



## News Release

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## **Johnson & Johnson Single-Shot COVID-19 Vaccine Granted Emergency Use Listing by the World Health Organization**

*Data have demonstrated vaccine protects against COVID-19 related hospitalization and death in broad geographic regions, including those with variants of significant concern<sup>1</sup>*

*Available on not-for-profit basis for emergency pandemic use*

*Compatible with standard vaccine storage, distribution channels, enabling delivery to remote areas*

**NEW BRUNSWICK, N.J., March 12, 2021**– Johnson & Johnson (NYSE: JNJ) (the Company) today announced that the World Health Organization (WHO) has issued Emergency Use Listing (EUL) for its single-shot COVID-19 vaccine, developed by the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen), to prevent COVID-19 in individuals 18 years of age and older.

Data from the Phase 3 ENSEMBLE study showed that the Johnson & Johnson COVID-19 vaccine was well tolerated and demonstrated a 67 percent reduction in symptomatic COVID-19 disease in participants who received the vaccine in comparison to participants given the placebo. The onset of protection was observed from day 14 and was maintained 28 days post-vaccination.

The data also demonstrated the vaccine was 85 percent effective in preventing severe disease across all regions studied, and showed protection against COVID-19 related hospitalization and death across countries with different variants, beginning 28 days after vaccination.<sup>1</sup> Variants observed in an ongoing analysis in the ENSEMBLE study

included the B.1.351 variant which was identified in 95 percent of the COVID-19 cases in South Africa.

"From the beginning of the pandemic, we have worked to develop and deliver a vaccine that could protect the health of people everywhere, and today's milestone represents significant progress toward ensuring global access to our single-shot vaccine," said Alex Gorsky, Chairman and Chief Executive Officer at Johnson & Johnson. "We are moving forward with urgency and purpose to meet our commitments to the global community as we do all we can to help end the pandemic."

The EUL procedure streamlines the process by which new or unlicensed products can be assessed for use during public health emergencies by governments and United Nations 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.

"The WHO listing of our single-shot COVID-19 vaccine advances our pledge to help stem this pandemic and our unwavering commitment to equitable access," said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer at Johnson & Johnson. "Achieving this important prerequisite for distributing our vaccine through the COVAX Facility which is co-led by Gavi is a major step forward in making our vaccine accessible for all."

In December 2020, Johnson & Johnson entered into an [agreement in principle](#) with Gavi, the Vaccine Alliance (Gavi) in support of the COVAX Facility. Johnson & Johnson and Gavi expect to enter into an Advance Purchase Agreement (APA) that would provide up to 500 million doses of the Company's vaccine to COVAX through 2022.<sup>2</sup>

"A single-shot COVID-19 vaccine that can be distributed and stored using established supply chains has the potential to be very meaningful in the face of this global pandemic," said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development at Johnson & Johnson. "In addition, the clinical data shared with WHO that informed the Emergency Use Listing demonstrated protection against disease across countries with multiple variants."

### **Commitment to Equitable Access**

Equitable access is at the center of Johnson & Johnson's COVID-19 response. The Johnson & Johnson single-shot 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 the Johnson & Johnson single-shot COVID-19 vaccine candidate on a not-for-profit basis for emergency pandemic use. 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.<sup>3</sup>

### **Regulatory Filings**

Johnson & Johnson received [Emergency Use Authorization \(EUA\) in the United States](#) on February 27<sup>4</sup> following a [unanimous vote](#) by the U.S. Food and Drug Administration's Vaccines and Related Biological Products Advisory Committee on February 26, 2021.<sup>5</sup> The Company's single-shot COVID-19 vaccine was also granted

Interim Order authorization in [Canada on March 5, 2021](#)<sup>6</sup> and [Conditional Marketing Authorization](#) (CMA) in the European Union on March 11, 2021.<sup>7</sup>

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

The Johnson & Johnson COVID-19 single-shot vaccine is compatible with standard vaccine storage and distribution channels enabling delivery to remote areas.<sup>4</sup> The vaccine is estimated to remain stable for two years at -25 to -15°C, and a maximum of three months of which can be at routine refrigeration at temperatures of 2°-8°C.<sup>4,8</sup> This enables the vaccine to be shipped using the same cold chain technologies used to transport other medicines and vaccines in routine use.<sup>4,9</sup>

### **Johnson & Johnson's COVID-19 Vaccine**

The Johnson & Johnson COVID-19 vaccine uses the [AdVac® vaccine platform](#), a proprietary technology that 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>6</sup>

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

The Phase 3 [ENSEMBLE](#) study is a randomized, double-blind, placebo-controlled clinical trial in individuals 18 years of age and older.<sup>10</sup> The study was designed to evaluate the safety and efficacy of the Company's vaccine candidate 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>11</sup> The study enrolled a total of 43,783 participants.

