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

News Release

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Johnson & Johnson Announces Real-World Evidence and Phase 3 Data Confirming Substantial Protection of Single-Shot COVID-19 Vaccine in the U.S.

Additional data show a booster increases protection[1]

94 percent protection in the U.S. with booster given at two months[2]
Four-fold increase in antibodies when given at two months[3]
12-fold increase in antibodies when booster given at six months[3]

NEW BRUNSWICK, N.J., 21 September 2021 – Johnson & Johnson (NYSE: JNJ) (the Company) today announced new data reinforcing the substantial protection of its COVID-19 vaccine.[1,2,4] New data also showed that protection against COVID-19 increases when a booster shot of the Johnson & Johnson vaccine is administered.[1] The safety profile of the vaccine remained consistent and was generally well tolerated when administered as a booster.[1]

"Our large real-world-evidence and Phase 3 studies confirm that the single-shot Johnson & Johnson vaccine provides substantial protection against COVID-19-related hospitalisations. Additionally, our Phase 3 trial data further confirm protection against COVID-19 related death," said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, Johnson & Johnson. "Our single-shot vaccine generates strong immune responses and long-lasting immune memory. And, when a booster of the Johnson & Johnson COVID-19 vaccine is given, the strength of protection against COVID-19 further increases."

"It is critical to prioritise protecting as many people as possible against hospitalisation and death given the continued spread of COVID-19 and rapidly emerging variants. A single-shot COVID-19 vaccine that is easy to use, distribute and administer, and that provides substantial protection is crucial to vaccinating the global population," said Paul Stoffels,

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M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer at Johnson & Johnson. "At the same time, we now have generated evidence that a booster shot further increases protection against COVID-19 and is expected to extend the duration of protection significantly."

The Company has provided available data to the U.S. Food and Drug Administration (FDA) and plans to submit the data to other regulators, the World Health Organization (WHO) and National Immunization Technical Advisory Groups (NITAGs) worldwide to inform decision making on local vaccine administration strategies, as needed.

The data are summarised below:

Johnson & Johnson single-shot vaccine showed substantial protection in the real world[4]
This real-world evidence study for a COVID-19 vaccine reported to date in the U.S. demonstrated stable vaccine effectiveness of 79 percent (CI, 77%-80%) for COVID-19-related infections and 81 percent (CI, 79%-84%) for COVID-19-related hospitalisations. There was no evidence of reduced effectiveness over the study duration, including when the Delta variant became dominant in the U.S.[4] Sequencing data were not available for analysis.[4] The study included 390,000 people who received the Johnson & Johnson COVID-19 vaccine and approximately 1.52 million unvaccinated people matched on age, sex, date, three-digit zip code, and comorbidities and predictors for COVID-19 infection severity conducted from March to late July 2021.[4]

These data were consistent with the Phase 3 ENSEMBLE trial, where substantial protection against severe/critical disease and death was observed at least 28 days post-final vaccination:[2]

- 75 percent overall efficacy (CI, 65%-82%) against severe/critical COVID-19, across all age cohorts and all countries included in the study.[2]
- In the U.S.: 74 percent efficacy against severe/critical COVID-19 (CI, 39%-91%); 89 percent against hospitalisation (CI, 24%-100%); 83 percent against COVID-19-related death (CI, 41%-97%).[2]

Another shot at two months provided 94 percent (CI, 58%-100%) protection against COVID-19 in the U.S.[2]
The Phase 3 ENSEMBLE 2 study showed that another shot of the Johnson & Johnson COVID-19 vaccine given 56 days after the first provided:[2]

- 100 percent protection (CI, 33%-100%) against severe/critical COVID-19 – at least 14 days post-final vaccination.[2]
- 76 percent protection against symptomatic COVID-19 globally (CI, 55%-88%).[2]
- 94 percent protection against symptomatic COVID-19 in the U.S. (CI, 58%-100).[2]

Booster shot at six months provided 12-fold increase in antibodies[1]
When a booster of the Johnson & Johnson COVID-19 vaccine was given six months after the single-shot, antibody levels increased nine-fold one week after the booster and continued to climb to 12-fold higher four weeks after the booster.[3]

When a booster of the Johnson & Johnson COVID-19 vaccine was given two months after the first shot, antibody levels rose to four to six times higher than observed after the single-shot.[3]

The Johnson & Johnson single-shot COVID-19 vaccine, developed by its Janssen Pharmaceutical Companies of Johnson & Johnson, received an Emergency Use Authorization

in the United States on 27 February 2021[5] and Conditional Marketing Authorisation (CMA) by the European Commission on 11 March.[6] The World Health Organization (WHO) issued Emergency Use Listing on 12 March,[7] and the Company received an interim recommendation by the Strategic Advisory Group of Experts (SAGE) on Immunization for the WHO on 17 March.[8] Many more authorisations have been granted in countries worldwide, and regulatory submissions are ongoing.

