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**Media Statement**

**16 December 2021**

## **Johnson & Johnson COVID-19 Vaccine Granted Conditional Marketing Authorisation Amendment for Use as Booster Dose by European Commission**

Today Johnson & Johnson (The Company) announced that the European Commission has granted an amendment to the Conditional Marketing Authorisation (cMA) for use of the Johnson & Johnson COVID-19 vaccine as a booster for adults aged 18 and older at least two months after primary vaccination with the Company's single-dose 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).<sup>1,2</sup>

This cMA amendment follows the Positive Opinion issued 15 December 2021 from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) for use of the Johnson & Johnson COVID-19 vaccine as a booster.<sup>3</sup>

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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.<sup>1</sup>

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](http://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](http://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](http://www.janssen.com/emea). Follow us at @JanssenEMEA.

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**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](http://www.sec.gov), [www.jnj.com](http://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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<sup>1</sup> European Medicines Agency. Summary of Product Characteristics. COVID-19 vaccine Janssen. Available at: [https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-janssen-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-janssen-epar-product-information_en.pdf) Last accessed: December 2021.

<sup>2</sup> European Commission. Commission Implementing Decision. Data on File. December 2021.

<sup>3</sup> EMA. COVID-19 Vaccine Janssen: EMA recommendation on booster dose. Available at: <https://www.ema.europa.eu/en/news/covid-19-vaccine-janssen-ema-recommendation-booster-dose> Last accessed: December 2021.