Johnson & Johnson Statement on its COVID-19 Vaccine Following CDC ACIP Meeting

December 16, 2021
United States

Johnson & Johnson remains confident in the overall positive benefit-risk profile of its COVID-19 vaccine. Studies have shown that the Johnson & Johnson COVID-19 vaccine generates strong antibody and cellular immune responses[i] and long-lasting immune memory[ii] and breadth of protection across variants. In addition, a growing body of evidence is revealing the strength of protection of our vaccine as a booster to either the Janssen COVID-19 vaccine or a different authorized or approved COVID-19 vaccine, both in terms of its efficacy and durability.[iii, iv, v, vi, vii, viii, ix]

"The safety and well-being of those who use the Johnson & Johnson vaccine continues to be our number one priority," says Mathai Mammen M.D., Ph.D., Global Head, Janssen Research & Development, LLC, Johnson & Johnson. "We appreciate today's discussion and look forward to working with the CDC on next steps. In addition, we strongly support education and generating awareness of rare events, such as Thrombosis with Thrombocytopenia Syndrome (TTS) and how to effectively manage it."

Given its strong durability, the Johnson & Johnson COVID-19 vaccine remains an important choice in the U.S. for people who can't or won't return for multiple vaccinations or who would remain unvaccinated without an alternative to the mRNA vaccines. With ease of storage and transport, it offers a vital tool, and in many populations, including in low- and middle-income countries, our vaccine is a critical and sometimes only option. Johnson & Johnson is one of the largest suppliers of COVID-19 vaccines to the African Union and COVAX, which supports equitable distribution of COVID-19 vaccines to the 190 participating countries.

The Johnson & Johnson COVID-19 vaccine aligns with the World Health Organization's (WHO) recommendations for medical interventions in a pandemic setting, which emphasize ease of distribution, administration, and compliance. The Company remains committed to facilitating equitable global access to its COVID-19 vaccine and is the first major Western vaccine manufacturer to support the COVAX Humanitarian Buffer.

The Company is collecting important humoral and cellular data in the coming weeks on the activity against the recently discovered omicron variant. Cellular immune responses are showing potential to be important for both breadth of protection and durability.

Johnson & Johnson continues to collaborate with health authorities around the world to ensure healthcare professionals and individuals are fully informed on reports of TTS, enabling correct diagnosis, appropriate treatment, and expedited reporting.

The Company has also updated its COVID-19 Vaccine Fact Sheet to include the latest information about cases of TTS, including a contraindication to not administer the Johnson & Johnson COVID-19 vaccine to individuals with a history of TTS following the Johnson & Johnson COVID-19 vaccine or any other adenovirus-vectored COVID-19 vaccines.

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AUTHORIZATION OF USE

The Janssen COVID-19 Vaccine, also known as the Johnson & Johnson COVID-19 vaccine, is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent Coronavirus Disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

- Primary vaccination regimen for the Janssen COVID-19 Vaccine is a single-dose (0.5 mL) administered to individuals 18 years of age and older.
- A single Janssen COVID-19 Vaccine booster dose (0.5 mL) may be administered at least 2 months after the primary vaccination to individuals 18 years of age and older.
- A single booster dose of the Janssen COVID-19 Vaccine (0.5 mL) may be administered to individuals 18 years of age and older as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.

IMPORTANT SAFETY INFORMATION

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 any allergies
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine
- have ever fainted in association with an injection

WHO SHOULD <u>NOT</u> GET THE JANSSEN COVID-19 VACCINE?

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

- had a severe allergic reaction after a previous dose of this vaccine.
- had a severe allergic reaction to any ingredient of this vaccine.
- had a blood clot along with a low level of platelets (blood cells that help your body stop bleeding) following Janssen COVID-19 Vaccine or following AstraZeneca's COVID-19 vaccine (not authorized or approved in the United States).

HOW IS THE JANSSEN COVID-19 VACCINE GIVEN?

The Janssen COVID-19 Vaccine will be given to you as an injection into the muscle.

<u>Primary Vaccination:</u> The Janssen COVID-19 Vaccine is administered as a single dose.

<u>Booster Dose:</u>

- A single booster dose of the Janssen COVID-19 Vaccine may be administered at least two months after primary vaccination with the Janssen COVID-19 Vaccine.
- A single booster dose of the Janssen COVID-19 Vaccine may be administered to individuals 18 years of age and older who have completed primary vaccination with a different authorized or approved COVID-19 vaccine. Please check with your health care provider regarding timing of the booster dose.

WHAT ARE THE RISKS OF THE JANSSEN COVID-19 VACCINE?

Side effects that have been reported with the Janssen COVID-19 Vaccine include:

- Injection site reactions: pain, redness of the skin, and swelling.
- General side effects: headache, feeling very tired, muscle aches, nausea, fever.
- Swollen lymph nodes.
- Blood clots.

- Unusual feeling in the skin (such as tingling or a crawling feeling) (paresthesia), decreased feeling or sensitivity, especially in the skin (hypoesthesia).
- Persistent ringing in the ears (tinnitus).
- Diarrhea, vomiting.