The trial, conducted in eight countries across three continents,<sup>10</sup> includes a diverse and broad population of which 34 percent of participants were over age 60.<sup>1</sup> Forty-one percent of participants in the study had comorbidities associated with an increased risk for progression to severe COVID-19.<sup>1</sup>

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](#).

### **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](#).

## **Cautions 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 January 3, 2021, 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.*

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<sup>1</sup> Janssen. Johnson & Johnson Announces Single-Shot Janssen COVID-19 Vaccine Candidate Met Primary Endpoints in Interim Analysis of its Phase 3 ENSEMBLE Trial. Available at: [https://www.janssen.com/emea/sites/www\\_janssen\\_com\\_emea/files/johnson\\_johnson\\_announces\\_single-shot\\_janssen\\_covid-19\\_vaccine\\_candidate\\_met\\_primary\\_endpoints\\_in\\_interim\\_analysis\\_of\\_its\\_phase\\_3\\_ensemble\\_trial.pdf](https://www.janssen.com/emea/sites/www_janssen_com_emea/files/johnson_johnson_announces_single-shot_janssen_covid-19_vaccine_candidate_met_primary_endpoints_in_interim_analysis_of_its_phase_3_ensemble_trial.pdf)  
Last accessed: March 2021.

<sup>2</sup> Johnson & Johnson. Johnson & Johnson Announces Agreement in Principle with Gavi to Supply Janssen's COVID-19 Vaccine Candidate to Lower-Income Countries in 2021. Available at: <https://www.jnj.com/our-company/johnson-johnson-announces-agreement-in-principle-with-gavi-to-supply-janssens-covid-19-vaccine-candidate-to-lower-income-countries-in-2021>. Last accessed: March 2021.

<sup>3</sup> Johnson & Johnson. Johnson & Johnson Joins Other Companies in Signing a Landmark Communiqué on Expanded Global Access for COVID-19. Available at: <https://www.jnj.com/latest-news/johnson-johnson-signs-communique-on-expanded-global-access-for-covid-19-vaccines>. Last accessed: March 2021.

<sup>4</sup> Johnson & Johnson. Johnson & Johnson COVID-19 Vaccine Authorized by U.S. FDA For Emergency Use - First Single-Shot Vaccine in Fight Against Global Pandemic. Available at: <https://www.jnj.com/johnson-johnson-covid-19-vaccine-authorized-by-u-s-fda-for-emergency-use-first-single-shot-vaccine-in-fight-against-global-pandemic>. Last accessed: March 2021.

<sup>5</sup> Johnson & Johnson. Johnson & Johnson Single-Shot COVID-19 Vaccine Candidate Unanimously Recommended for Emergency Use Authorization by U.S. FDA Advisory Committee. Available at: <https://www.jnj.com/johnson-johnson-single-shot-covid-19-vaccine-candidate-unanimously-recommended-for-emergency-use-authorization-by-u-s-fda-advisory-committee>

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[recommended-for-emergency-use-authorization-by-u-s-fda-advisory-committee](#). Last accessed: March 2021.

<sup>6</sup> Johnson & Johnson. Johnson & Johnson COVID-19 Vaccine Granted Authorization under Interim Order by Health Canada For Emergency Use. Available at: <https://www.jnj.com/johnson-johnson-covid-19-vaccine-granted-authorization-under-interim-order-by-health-canada-for-emergency-use>. Last accessed: March 2021.

<sup>7</sup> Johnson & Johnson. Johnson & Johnson Single-Shot COVID-19 Vaccine Granted Conditional Marketing Authorization by European Commission. Available at: <https://www.jnj.com/johnson-johnson-single-shot-covid-19-vaccine-granted-conditional-marketing-authorization-by-european-commission>

<sup>8</sup> Custers, J., Kim, D., et al. Vaccines based on replication incompetent Ad26 viral vectors: Standardized template with key considerations for a risk/benefit assessment. Vaccine. 2020.

<sup>9</sup> ClinicalTrials.gov. A study of Ad26.COV2.S for the Prevention of SARS-CoV-2-Mediated COVID-19 in Adult Participants (ENSEMBLE). Available at: <https://clinicaltrials.gov/ct2/show/NCT04505722>. Last accessed: March 2021.

<sup>10</sup> ClinicalTrials.gov. A study of Ad26.COV2.S for the Prevention of SARS-CoV-2-Mediated COVID-19 in Adult Participants (ENSEMBLE). Available at: <https://clinicaltrials.gov/ct2/show/NCT04505722>. Last accessed: March 2021.

<sup>11</sup> 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: March 2021.