

J&J to commence Ph III trial of COVID-19 vaccine in Sept

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First-in-human Phase 1/2a clinical trial now underway in United States and Belgium



American multinational corporation Johnson & Johnson (J&J) has announced that its lead vaccine candidate protected against infection with SARS-CoV-2, the virus that causes COVID-19, in pre-clinical studies.

The data, published in <u>Nature</u>, show the Company's investigational adenovirus serotype 26 (Ad26) vector-based vaccine elicited a robust immune response as demonstrated by "neutralizing antibodies," successfully preventing subsequent infection and providing complete or near-complete protection in the lungs from the virus in non-human primates (NHPs) in the pre-clinical study.

Based on the strength of the data, a Phase 1/2a first-in-human clinical trial of the vaccine candidate, Ad26.COV2.S, in healthy volunteers, has now commenced in the United States and Belgium.

"We are excited to see these pre-clinical data because they show our SARS-CoV-2 vaccine candidate generated a strong antibody response and provided protection with a single dose. The findings give us confidence as we progress our vaccine development and upscale manufacturing in parallel, having initiated a Phase 1/2a trial in July with the intention to move into a Phase 3 trial in September," said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer, Johnson & Johnson.

The robust Janssen COVID-19 clinical trial program, including the Phase 1/2a clinical trial and the Phase 3 clinical trial program, will evaluate both one- and two-dose regimens of Ad26.COV2.S in parallel studies.