

This statement has been adapted for audiences in the EMEA region.



**News Release**

**Media Contacts:**

Jake Sargent  
+1 732-524-1090  
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

**Positive New Data for Johnson & Johnson Single-Shot COVID-19 Vaccine on Activity Against Delta Variant and Long-lasting Durability of Response**

*Demonstrates strong neutralising antibody activity against the Delta (B.1.617.2) variant<sup>1</sup>*

*Persistent immune responses through at least eight months<sup>2</sup>*

**NEW BRUNSWICK, N.J., July 1, 2021** – Johnson & Johnson (NYSE: JNJ) (the Company) today announced data that demonstrated its single-shot COVID-19 vaccine generated strong, persistent activity against the rapidly spreading Delta variant and other highly prevalent SARS-CoV-2 viral variants.<sup>1,2</sup> In addition, the data showed that the durability of the immune response lasted through at least eight months, the length of time evaluated to date.<sup>2</sup> The two preprint study summaries have been submitted to *bioRxiv*.<sup>1,2</sup>

“Today’s newly announced studies further demonstrate the ability of the Johnson & Johnson COVID-19 vaccine to help protect the health of people globally,” said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer at Johnson & Johnson. “Based on this data, we believe that our vaccine offers durable protection against COVID-19 and elicits neutralising activity against the Delta variant. This adds to the body of clinical data supporting our single-shot vaccine’s ability to protect against existing multiple variants of concern.”

“Current data for the eight months studied so far show that the single-shot Johnson & Johnson COVID-19 vaccine generates a strong neutralising antibody response that does not wane; rather, we observe an improvement over time. In addition, we observe a persistent, durable cellular immune response,” said Mathai Mammen, M.D., Ph.D., Global Head,

Janssen Research & Development, Johnson & Johnson. "With each new dataset, we build on our solid foundation of evidence that our single-shot COVID-19 vaccine can play a critical role in ending the pandemic, which continues to evolve and pose new challenges to global health."

### **Demonstrates strong neutralising antibody activity against the Delta (B.1.617.2) variant**

A preprint submitted by the Company today to *bioRxiv* contains a new analysis from blood samples obtained from a subset of participants (n=8) in the Phase 3 ENSEMBLE study.<sup>1,3</sup> These data showed that the Johnson & Johnson single-shot COVID-19 vaccine elicited neutralising antibody activity against the Delta variant at an even higher level than what was recently observed for the Beta (B.1.351) variant in South Africa where high efficacy against severe/critical disease was demonstrated.<sup>1,4</sup>

In the ENSEMBLE trial, Johnson & Johnson's single-dose COVID-19 vaccine was 85 percent effective against severe/critical disease and demonstrated protection against hospitalisation and death.<sup>4</sup> The vaccine was consistently effective across all regions studied globally, including in South Africa and Brazil, where there was a high prevalence of rapidly emerging Beta and Zeta (P.2) variants during the study period.<sup>4</sup>

### **Immune responses persisted through at least eight months<sup>2</sup>**

Data submitted by Dan Barouch, M.D., Ph.D., of Beth Israel Deaconess Medical Center *et al.*, to *bioRxiv* from a sub-study of the Johnson & Johnson Phase 1/2a COVID-19 vaccine study (n=20) showed that humoral and cellular immune responses generated by the Johnson & Johnson single-shot COVID-19 vaccine lasted through at least eight months, the latest timepoint recorded in the study thus far. Data showed that T-cell responses – including CD8+ T-cells that seek out and destroy infected cells – persisted over the eight-month timeframe examined.<sup>2</sup>

A single dose of the Johnson & Johnson COVID-19 vaccine generated neutralising antibodies against a range of SARS-CoV-2 variants of concern, which increased over time (the average neutralising titre at eight months exceeded that average at 29 days), including against the increasingly prevalent and more transmissible Delta (B.1.617.2) variant,<sup>5,6</sup> the partially neutralization-resistant Beta (B.1.351),<sup>5,7</sup> the Gamma (P.1) variants and others, including the Alpha (B.1.1.7), Epsilon (B.1.429), Kappa (B.1.617.1) and D614G variants, as well as the original SARS-CoV-2 strain (WA1/2020).<sup>2</sup>

### **Johnson & Johnson's single-dose COVID-19 vaccine is now available in many regions and countries on a not-for-profit basis for the emergency pandemic period**

The vaccine received Emergency Use Authorization (EUA) in the United States on 27 February<sup>8</sup> and Conditional Marketing Authorisation (CMA) by the European Commission on 11 March 2021.<sup>9</sup> The World Health Organization (WHO) issued Emergency Use Listing on 12 March 2021<sup>10</sup> and the Company received an interim recommendation by the Strategic Advisory Group of Experts (SAGE) on Immunization for the WHO on 17 March 2021.<sup>11</sup> Many more authorisations have been granted in countries worldwide, and regulatory submissions are ongoing.

