Media Statement

22 November 2021

Johnson & Johnson Announces Submission of Application to the European Medicines Agency (EMA) for use of its COVID-19 Vaccine as a Booster Dose

Submission includes data showing a booster (second dose) increased protection to 75 and 94 percent protection against symptomatic (moderate to severe/critical) COVID-19 globally and in the U.S., respectively[1]

Substantial increase in immune response when booster (second dose) was given at two months and longer[1]

The Company's single dose vaccine has demonstrated durable immune responses in clinical studies[2]

Johnson & Johnson (the Company) announced it has submitted data to the European Medicines Agency (EMA) to support use of a booster (second dose) of the Johnson & Johnson COVID-19 vaccine for people aged 18 years and older.

A comprehensive submission package that includes results from more than 14,000 adults who received a second dose of COVID-19 Vaccine Janssen or placebo (a dummy treatment) two months after the initial dose was made.[3] Data demonstrate that the Johnson & Johnson COVID-19 vaccine provides protection when administered as a single dose for an effective response to the pandemic.[1] When given as a booster (second dose), the strength of protection further increases, especially against symptomatic COVID-19.[1]

"Our data demonstrate our COVID-19 vaccine provides effective protection both as a single dose and as a booster dose to further increase the strength of protection. We look forward to our discussions with the EMA and other health authorities to support their decision regarding boosters," said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer at Johnson & Johnson. "At the same time, a single dose of our COVID-19 vaccine continues to play a crucial role in the global fight to end this pandemic, and we are confident in the benefit it is providing to millions of people around the world."

The Company looks forward to a decision by the EMA's human medicines committee (CHMP) on whether to grant a positive recommendation for the use of the Johnson & Johnson COVID-19 vaccine as a booster dose in the coming weeks.

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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.[4]

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 of our 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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References

[1] FDA. Vaccines and Related Biological Products Advisory Committee October 14-15, 2021 Meeting Presentation. Available at: https://www.fda.gov/media/153129/download Last accessed: November 2021.

[2] 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 Last accessed: November 2021.

[3] EMA. EMA evaluating data on booster dose of COVID-19 Vaccine Janssen. Available at: https://www.ema.europa.eu/en/news/ema-evaluating-data-booster-dose-covid-19-vaccine-janssen Last accessed: November 2021.

[4] 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: November 2021.