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

Media Statement

14 July 2021

Johnson & Johnson Single-Shot COVID-19 Vaccine Demonstrated a Durable Immune Response and Elicited Neutralising Antibody Responses Against Delta and Other SARS-CoV-2 Variants of Concern in Data Published in *New England Journal of Medicine*

Antibody and T-cell immune responses observed through at least eight months after immunisation[1]

Demonstrated neutralising antibody activity against the Delta variant (B.1.617.2) over time[1]

Interim results from a Phase 1/2a sub-study published in the *New England Journal of Medicine (NEJM)* demonstrated that humoral (antibody) and cellular (T-cell) immune responses generated by the Johnson & Johnson single-shot COVID-19 vaccine were strong and stable through eight months after immunisation, the length of time evaluated to date, with minimal decline.[1] Data showed that T-cell responses – including CD8+ T-cells that seek out and destroy infected cells[2] – persisted over the eight-month timeframe examined.[1] The Company announced topline preprint study results from this Phase 1/2a sub-study on July 1, 2021.[3]

Data from the study conducted in collaboration with Dan Barouch, M.D., Ph.D., et al. of Beth Israel Deaconess Medical Center suggest maturation of B-cell response without further boosting.[1] Mature B-cells produce antibodies, which can help fight the virus that causes COVID-19.[4]

Findings indicate that a single dose of the Johnson & Johnson COVID-19 vaccine elicited durable humoral and cellular immune responses, including neutralising antibody responses against the Delta variant (B.1.617.2) and other SARS-CoV-2 variants of concern,[5] including the Alpha (B.1.1.7), Beta (B.1.351), Gamma (P.1), Epsilon (B.1.429) and Kappa (B.1.617.1) variants, as well as the original SARS-CoV-2 strain (WA1/2020).[1] These data suggest an expansion of neutralising antibodies over eight months, along with the observations of durable T-cell responses and the suggestion of B-cell maturation.[1]

"These peer-reviewed data provide further and deeper insights into the durable humoral and cellular immune responses elicited by the single-shot Johnson & Johnson COVID-19 vaccine against the Delta variant and other existing variants of concern," said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, Johnson & Johnson. "The study showed that variant specific neutralising antibodies increased over the eight months examined after vaccination which suggests the maturation of B cell responses. In addition, the T-cell responses are especially strong and stable over time, which is also potentially important for activity against these variants."

Sum total of recent data affirm ability to generate multiple components of immune responses

These data also extend and complement previously published results in *Nature,*[6] which provided evidence of the vaccine's ability to elicit multiple components of the immune

system in individuals, as well as preclinical data in *Nature*[7] related to efficacy against SARS-CoV-2 infection due to the Beta variant in non-human primates. Collectively, these analyses indicate that the potential efficacy of vaccines against COVID-19, including disease caused by variants, should be considered in a broader immunological context regarding the role of non-neutralising antibodies, B- and T-cells.

Additional data from a new analysis of blood samples obtained from a subset of participants (n=8) in the Phase 3 ENSEMBLE study[8] posted on *bioRxiv*[9] showed that the Johnson & Johnson single-shot COVID-19 vaccine elicited neutralising antibody activity against the Delta variant at a higher level than what was recently observed for the Beta variant in South Africa.[1,10]

Phase 1/2a study design (VAC31518COV1001)
This ongoing Phase 1/2a multi-centre, randomised, double-blind, placebo-controlled trial aims to evaluate the safety, reactogenicity and immunogenicity of the Janssen COVID-19 Vaccine at two dose levels ($5x10^{10}$ or $1x10^{11}$ virus particles), administered intramuscularly as single-dose or two-dose schedules, eight weeks apart, in healthy adults.[11] The study is ongoing at multiple clinical sites in Belgium and the United States.[12]

The results from this sub-study are from cohort 1b of this ongoing Phase 1/2a study, which enrolled 25 adults who are 18-55 years of age at a single site at Beth Israel Deaconess Medical Center for detailed descriptive exploratory immunogenicity studies.[13] Additional follow-up with trial participants is currently underway.

