [REDACTED]
Cc: RYAN John-F (SANTE); SEYCHELL Martin (DEVCO); RYS Andrzej Jan (SANTE);
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] BUCHER Anne (SANTE); [REDACTED]
Subject: RE: Study: Johnson and Johnson vaccine successfully prevents COVID-19 infections in monkeys

Dear [REDACTED]

thank you for your e-mail of 3 August, in which you inform about important positive developments and future plans regarding your company's efforts to develop the COVID-19 vaccine.

Best regards,

[REDACTED]

From: [REDACTED]
Sent: Monday, August 3, 2020 11:32 AM
To: BUCHER Anne (SANTE) <Anne.Bucher@ec.europa.eu>
Cc: RYAN John-F (SANTE) <John-F.Ryan@ec.europa.eu>; SEYCHELL Martin (DEVCO) <Martin.SEYCHELL@ec.europa.eu>; RYS Andrzej Jan (SANTE) <Andrzej.RYS@ec.europa.eu>;
[REDACTED]
[REDACTED]
[REDACTED]

Subject: Study: Johnson and Johnson vaccine successfully prevents COVID-19 infections in monkeys



WORLDWIDE GOVERNMENT
AFFAIRS & POLICY

Johnson & Johnson begins in-person clinical trials of single-dose COVID-19 vaccine candidate in Belgium in July, as study published in *Nature* shows promising pre-clinical primates. Plans are underway for a Phase 2 study in the **Netherlands, Spain, Germany**. Phase 1 trials are to commence in September, emphasizing representation of populations that have been disproportionately impacted by the pandemic.

Esteemed Director General,

I hope this letter finds you and yours well during these challenging times.

I am writing to update you on important positive developments regarding our efforts to develop a **safe and effective vaccine for COVID-19**.

The prestigious scientific journal [*Nature*](#) has published a study that shows Johnson & Johnson's SARS-CoV-2 vaccine candidate, named Ad26.COV2.S, recombinant, demonstrates robust protection in pre-clinical studies. The study, published 30 July, found that **a single dose of the company's investigational vaccine elicits a strong immune response against infection with SARS-CoV-2, completely protecting the lungs from the virus in non-human primates in the pre-clinical study.**

Based on the strength of the data, **Phase 1/2a "first-in-human" clinical trials in healthy volunteers commenced in July in Belgium and the U.S.** Plans are also underway for a **Phase 2 study** in the **Netherlands, Spain and Germany**.

As we work to do our part in the global effort to end the COVID-19 pandemic, we are excited to see these promising data because they show our vaccine candidate generated a strong antibody response and provided clinical protection with a **single dose**.

The findings give us confidence as we progress our vaccine development while **upscaling global manufacturing capacity**. We have ramped up our **R&D** processes to unprecedented levels and our teams are working tirelessly to expand our manufacturing capacity in **multiple countries**.

"I'm pleased to report that data from a pre-clinical study published in the journal Nature show that a single dose of Johnson & Johnson's lead COVID-19 vaccine candidate elicited a robust immune response as demonstrated by neutralizing antibodies that protects against infection with SARS-CoV-2. The data support our recent initiation of a Phase 1/2a first-in-human clinical trial; the first healthy volunteer received an injection of the investigational vaccine last week in Belgium"

We are moving swiftly with **patient safety at the center of all we do**. The Phase 1/2a trial will evaluate the reactogenicity (expected reactions to vaccination, such as swelling or soreness), and immunogenicity in more than 1,000 healthy adults aged 18 to 55 years, as well as adults aged 65 years and older. These first-in-human trials will take a robust approach to evaluate both one- and two-dose regimens of the vaccine candidate.

The company is in discussions with partners to move into pivotal **Phase 3 trials in September** of the single dose versus placebo, pending the interim data of the Phase 1 and 2 trials and approval of regulators. We are planning to conduct a parallel Phase 3 clinical trial of a two-dose regimen versus placebo.

J&J will emphasize representation of **populations that have been disproportionately impacted by the pandemic** in its designs and implements its COVID-19 Phase 3 trial program, making our COVID-19 vaccine accessible to populations at greatest risk and where it could provide the greatest good, according to our vaccine's profile.

As we collectively battle this pandemic, we remain deeply committed to our goal of providing a safe and effective vaccine to the world. We know that, if successful, our vaccine can be rapidly developed, produced on a large scale and delivered around the world. **Our goal is to supply more than one billion doses globally through the end of 2021, provided the vaccine is safe and effective.** We are committed to bringing an affordable COVID-19 vaccine to the public on a **not-for-profit** basis for emergency pandemic use and will continue to work with local and international health authorities, governments, regulators and NGOs on broad and timely access to our COVID-19 healthcare solutions.

J&J's fundamental responsibility is to provide patients, consumers and healthcare workers with products that are as effective and safe as possible. We take an evidence- and science-based, ethics- and values-driven approach to vaccine development, putting patient and consumer wellbeing first and foremost in our decision making and actions, with an emphasis on transparency.

Please don't hesitate to reach out to me for more information on this progress and our broader efforts to combat the pandemic. Our team remains available to answer any questions you may have.

Johnson & Johnson was built for times like these and we remain relentlessly committed to working together to protect a healthy Europe.

Sincerely,

Johnson & Johnson

