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 From: Office Of [REDACTED] [JRDBE]  
 Sent: Fri 1/29/2021 2:24:15 PM  
 Subject: J&J Announces Topline Phase 3 Data for COVID-19  
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[JNJ\\_FINAL COVID-19 Ph3 ENSEMBLE ToplineData Press Release .pdf](#)



January 29, 2020

**Important Update on our COVID-19 Vaccine Program**

Dear Minister of Health Jonge,

Johnson & Johnson is working around the clock to deliver a potential solution to help end the COVID-19 pandemic. As we strive to protect people and communities from the novel coronavirus, we are advancing a single-dose vaccine candidate that is in development at our Janssen Pharmaceutical Companies. Pending clinical trials and regulatory authorizations, we are committed to providing the vaccine on a not-for-profit basis, globally, for emergency pandemic use.

**Today, we announced topline safety and efficacy data from our Phase 3 global clinical trial for the Janssen single-dose vaccine candidate.** The ENSEMBLE trial enrolled approximately 45,000 participants across eight countries: the United States, Argentina, Brazil, Chile, Colombia, Mexico, Peru and South Africa. Full details are in the enclosed press release, but in summary these data show that:

- Janssen's COVID-19 vaccine candidate was **66% effective overall in preventing moderate to severe COVID-19**, 28 days after vaccination, among all participants from different geographies and including those infected with an emerging viral variant.
- The vaccine candidate was **85% effective in preventing severe disease across all regions studied**, 28 days after vaccination in all adults 18 years and older.
- The Janssen vaccine candidate demonstrated **complete protection against COVID-related hospitalization and death.**
- A review of adverse events indicated that a single-dose of Janssen's COVID-19 vaccine candidate was **generally well-tolerated and did not report any significant safety concerns** relating to the vaccine.

These topline results with a single-shot COVID-19 vaccine candidate represent a promising moment. The potential to significantly reduce the burden of severe disease, by providing an effective and well-tolerated vaccine with just one immunization, is a critical component of the global public health response. A one-shot vaccine is considered by the World Health Organization to be the best option in pandemic settings, enhancing access, distribution and compliance. Eighty-five percent efficacy in preventing severe COVID-19 disease and prevention of COVID-19-related medical interventions will potentially protect hundreds of millions of people from serious and fatal outcomes of COVID-19. It also offers the hope of helping ease the huge burden placed on healthcare systems and communities.

Now, our focus intensifies on the complex challenge of vaccine production and distribution. As we move forward to regulatory filings, to ensure broad access to the Janssen COVID-19 vaccine, we continue to build our global supply network and scale up production of the vaccine to achieve our goal of delivering at a rate of one billion doses per year by the end of 2021.

We continue to be in ongoing discussions with many stakeholders, including national governments and other organizations, regarding access arrangements for the Janssen vaccine, and welcome any questions you may have. We appreciate your ongoing interest in Johnson & Johnson's efforts to combat COVID-19, and will continue to keep you updated.

Sincerely,

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