



## News Release

### Media Contacts:

Jake Sargent  
+1 202-569-5086  
JSargen3@its.jnj.com

Seema Kumar  
+1 908-405-1144  
SKumar10@its.jnj.com

Katie Buckley  
+44 7900-655-261  
KBuckle8@its.jnj.com

### Investor Relations:

Chris DeLOrefice  
+1 732-524-2955

Jennifer McIntyre  
+1 732-524-3922

## **Johnson & Johnson Announces Submission to World Health Organization for Emergency Use Listing of Investigational Single-Shot Janssen COVID-19 Vaccine Candidate**

**NEW BRUNSWICK, N.J., February 19, 2021**– Johnson & Johnson (NYSE: JNJ) (the Company) announced that Janssen-Cilag International N.V. has submitted for Emergency Use Listing (EUL) to the World Health Organization (WHO) for the investigational single-dose Janssen COVID-19 vaccine candidate. The data package delivered today includes interim efficacy and safety results from the Phase 3 ENSEMBLE clinical trial. The Company's rolling submission of clinical data to WHO is now complete.

"Our filing with the World Health Organization marks another important step in our effort to combat COVID-19 and also in our unwavering commitment to equitable access," said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer of Johnson & Johnson. "If we are to end the global pandemic, life-saving innovations like vaccines must be within reach for all countries."

The EUL procedure streamlines the process by which new or unlicensed products can be assessed for use during public health emergencies by governments and UN procurement agencies. The EUL process expedites access to such products in many countries around the world and is also a prerequisite to supply vaccines to the new COVAX Facility, a global mechanism for pooled procurement and distribution of COVID-19 vaccines in 190 participating countries, including 92 lower-income countries.

In December 2020, the Company entered into an [agreement in principle](#) with Gavi, the Vaccine Alliance (Gavi) in support of the COVAX Facility. The Company and Gavi expect to enter into an Advance Purchase Agreement (APA) that would provide up to 500 million doses of the Janssen vaccine to COVAX through 2022.

### **Commitment to Equitable Access**

Equitable access is at the forefront of Johnson & Johnson's COVID-19 response. The Company's single-dose vaccine candidate and its compatibility with standard vaccine distribution channels align with WHO's recommendations for medical interventions in a pandemic setting, which emphasize ease of distribution, administration and compliance.

The Company is committed to ensuring global access to its COVID-19 vaccine candidate on a not-for-profit basis during the acute phase of the pandemic. In September 2020, Johnson & Johnson joined other life sciences companies and the Bill & Melinda Gates Foundation in [signing an unprecedented communiqué](#) which outlined a steadfast commitment to facilitating equitable access to the innovations being developed to fight the pandemic.

### **Regulatory Filings**

The Company [filed for Emergency Use Authorization \(EUA\)](#) in the United States on February 4, 2021 and [submitted a Conditional Marketing Authorisation Application \(cMAA\)](#) in the European Union on February 15, 2021. In addition, rolling submissions for the investigational single-dose COVID-19 vaccine have been initiated in several countries worldwide. The Company will continue to provide data on an ongoing basis in support of WHO prequalification for the Janssen COVID-19 vaccine candidate.

### **Manufacturing and Supply Chain Information**

The Janssen investigational vaccine is compatible with standard vaccine distribution channels. If authorized, Janssen's investigational single-dose vaccine is estimated to remain stable for two years at -20°C (-4°F), at least three months of which can be stored in most standard refrigerators at temperatures of 2°-8°C (36°F-46°F).

### **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.

### **Phase 3 ENSEMBLE Study Design**

The Phase 3 ENSEMBLE study is a randomized, double-blind, placebo-controlled clinical trial in adults 18 years old and older. The trial, conducted in eight countries across three continents, includes a diverse and broad population. 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. The Company announced [topline efficacy and safety data](#) from ENSEMBLE on January 29, 2021.

For more information on the Company's multi-pronged approach to helping combat the pandemic, visit: [www.jnj.com/coronavirus](http://www.jnj.com/coronavirus).

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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.jnj.com](http://www.jnj.com). Follow us at [@JNJNews](https://twitter.com/JNJNews).

**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](http://www.janssen.com). Follow us at [@JanssenGlobal](https://twitter.com/JanssenGlobal).

**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.*

