

## **Johnson & Johnson statement on FDA approval of shelf life extension for company's COVID-19 vaccine**

June 10, 2021  
United States

We are pleased to confirm the U.S. Food & Drug Administration (FDA) has authorized an extension of the shelf life for the Johnson & Johnson single-shot COVID-19 vaccine from 3 months to 4.5 months. The decision is based on data from ongoing stability assessment studies, which have demonstrated that the vaccine is stable at 4.5 months when refrigerated at temperatures of 36 – 46 degrees Fahrenheit (2 – 8 degrees Celsius). Expiration dates will be updated on [www.vaxcheck.jnj](http://www.vaxcheck.jnj). Vaccine providers should visit [www.vaxcheck.jnj](http://www.vaxcheck.jnj) to confirm the latest expiration dates of our vaccine, including those currently available for administration throughout the U.S.

A single-shot vaccine that provides protection and prevents hospitalization and death is an important tool in the global fight against COVID-19. [Evidence](#) from our Phase 3 ENSEMBLE study demonstrates the efficacy of our single-shot COVID-19 vaccine, including against viral variants that are highly prevalent. Regardless of race and ethnicity, age, geographic location and comorbidities, these results remain consistent.

We continue to work with the U.S. government and health authorities to support the use of our vaccine, which plays an important role in combatting the pandemic, including among those who wish to be fully vaccinated with one shot.

### **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 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](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.