News Release

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Johnson & Johnson Announces Data to Support Boosting its Single-Shot COVID-19 Vaccine

Johnson & Johnson COVID-19 vaccine booster, after single dose primary regimen, provided rapid and robust increase in spike-binding antibodies[1]

New interim data from studies build on previous data demonstrating strong durability through eight months after immunisation[2,3,4]

NEW BRUNSWICK, N.J., August 25, 2021 – Johnson & Johnson today announced data supporting the use of its COVID-19 vaccine as a booster shot for people previously vaccinated with the single-shot Johnson & Johnson vaccine.[1]

In July, the Company reported interim Phase 1/2a data published in the *New England Journal of Medicine* that demonstrated neutralising antibody responses generated by the Johnson & Johnson COVID-19 vaccine were strong and stable through eight months after immunisation.[4]

In anticipation of the potential need for boosters, the Company conducted a Phase 1/2a study and a Phase 2 study in individuals previously vaccinated with its vaccine.[2,3] Interim data from these studies demonstrate that a booster dose of the Johnson & Johnson COVID-19 vaccine generated a rapid and robust increase in spike-binding antibodies, nine-fold higher than 28 days after the primary single-dose vaccination.[1] Significant increases in binding antibody responses were observed in participants between ages 18 and 55, and in those 65 years and older who received a lower booster dose.[1] The study summaries were submitted to *medRxiv* on August 24.

"We have established that a single shot of our COVID-19 vaccine generates strong and robust immune responses that are durable and persistent through eight months. With these data, we also see that a booster dose of the Johnson & Johnson COVID-19 vaccine further increases antibody responses among study participants who had previously received our vaccine," said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, Johnson & Johnson. "We look forward to discussing with public health officials a potential strategy for our Johnson & Johnson COVID-19 vaccine, boosting eight months or longer after the primary single-dose vaccination."

The Company is engaging with the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and other health authorities regarding boosting with the Johnson & Johnson COVID-19 vaccine. Johnson & Johnson continues to diligently generate and evaluate data from ongoing trials as well as emerging real-world evidence of its COVID-19 vaccine.

The two clinical trials (VAC31518COV1001 and VAC31518COV2001) 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 other transaction authority ("OTA") agreement No. HHSO100201700018C.

For more information on the Company's multi-pronged approach to helping combat the pandemic, visit: 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.[5]

IMPORTANT SAFETY INFORMATION[5]

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 <u>NOT</u> GET THE JANSSEN COVID-19 VACCINE?[5]
You should not get the Janssen COVID-19 Vaccine if you:

- you are allergic to the active substance or any of the other ingredients of this vaccine.
- you have a previous diagnosis of capillary leak syndrome, (a condition causing fluid leakage from small blood vessels).

HOW IS THE JANSSEN COVID-19 VACCINE GIVEN?[5]
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?[5]
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.

A combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed very rarely following vaccination with COVID-19 Vaccine Janssen. This includes severe cases of venous thrombosis at unusual sites such as cerebral venous sinus thrombosis (CVST), splanchnic vein thrombosis as well as arterial thrombosis concomitant with thrombocytopenia. Fatal outcome has been reported. These cases occurred within the first three weeks following vaccination, and mostly in women under 60 years of age.[5]

Very rare cases of capillary leak syndrome (CLS) have been reported following vaccination with COVID-19 Vaccine Janssen. At least one affected patient had a previous diagnosis of CLS. CLS is a serious, potentially fatal condition causing fluid leakage from small blood vessels (capillaries) resulting in rapid swelling of the arms and legs, sudden weight gain and feeling faint (low blood pressure). Seek **immediate** medical attention if you develop these symptoms in the days following vaccination.[5]

Seek immediate medical attention if you develop weakness and paralysis in the extremities that can progress to the chest and face (Guillain-Barré syndrome). This has been reported very rarely after vaccination with COVID-19 Vaccine Janssen.

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.

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.[5]

Very rare cases of capillary leak syndrome (CLS) have been reported in the first days after vaccination with COVID-19 vaccine Janssen, in some cases with a fatal outcome. A history of CLS has been reported. CLS is a rare disorder characterised by acute episodes of oedema mainly affecting the limbs, hypotension, haemoconcentration and hypoalbuminaemia. Patients with an acute episode of CLS following vaccination require prompt recognition and treatment. Intensive supportive therapy is usually warranted. Individuals with a known history of CLS should not be vaccinated with this vaccine.[5]

Guillain-Barré syndrome (GBS) has been reported very rarely following vaccination with COVID-19 Vaccine Janssen. Healthcare professionals should be alert of GBS signs and symptoms to ensure correct diagnosis, in order to initiate adequate supportive care and treatment and to rule out other causes.[5]

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.

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. 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. Follow us at @JanssenEMEA.

Cautions Concerning Forward-Looking Statements

This statement 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, 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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References

[1] Janssen Data on File. COV1001-COV2001 manuscript submitted to MedRxiv.

[2] ClinicalTrials.gov. A Study to Evaluate a Range of Dose Levels and Vaccination Intervals of Ad26.COV2.S in Healthy Adults and Adolescents. Available from: https://clinicaltrials.gov/ct2/show/NCT04535453. Last accessed: August 2021.

[3] ClinicalTrials.gov. A Study of Ad26.COV2.S in Adults (COVID-19). Available from: https://clinicaltrials.gov/ct2/show/NCT04436276. Last accessed: August 2021.

[4] Barouch DH, et al. Durable Humoral and Cellular Immune Responses 8 Months after Ad26.COV2.S Vaccination. NEJM. 2021;DOI: 10.1056/NEJMc2108829. Available from: https://www.nejm.org/doi/pdf/10.1056/NEJMc2108829. Last accessed: August 2021.

[5] European Medicines Agency. Janssen vaccine COVID-19 Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-janssen-epar-product-information_en.pdf. Accessed August 2021.