Research and development activities for the Company's COVID-19 vaccine, including the ENSEMBLE clinical trial and the delivery of doses for the U.S., have been funded in part with federal funds from the U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority (BARDA), under Contract No. HHSO100201700018C, and in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID), part of

the National Institutes of Health (NIH) at the U.S. Department of Health and Human Services (HHS).

Johnson & Johnson has worked with BARDA since 2015 on innovative solutions for influenza, chemical, biological, radiation and nuclear threats and emerging infectious diseases such as Ebola.

### **Storage and distribution**

The Johnson & Johnson COVID-19 single-dose vaccine is compatible with standard vaccine storage and distribution channels with ease of delivery to remote areas. The vaccine is estimated to remain stable for two years at -4°F (-20°C), and a maximum of 3 months at routine refrigeration temperatures of 36° to 46°F (2° to 8°C).<sup>12</sup> The Company will ship the vaccine using the same cold chain technologies it uses today to transport other medicines. The COVID-19 vaccine should not be re-frozen if distributed at temperatures of 36°F to 46°F (2°-8°C).<sup>12</sup>

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

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### **Authorised use**

The Janssen COVID-19 vaccine has been granted Conditional Marketing Authorisation in the EU for active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.<sup>12</sup>

### **Important safety information<sup>12</sup>**

#### **WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE JANSSEN COVID-19 VACCINE?**

Tell the vaccination provider about all of your medical conditions, including if you:

- have ever had a severe allergic reaction after injection of any other vaccine.
- have ever fainted following any needle injection.
- you have a severe infection with a high temperature (over 38C). However, you can have your vaccination if you have a mild fever or upper airway infection like a cold.
- you have a problem with bleeding or bruising, or if you are taking anticoagulant medicine (to prevent blood clots).
- your immune system does not work properly (immunodeficiency) or you are taking medicines that weaken the immune system (such as high-dose corticosteroids, immunosuppressants or cancer medicines).

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before you receive this vaccine.

#### **WHO SHOULD NOT GET THE JANSSEN COVID-19 VACCINE?<sup>12</sup>**

You should not get the Janssen COVID-19 Vaccine if you:

- you are allergic to the active substance or any of the other ingredients in this vaccine.

#### **HOW IS THE JANSSEN COVID-19 VACCINE GIVEN?<sup>12</sup>**

Your doctor, pharmacist or nurse will inject the vaccine into the muscle – usually in the upper arm.

## **WHAT ARE THE RISKS OF THE JANSSEN COVID-19 VACCINE?<sup>12</sup>**

Like all vaccines, COVID-19 Vaccine Janssen can cause side effects, although not everybody gets them. Most of the side effects occur in the 1 or 2 days of getting the vaccination. Get medical attention immediately within 3 weeks of vaccination if you get any of the following symptoms:

- experience severe or persistent headaches, blurred vision, mental status changes or seizures (fits);
- develop shortness of breath, chest pain, leg swelling, leg pain or persistent abdominal pain;
- notice unusual skin bruising or pinpoint round spots beyond the site of vaccination.

Get **urgent** medical attention if you get symptoms of a severe allergic reaction. Such reactions may include a combination of any of the following symptoms:

- feeling faint or light-headed
- changes in your heartbeat
- shortness of breath
- wheezing
- swelling of your lips, face, or throat
- hives or rash
- nausea or vomiting
- stomach pain.

## **WHAT SHOULD I DO ABOUT SIDE EFFECTS?**

If you experience a severe allergic reaction, please seek immediate medical care. Afterwards you should report adverse reactions to Janssen in your region. Contact details can be found here:  
[www.janssen.com/sites/www\\_janssen\\_com/files/janssen\\_site\\_q3\\_2020.pdf](http://www.janssen.com/sites/www_janssen_com/files/janssen_site_q3_2020.pdf).

Healthcare professionals should be alert to the signs and symptoms of thromboembolism and/or thrombocytopenia. Those vaccinated should be instructed to seek immediate medical attention if they develop symptoms such as shortness of breath, chest pain, leg pain, leg swelling, or persistent abdominal pain following vaccination. Additionally, anyone with neurological symptoms including severe or persistent headaches, seizures, mental status changes or blurred vision after vaccination, or who experiences skin bruising (petechia) beyond the site of vaccination after a few days, should seek prompt medical attention.<sup>12</sup>

For more information, the EMA Summary of Product Characteristics is available at:  
[www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-janssen-epar-product-information\\_en.pdf](http://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-janssen-epar-product-information_en.pdf).

## **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 @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.

## **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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