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WHO grants EUL to J&J's single-shot COVID-19 vaccine

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Johnson & Johnson has announced that the World Health Organization (WHO) has issued emergency use listing (EUL) for its single-shot COVID-19 vaccine, developed by the Janssen Pharmaceutical Companies of Johnson & Johnson, to prevent COVID-19 in individuals 18 years of age and older.

Data from the Phase 3 ENSEMBLE study showed that the Johnson & Johnson COVID-19 vaccine was well tolerated and demonstrated a 67 per cent reduction in symptomatic COVID-19 disease in participants who received the vaccine in comparison to participants given the placebo. The onset of protection was observed from day 14 and was maintained 28 days post-vaccination.

The data also demonstrated the vaccine was 85 per cent effective in preventing severe disease across all regions studied, and showed protection against COVID-19 related hospitalisation and death across countries with different variants, beginning 28 days after vaccination. Variants observed in an ongoing analysis in the ENSEMBLE study included the B.1.351 variant which was identified in 95 per cent of the COVID-19 cases in South Africa.

"From the beginning of the pandemic, we have worked to develop and deliver a vaccine that could protect the health of people everywhere, and today's milestone represents significant progress toward ensuring global access to our single-shot vaccine," said Alex Gorsky, Chairman and Chief Executive Officer, Johnson & Johnson.

"The WHO listing of our single-shot COVID-19 vaccine advances our pledge to help stem this pandemic and our unwavering commitment to equitable access," said Paul Stoffels, MD, Vice Chairman of the Executive Committee and Chief Scientific Officer, Johnson & Johnson. "Achieving this important prerequisite for distributing our vaccine through the COVAX Facility which is co-led by Gavi is a major step forward in making our vaccine accessible for all."

In December 2020, Johnson & Johnson entered into an agreement in principle with Gavi, the Vaccine Alliance (Gavi) in support of the COVAX Facility. Johnson & Johnson and Gavi expect to enter into an Advance Purchase Agreement (APA)

that would provide up to 500 million doses of the Company's vaccine to COVAX through 2022.

"A single-shot COVID-19 vaccine that can be distributed and stored using established supply chains has the potential to be very meaningful in the face of this global pandemic," said Mathai Mammen, Global Head, Janssen Research & Development, Johnson & Johnson.