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. Vaccine providers should visit 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.