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News Release

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Johnson & Johnson Announces Positive CHMP Opinion for a Booster Dose of its COVID-19 Vaccine

CHMP recommendation based on data showing a booster (second dose) of the Johnson & Johnson COVID-19 vaccine increased protection to 75 percent against symptomatic COVID-19 infection globally[1]

Data also demonstrated 100 percent protection against severe COVID-19, at least 14 days post-booster vaccination[1]

The Johnson & Johnson COVID-19 vaccine, when given as a booster or primary dose, was generally well-tolerated[1,2]

BEERSE, BELGIUM, 15 December 2021 – Johnson & Johnson (the Company) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a Positive Opinion for use of the Company's COVID-19 vaccine as a booster for adults aged 18 and older at least two months after primary vaccination with a single-dose of the Johnson & Johnson COVID-19 vaccine, and as a 'mix and match' booster following primary vaccination with an approved two-dose mRNA COVID-19 vaccine regimen (known as heterologous boosting).[3]

"We are pleased with today's Positive Opinion from the CHMP supporting the use of our COVID-19 vaccine as a booster for eligible individuals in Europe," said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, Johnson & Johnson. "There is a growing body of data showing that the Johnson & Johnson COVID-19 vaccine induces broad and durable humoral and cellular immune responses, whether administered as a single dose for an efficient response to the pandemic, or as a booster dose after at least two months to

strengthen protection against symptomatic COVID-19. Cellular immune responses are showing potential to be important for both breadth of protection and durability."

The CHMP Opinion was based on a comprehensive data package that included results from the Phase 3 ENSEMBLE 2 study, which found a booster of the Johnson & Johnson COVID-19 vaccine given two months after the primary dose provided 75 percent protection against symptomatic (moderate to severe) COVID-19 globally (CI, 55%-87%) and 94 percent protection against symptomatic (moderate to severe) COVID-19 in the U.S. (CI, 59%-100%).[1] It also demonstrated 100 percent protection against severe COVID-19, at least 14 days post-booster vaccination (CI, 33%-100%).[1] The vaccine, when given as a booster or primary dose, was generally well-tolerated, with no new safety signals observed in the two-dose ENSEMBLE 2 trial compared with single-dose studies.[1,4,5]

Also included in the data package reviewed by the CHMP were results from multiple real-world evidence (RWE) studies, including the Company's previously announced RWE study that demonstrated similar estimates of single-dose vaccine effectiveness as observed in our randomised clinical trials.[6] The effectiveness estimates remained stable with no evidence of reduced effectiveness over time before the Delta variant emerged and after it became the dominant strain in the U.S. from March through August (sequencing data were not available for analysis).[1,7]

The CHMP recommendation is supported by latest data for heterologous boosting with the Johnson & Johnson COVID-19 vaccine.[8,10] Interim data from the National Institute of Allergy and Infectious Disease (NIAID) "MixNMatch" study demonstrated that a booster of the Johnson & Johnson COVID-19 vaccine increases immune response regardless of a person's primary vaccination.[8] A second study by the Beth Israel Deaconess Medical Center (BIDMC), including a subset of participants from the Janssen-sponsored COV2008 study,[9] demonstrated the potential benefits of heterologous boosting: a booster dose of the Johnson & Johnson vaccine administered at six months after a two-dose primary regimen of the Pfizer/BioNTech vaccine, increased both antibody and T-cell responses.[10] In these participants, antibodies continued to increase for at least four weeks whereas in individuals who received a homologous boost with the BNT162b2 vaccine, antibodies declined from week two to week four post-boost, resulting in similar antibody levels in both groups.[10]

The Company's single-dose 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[11] and Conditional Marketing Authorisation (CMA) by the European Commission on 11 March.[12] On 21 October 2021, the U.S. Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) authorised for emergency use a booster dose of the Johnson & Johnson COVID-19 vaccine for adults aged 18 and older.[13] On 9 December 2021, the Strategic Advisory Group of Experts (SAGE) on Immunization for the World Health Organization (WHO) supported the use of the Johnson & Johnson COVID-19 vaccine as a heterologous booster dose in persons aged 18 years and above.[14]

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.[15]

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, manufacture and distribution of 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 behaviour 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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