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Johnson & Johnson receives EUA for COVID-19 vaccine

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The company plans to deliver 100 million single-shot vaccines to the US during the first half of 2021

Johnson & Johnson has announced that the US Food and Drug Administration (FDA) has issued emergency use authorisation (EUA) for its single-dose COVID-19 vaccine, developed by the Janssen Pharmaceutical Companies of Johnson & Johnson, to prevent COVID-19 in individuals 18 years of age and older.

This decision was based on the totality of scientific evidence, including data from the Phase 3 ENSEMBLE study that 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, beginning 28 days after vaccination.

The terms of the EUA allow use of the vaccine while more data are gathered. The company plans to file for a Biologics License Application (BLA) with the FDA later in 2021.

"This milestone follows a year of incredible work by our dedicated teams and unprecedented collaboration with health leaders around the world – all of whom shared a goal of bringing a single-shot vaccine to the public," said Alex Gorsky, Chairman and Chief Executive Officer, Johnson & Johnson.

"We believe the Johnson & Johnson single-shot COVID-19 vaccine is a critical tool for fighting this global pandemic, particularly as it shows protection across countries with different variants," said Paul Stoffels, Vice Chairman, Executive Committee and Chief Scientific Officer, Johnson & Johnson.

Johnson & Johnson is committed to making its COVID-19 vaccine available on a not-for-profit basis for emergency pandemic use. The company has begun shipping its COVID-19 vaccines to the US government and expects to deliver enough single-shot vaccines by the end of March to enable the full vaccination of more than 20 million people in the US. The company plans to deliver 100 million single-shot vaccines to the US during the first half of 2021.

Johnson & Johnson also recently announced its submission of a European Conditional Marketing Authorisation Application to the European Medicines Agency as well as its filing for an Emergency Use Listing (EUL) with the World Health Organization

for its COVID-19 vaccine candidate.