Severe Allergic Reactions

There is a remote chance that the Janssen COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Janssen COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

Blood Clots with Low Levels of Platelets

Blood clots involving blood vessels in the brain, lungs, abdomen, and legs along with low levels of platelets (blood cells that help your body stop bleeding), have occurred in some people who have received the Janssen COVID-19 Vaccine. In people who developed these blood clots and low levels of platelets, symptoms began approximately one to two-weeks after vaccination. Blood clots with low levels of platelets following the Janssen COVID-19 Vaccine have been reported in males and females, across a wide age range of individuals 18 years and older; reporting has been highest in females ages 30 through 49 years (about 1 case for every 100,000 vaccine doses administered), and about 1 out of every 7 cases has been fatal. You should seek medical attention right away if you have any of the following symptoms after receiving the Janssen COVID-19 Vaccine:

- Shortness of breath,
- Chest pain,
- Leg swelling,
- Persistent abdominal pain,
- Severe or persistent headaches or blurred vision,
- Easy bruising or tiny blood spots under the skin beyond the site of the injection.

These may not be all the possible side effects of the Janssen COVID-19 Vaccine. Serious and unexpected effects may occur. The Janssen COVID-19 Vaccine is still being studied in clinical trials.

Guillain Barré Syndrome

Guillain Barré syndrome (a neurological disorder in which the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis) has occurred in some people who have received the Janssen COVID-19 Vaccine. In most of these people, symptoms began within 42 days following receipt of the Janssen COVID-19 Vaccine. The chance of having this occur is very low. You should seek medical attention right away if you develop any of the following symptoms after receiving the Janssen COVID-19 Vaccine:

- Weakness or tingling sensations, especially in the legs or arms, that's worsening and spreading to other parts of the body.
- Difficulty walking.
- Difficulty with facial movements, including speaking, chewing, or swallowing.
- Double vision or inability to move eyes.
- Difficulty with bladder control or bowel function.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital. Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS).** The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include "Janssen COVID-19 Vaccine EUA" in the first line of box #18 of the report form. In addition, you can report side effects to Janssen Biotech Inc. at 1-800-565-4008.

CAN I RECEIVE THE JANSSEN COVID-19 VACCINE AT THE SAME TIME AS OTHER VACCINES?
Data have not yet been submitted to FDA on administration of the Janssen COVID-19 Vaccine at the same time as other vaccines. If you are considering receiving the Janssen COVID-19 Vaccine with other vaccines, discuss your options with your healthcare provider.

Please read Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including full EUA Prescribing Information available at: www.JanssenCOVID19Vaccine.com/EUA-factsheet.

Cautions Concerning Forward-Looking Statements
This media statement contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding development, manufacture and distribution the Johnson & Johnson COVID-19 vaccine. 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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[i] Barouch, D. H., Stephenson, K. E., Sadoff, J., Yu, J., Chang, A., Gebre, M., ... & Schuitemaker, H. (2021). Durable humoral and cellular immune responses 8 months after Ad26. COV2. S vaccination. *New England Journal of Medicine*, *385*(10), 951-953.

[ii] Polinski, J. M., Weckstein, A. R., Batech, M., Kabelac, C., Kamath, T., Harvey, R., Jain, S., Rassen, J. A., Khan, N., & Schneeweiss, S. (2021, January 1). Effectiveness of the single-dose ad26.cov2.s COVID vaccine. medRxiv. Retrieved December 16, 2021, from https://www.medrxiv.org/content/10.1101/2021.09.10.21263385v2

[iii] FDA. Vaccines and Related Biological Products Advisory Committee October 14-15, 2021 Meeting Presentation. Available at: https://www.fda.gov/media/153037/download Last accessed: December 2021.

[iv] Atmar, R.L et al. Heterologous SARS-CoV-2 Booster Vaccinations – Preliminary Report. medRxiv 2021.10.10.21264827

[v] Tan SC, Collier AY, Jingyou JL et al. Ad26.COV2.S or BNT162b2 Boosting of BNT162b2 Vaccinated Individuals. Available at: https://doi.org/10.1101/2021.12.02.21267198. Accessed December 2021.

[vi] Janssen Data on File. ENSEMBLE Study. 2021.

[vii] Janssen data on file. ENSEMBLE 2 data. December 2021.

[viii] 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. Available at: https://www.medrxiv.org/content/10.1101/2021.09.10.21263385v2. Last accessed: December 2021.

[ix] Tan, C. S., Collier, A.-ris Y., Liu, J., Yu, J., Wan, H., McMahan, K., He, X., Jacob-Dolan, C., Chandrashekar, A., Sellers, D., Stephenson, K. E., Vidal, S. J., Jaegle, K., Curran, J. L., Rowe, M., Hemond, R., Rivera, L. B., Anioke, T., Barrett, J., … Barouch, D. H. (2021, January 1). Ad26.COV2.S or BNT162B2 boosting of BNT162B2 vaccinated individuals. medRxiv. Retrieved December 16, 2021, from https://www.medrxiv.org/content/10.1101/2021.12.02.21267198v1