Johnson & Johnson's COVID-19 vaccine
The Johnson & Johnson COVID-19 vaccine leverages the AdVac® vaccine platform 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.[14]

This Phase 1/2a clinical trial has 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/our-focus/infectious-diseases-vaccines/respiratory-infections/covid-19.

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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.[15]

Important safety information[15]
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?[15]
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.
- 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?[15]
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?[15]
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.

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.[15]

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.[15]

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.[15]

For more information, the EMA Summary of Product Characteristics is available at:
https://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.

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

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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.

References

[1] Barouch DH, *et al.* Durable Humoral and Cellular Immune Responses 8 Months after Ad26.COV2.S Vaccination. *NEJM.* 2021;DOI: 10.1056/NEJMc2108829. Available at: https://www.nejm.org/doi/pdf/10.1056/NEJMc2108829. Accessed July 2021.
[2] Ledford H, *et al.* How 'killer' T cells could boost COVID immunity in face of new variants. Nature. 2021;590:374-375.
[3] Johnson & Johnson Press Release. Positive New Data for Johnson & Johnson Single-Shot COVID-19 Vaccine on Activity Against Delta Variant and Long-lasting Durability of Response. Available at: https://www.jnj.com/positive-new-data-for-johnson-johnson-single-shot-covid-19-vaccine-on-activity-against-delta-variant-and-long-lasting-durability-of-response. Accessed July 2021.
[4] Alberts B, *et al.* Molecular Biology of the Cell. 4th edition. New York: Garland Science; 2002. B Cells and Antibodies. Available at: www.ncbi.nlm.nih.gov/books/NBK26884/. Accessed July 2021.
[5] World Health Organization. Tracking SARS-CoV-2 variants. Available at: https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/. Accessed July 2021.
[6] Alter G, *et al.* Immunogenicity of Ad26.COV2.S vaccine against SARS-CoV-2 variants in humans. *Nature.* 2021; https://doi.org/10.1038/s41586-021-03681-2. Accessed July 2021.
[7] Yu J, *et al.* Protective efficacy of Ad26.COV2.S against SARS-CoV-2 B.1.351 in macaques. *Nature.* 2021; https://doi.org/10.1038/s41586-021-03732-8. Accessed July 2021.
[8] 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. Accessed July 2021.
[9] Barouch DH, *et al.* Durable Humoral and Cellular Immune Responses Following Ad26.COV2.S Vaccination for COVID-19. bioRxiv preprint.
[10] Moore PL, *et al.* Neutralizing antibodies elicited by the Ad26.COV2.S COVID-19 vaccine show reduced activity against 501Y.V2 (B.1.351), despite protection against severe disease by this variant. bioRxiv preprint. Available at: https://www.biorxiv.org/content/10.1101/2021.06.09.447722v2.full.pdf. Accessed July 2021.
[11] Janssen Vaccines & Prevention B.V. Clinical Protocol: Protocol VAC31518COV1001; Phase 1/2a VAC31518 JNJ-78436735. Available at: https://www.nejm.org/doi/suppl/10.1056/NEJMoa2034201/suppl_file/nejmoa2034201_protocol.pdf. Accessed July 2021.
[12] ClinicalTrials.gov. A Study of Ad26.COV2.S in Adults (COVID-19). Available at: https://clinicaltrials.gov/ct2/show/NCT04436276. Accessed July 2021.
[13] Stephenson KE, *et al.* Immunogenicity of the Ad26.COV2.S Vaccine for COVID-19. *JAMA.* 2021;325(15):1535-44.
[14] Custers J et al. Vaccines based on replication incompetent Ad26 viral vectors: Standardized template with key considerations for a risk/benefit assessment. Vaccine. 2020;39(22):3081-3101.
[15] 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 July 2021.