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J&J accelerates COVID-19 vaccine candidate

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Phase 1/2a Clinical Trial to Begin in Second Half of July

Johnson & Johnson (J&J) has announced that through its Janssen Pharmaceutical Companies (Janssen) it has accelerated the initiation of the Phase 1/2a first-in-human clinical trial of its investigational SARS-CoV-2 vaccine, Ad26.COV2-S, recombinant. Initially scheduled to begin in September, the trial is now expected to commence in the second half of July.

The randomized, double-blind, placebo-controlled Phase 1/2a study will evaluate the safety, reactogenicity (response to vaccination), and immunogenicity (immune response) of the investigational SARS-CoV-2 vaccine, Ad26.COV2-S, recombinant in 1045 healthy adults aged 18 to 55 years, as well as adults aged 65 years and older. The study will take place in the U.S. and Belgium.

The Company is in discussions with the National Institutes of Allergy and Infectious Diseases with the objective to start the Phase 3 SARS-CoV-2 vaccine, Ad26.COV2-S, recombinant, clinical trial ahead of its original schedule, pending outcome of phase 1 studies and approval of regulators.

As the Company progresses the clinical development of its investigational SARS-CoV-2 vaccine, Ad26.COV2-S, recombinant, it continues to increase manufacturing capacity and is in active discussions with global partners to ensure worldwide access. The Company committed to the goal of supplying more than one billion doses globally through the course of 2021, provided the vaccine is a safe and effective.