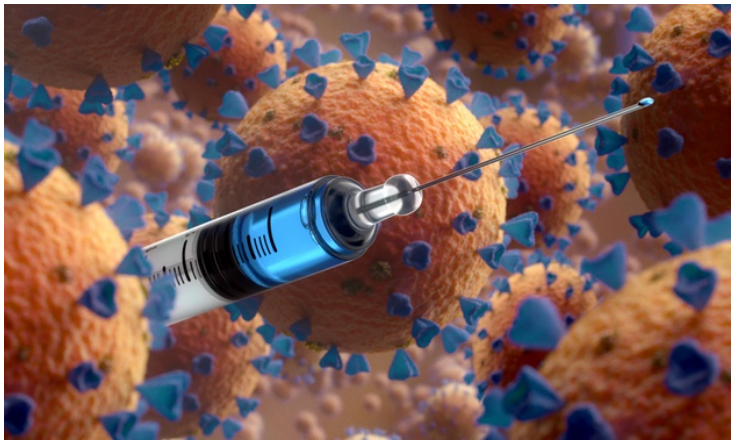
BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

J&J to produce 100M investigational COVID-19 Vaccine Doses for U.S.

05 August 2020 | News | By Hithaishi CB

Company working to ensure broad global access to Janssen's SARS-CoV-2 investigational vaccine, Ad26.COV2.S, following approval from regulators



Johnson & Johnson on 5 August 2020 announced it's Janssen Pharmaceutical Companies have entered into an agreement with the U.S. government for the large scale domestic manufacturing and delivery in the U.S. of 100 million doses of Janssen's SARS-CoV-2 investigational vaccine, Ad26.COV2.S, for use in the United States following approval or Emergency Use Authorization by the U.S. Food and Drug Administration (FDA).

The Biomedical Advanced Research and Development Authority (BARDA), part of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response, in collaboration with the U.S. Department of Defense, is committing over $1 billion for this agreement. The vaccine will be provided at a global not-for-profit basis for emergency pandemic use. The U.S. government may also purchase an additional 200 million doses of Ad26.COV2.S under a subsequent agreement.

"We greatly appreciate the U.S. government's confidence in, and support for, our R&D platform and efforts and the scalability of our vaccine technology. We are scaling up production in the U.S. and worldwide to deliver a SARS-CoV-2 vaccine for emergency use," said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer, Johnson & Johnson.

Johnson & Johnson's efforts to develop a SARS-CoV-2 vaccine have been undertaken pursuant to an ongoing research and development collaboration with BARDA and under the oversight of the FDA. Based on the positive preclinical data recently published in the peer reviewed journal *Nature*, the Phase 1/2a first-in-human clinical trial of the vaccine candidate, Ad26.COV2.S, is underway in healthy volunteers in the United States and Belgium.

The Company is evaluating one- and two-dose regimens, in its clinical program and working diligently to ensure broad, global access to the vaccine following approval or authorization by regulators. Johnson & Johnson aims to meet its goal to supply more than one billion doses globally through the course of 2021, provided the vaccine is safe and effective.

Johnson & Johnson's SARS-CoV-2 vaccine program leverages Janssen's AdVac® technology. The same technology was used to develop Janssen's European Commission-approved Ebola vaccine and construct its HIV, RSV and Zika vaccine

candidates. More than 90,000 individuals have been vaccinated to date using the Janssen AdVac®-based platform.