- **Additional notes -**

Real-world evidence study[4]
In the largest real-world evidence Vaccine Effectiveness (VE) study of participants receiving the Johnson & Johnson single-shot COVID-19 vaccine in the U.S. to date, the Janssen R&D Data Science team, Harvard University and Aetion utilised the HealthVerity database, which consisted of longitudinal de-identified patient-level information.[4] This study compared approximately 390,000 people who received the Company's single-shot COVID-19 vaccine and approximately 1.52 million unvaccinated people matched on age, sex, date, three-digit zip code, and comorbidities and predictors for COVID-19 infection severity.[4]

This study is a longitudinal cohort design, using robust propensity matching methods to create a comparator cohort to assess real-world VE.[4] All analyses were performed using the Aetion Evidence Platform, which is a scientifically validated software that is also used by regulators, payers, and health technology assessment bodies to assess the safety, effectiveness, and value of medical technologies.[4] All transformations of the raw data are preserved for full reproducibility and audit trails are available, including a quality check of the data ingestion process.

In the real-world U.S. data, the Johnson & Johnson single-shot COVID-19 vaccine showed VE of 81 percent (CI, 79%-84%) for COVID-19-related hospitalisations and effectiveness of 79 percent (CI, 77%-80%) for COVID-19 related infections (VE was corrected to compensate for vaccination status misclassification due to under-recording of true vaccination status in health care claims data).[4] Uncorrected VE was 69 percent (CI, 67%-71%) for COVID-19-related infections, VE of 73 percent (CI, 69%-76%) for COVID-19 hospitalisations.[4]

The Johnson & Johnson single-shot COVID-19 vaccine showed VE against COVID-19-related hospitalisations at 86 percent (CI, 83% -89%) for participants younger than 60 years, and 78 percent (CI, 74%-81%) for those 60 years and older.[4] VE against COVID-19 infections was 81 percent (CI, 79%-82%) for people younger than 60 years, and 75 percent (CI, 73%-78%) for those 60 years and older.[4]

ENSEMBLE 1 study[2,9]
The Phase 3 ENSEMBLE study is a randomised, double-blind, placebo-controlled clinical trial designed to evaluate the safety and efficacy of a single-dose vaccine versus placebo in adults 18 years old and older.[9]

The ENSEMBLE study was designed to evaluate the safety and efficacy of the Johnson & Johnson vaccine candidate in protecting against moderate to severe/critical COVID-19 disease, with assessment of efficacy as of day 14 and as of day 28 as co-primary endpoints.[10]

In the Phase 3 ENSEMBLE study, a single dose of the Johnson & Johnson COVID-19 vaccine offered substantial overall efficacy (75%; CI 65%-82%; n=46 cases vaccine arm, n=176 cases placebo arm) against severe/critical COVID-19, across all age cohorts and all

countries included in the study, after at least 28 days post vaccination.[2] While efficacy against severe/critical COVID-19 caused by the initial circulating SARS-COV-2 reference strain (Wuhan) remained high (93%; CI 54%-100%; n=1 case vaccine arm, n=14 cases placebo arm), there was somewhat lower vaccine efficacy (72%; CI 56%-82%; n=27 cases vaccine arm, n=93 cases placebo arm) against severe/critical disease caused by variants.[2]

The single dose regimen had 53 percent (CI, 47%-58%; n=433 cases vaccine arm, n=883 cases placebo arm) efficacy against moderate to severe/critical infection with 58 percent (CI, 35%-74%; n=30 cases vaccine arm, n=69 cases placebo arm) efficacy against the reference strain.[2] Efficacy against hospitalisations related to COVID-19 in the ENSEMBLE trial was 76 percent (CI, 54%-88%; n=16 cases vaccine arm, n=64 cases placebo arm), and efficacy against COVID-19-related deaths was 83 percent (CI, 41%-97%; n=3 cases vaccine arm, n=17 cases placebo arm).[2]

In the U.S., the ENSEMBLE trial demonstrated vaccine efficacy against moderate to severe/critical COVID-19 infection of 70 percent 28-days post-vaccination (CI, 61%-77%; n=77 cases vaccine arm, n=239 cases placebo arm), 74 percent against severe/critical infection (CI, 39%-91%; n=7 cases vaccine arm, n=26 cases placebo arm) and 89 percent against hospitalisation (CI, 24%-100%; n=1 case vaccine arm, n=9 cases placebo arm).

Median follow up time in the ENSEMBLE study was four months, with 23 percent of the participants with follow up of greater than six months.[2]

The vaccine was generally well tolerated by all participants, with fewer local and systemic reactions as compared with Phase 1/2 data.[2]

ENSEMBLE was initiated in collaboration with the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services (HHS) under Other Transaction Agreement HHSO100201700018C, and the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH) at HHS.

Full data will be submitted for publication in the coming months.

