



## News Release

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## **Johnson & Johnson Announces Submission of European Conditional Marketing Authorisation Application to the EMA for its Investigational Janssen COVID-19 Vaccine Candidate**

**NEW BRUNSWICK, N.J., 16 February 2021** – Johnson & Johnson (NYSE: JNJ) (the Company) today announced that Janssen-Cilag International N.V., has submitted a conditional Marketing Authorisation Application (cMAA) to the European Medicines Agency (EMA) seeking authorisation for its investigational single-dose Janssen COVID-19 vaccine candidate. The submission is based on topline efficacy and safety data from the Phase 3 ENSEMBLE clinical trial.<sup>1</sup>

“Throughout Europe, there remains an urgent need for additional COVID-19 vaccines, and today’s submission is a significant step forward in ensuring the European Union has another option to help reduce the impact the pandemic has had in Europe and around the world,” said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer at Johnson & Johnson.

Once a conditional Marketing Authorisation has been granted, the Company must fulfil specific obligations within defined timelines, including the supply of additional data.

The Company announced in December it had initiated a rolling submission with the EMA for its investigational Janssen COVID-19 vaccine,<sup>2</sup> enabling the EMA to review data as they become available. In addition, rolling submissions for the investigational single-dose COVID-19 vaccine have been initiated in several countries worldwide and with the World Health Organization (WHO). The Company filed for Emergency Use Authorization (EUA) in the United States on 4 February 2021.<sup>3</sup>

### **Janssen's investigational COVID-19 vaccine**

The Janssen investigational COVID-19 vaccine leverages the Company's AdVac® vaccine platform, which was also used to develop and manufacture Janssen's European Commission-approved Ebola vaccine regimen and construct its investigational Zika, RSV, and HIV vaccines.<sup>4</sup>

### **Phase 3 ENSEMBLE study design**

The Phase 3 ENSEMBLE study is a randomised, double-blind, placebo-controlled clinical trial in adults 18 years old and older.<sup>5</sup> The study was designed to evaluate the safety and efficacy of the Janssen investigational vaccine in protecting against both moderate and severe COVID-19 disease, with assessment of efficacy as of day 14 and as of day 28 as co-primary endpoints.<sup>6</sup>

The trial, conducted in eight countries across three continents, includes a diverse and broad population.<sup>1,5</sup>

For more information on the Company's multi-pronged approach to helping combat the pandemic, visit: <https://www.janssen.com/emea/our-focus/infectious-diseases-vaccines/respiratory-infections/covid-19>.

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### **About Johnson & Johnson**

At Johnson & Johnson, we believe good health is the foundation of vibrant lives, thriving communities and forward progress. That's why for more than 130 years, we have aimed to keep people well at every age and every stage of life. Today, as the world's largest and most broadly-based healthcare company, we are committed to using our reach and size for good. We strive to improve access and affordability, create healthier communities, and put a healthy mind, body and environment within reach of everyone, everywhere. We are blending our heart, science and ingenuity to profoundly change the trajectory of health for humanity. Learn more at [www.Janssen.com/EMEA](http://www.Janssen.com/EMEA). Follow us at @JanssenEMEA.

### **About the Janssen Pharmaceutical Companies of Johnson & Johnson**

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension. Learn more at [www.Janssen.com/EMEA](http://www.Janssen.com/EMEA). Follow us at @JanssenEMEA.

### **Notice to Investors Concerning Forward-Looking Statements**

*This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding development of a potential preventive vaccine for COVID-19. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of the Janssen Pharmaceutical Companies, and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success;*

*manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 29, 2019, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at [www.sec.gov](http://www.sec.gov), [www.jnj.com](http://www.jnj.com) or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.*

## REFERENCES

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- 6 Johnson & Johnson. COVID-19 Phase 3 study clinical protocol. Available at: <https://www.jnj.com/coronavirus/covid-19-phase-3-study-clinical-protocol>. Last accessed: February 2021.