Johnson Johnson

**Media Statement** 

**28 February 2022** 

# **European Medicines Agency Approves Extended Shelf-life of up** to 11 Months for the Johnson & Johnson COVID-19 Vaccine

Johnson & Johnson is committed to providing a COVID-19 vaccine to people most at risk around the world. We are pleased to confirm that the European Medicines Agency (EMA) has extended the shelf life for the Johnson & Johnson COVID-19 vaccine from 4.5 months to 11 months.<sup>1</sup>

The EMA decision is based on data from ongoing stability assessment studies, which have demonstrated the Company's COVID-19 vaccine can be stored for up to 11 months when refrigerated at temperatures of 2 to 8 degrees Celsius (36 to 46 degrees Fahrenheit). <sup>1</sup> There is no change in the shelf life of 24 months when stored frozen at -25 to -15 degrees Celsius (-13 to -5 degrees Fahrenheit). <sup>1</sup>

###

#### Authorised use

The Janssen COVID-19 vaccine has been granted Conditional Marketing Authorisation in the EU/EEA 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>2</sup>

For more information, the EMA Summary of Product Characteristics is available at: www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-janssenepar-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 media statement 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; 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.

## References

<sup>&</sup>lt;sup>1</sup> Janssen data on file. Shelf-life extension application. Feb 2022.

<sup>&</sup>lt;sup>2</sup> 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-productinformation\_en.pdf. Last accessed: February 2022.