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ASIA EDITION

J&J initiates global Ph 3 trial of COVID-19 vaccine candidate

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First participants dosed in Phase 3 trial (ENSEMBLE) evaluating safety and efficacy of Janssen's COVID-19 vaccine candidate, JNJ-78436735, also known as Ad26.COV2.S



Johnson & Johnson has announced the launch of its large-scale, pivotal, multi-country Phase 3 trial (ENSEMBLE) for its COVID-19 vaccine candidate, JNJ-78436735, being developed by its Janssen Pharmaceutical Companies.

The initiation of the ENSEMBLE trial follows positive interim results from the Company's Phase 1/2a clinical study, which demonstrated that the safety profile and immunogenicity after a single vaccination were supportive of further development.

These results have been submitted to medRxiv and are due to be published online imminently. Based on these results and following discussions with the U.S. Food and Drug Administration (FDA), ENSEMBLE will enroll up to 60,000 volunteers across three continents and will study the safety and efficacy of a single vaccine dose versus placebo in preventing COVID-19.

Johnson & Johnson anticipates the first batches of a COVID-19 vaccine to be available for emergency use authorization in early 2021, if proven to be safe and effective.

The American multinational firm will develop and test its COVID-19 vaccine candidate in accordance with high ethical standards and sound scientific principles. The Company is committed to transparency and sharing information related to the Phase 3 ENSEMBLE study – including the study protocol.

The Janssen COVID-19 vaccine candidate leverages the Company's AdVac® technology platform, which was also used to develop and manufacture Janssen's European Commission approved Ebola vaccine and construct its Zika, RSV, and HIV vaccine candidates.

Janssen's AdVac® technology platform has been used to vaccinate more than 100,000 people to date across Janssen's investigational vaccine programs.