ENSEMBLE 2 study[2,11]

The Phase 3 ENSEMBLE 2 study is a randomised, double-blind, placebo-controlled clinical trial designed to evaluate the safety and efficacy of a two-dose vaccine regimen given at a 56-day interval versus placebo in adults 18 years old and older with and without comorbidities associated with an increased risk for severe COVID-19.[11,12]

The study was designed to assess efficacy of the investigational vaccine after both the first and second dose to evaluate protection against the virus and potential incremental benefits for duration of protection with a second dose.[12] In the ENSEMBLE 2 Phase 3 study solicited and unsolicited adverse events following this second dose are similar to those seen in single-dose studies.[2]

Compared to the single-dose results, ENSEMBLE 2 showed increased efficacy of a two-dose schedule against moderate to severe/critical COVID-19 of 75 percent (CI, 55%-87%; n=14 cases vaccine arm, n=52 cases placebo arm) and severe/critical COVID-19 of 100 percent (CI, 33%-100%; n=0 cases vaccine arm, n=8 cases placebo arm) at least 14 days following the second vaccination prior to unblinding.[2] In the U.S., efficacy against moderate to

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severe/critical COVID-19 was 94 percent (CI, 58%-100%; n=1 case vaccine arm, n=14 cases placebo arm).[2]

Median follow up time in the ENSEMBLE 2 study was 36 days since second vaccination, with 29 percent of participants having at least two months of follow up after receipt of their second dose.[2]

The vaccine, when given as a second dose, remained generally well tolerated.[2]

Full data will be submitted for publication in the coming months.

For more information on the Company's multi-pronged approach to helping combat the pandemic, visit: https://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.[13]

IMPORTANT SAFETY INFORMATION[13]

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?[13]
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?[13]
Your doctor, pharmacist or nurse will inject the vaccine into the muscle – usually in the upper arm.

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WHAT ARE THE RISKS OF THE JANSSEN COVID-19 VACCINE?[13]

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** if within 3 weeks of vaccination 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.[13]

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.[13]

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.[13]

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.[13]

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.[13]

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.janssen.com/emea. 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 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;

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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 Sadoff J., *et al.* Durability of antibody responses elicited by a single dose of Ad26.COV2.S and substantial increase following late boosting. bioRxiv preprint. doi: https://doi.org/10.1101/2021.08.25.21262569.
2 Janssen data on file. ENSEMBLE and ENSEMBLE 2 data. September 2021.
3 Janssen data on file. 1001/2001 data. September 2021.
4 Polinski J. et al. Effectiveness of the Single-Dose Ad26.COV2.S COVID Vaccine. medRxiv 2021.09.10.21263385; doi: https://doi.org/10.1101/2021.09.10.21263385
5 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-usefirst-single-shot-vaccine-in-fight-against-global-pandemic. Last accessed: September 2021.
6 Janssen. Johnson & Johnson Single-Shot COVID-19 Vaccine Granted Conditional Marketing Authorization by European Commission. Available at: https://www.janssen.com/emea/sites/www_janssen_com_emea/files/jj_single-shot_covid-19_vaccine_granted_conditional_marketing_authorization_by_ec.pdf. Last accessed: September 2021.
7 Janssen. Johnson & Johnson Single-Shot COVID-19 Vaccine Granted Emergency Use Listing by the World Health Organization. Available at: https://www.janssen.com/emea/sites/www_janssen_com_emea/files/johnson_johnson_single-shot_covid-19_vaccine_granted_emergency_use_listing_by_the_world_health_organization.pdf. Last accessed: September 2021.
8 Johnson & Johnson. Statement on the Interim SAGE Recommendation Supporting the Use of the Johnson & Johnson COVID-19 Vaccine. Available at: https://www.jnj.com/statement-on-the-interim-sage-recommendation-supporting-the-use-of-the-johnson-johnson-covid-19-vaccine. Last accessed: September 2021.
9 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: September 2021.
10 Janssen Clinical Protocol. A Randomized, Double-blind, Placebo-controlled Phase 3 Study to Assess the Efficacy and Safety of Ad26.COV2.S for the Prevention of SARS-CoV-2-mediated COVID-19 in Adults Aged 18 Years and Older (ENSEMBLE). Available at: https://www.jnj.com/coronavirus/ensemble-1-study-protocol. Last accessed: September 2021.
11 ClinicalTrials.gov. A Study of Ad26.COV2.S for the Prevention of SARS-CoV-2-mediated COVID-19 in Adults (ENSEMBLE 2). Available at: https://clinicaltrials.gov/ct2/show/NCT04614948. Last accessed: September 2021.
12 Janssen Clinical Protocol. A Randomized, Double-blind, Placebo-controlled Phase 3 Study to Assess the Efficacy and Safety of Ad26.COV2.S for the Prevention of SARS-CoV-2-mediated COVID-19 in Adults Aged 18 Years and Older (ENSEMBLE 2). Available at: https://www.jnj.com/coronavirus/ensemble-2-study-protocol. Last accessed: September 2021.
13 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. Last accessed: September 2021.