Covaxin approval requested in US for ages 2-18

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A medical assistant prepares a dose of a COVID-19 vaccine to be administered to a patient. Credit: Public domain image courtesy of Lisa Ferdinando, U.S. Department of Defense

US company Ocugen announced Friday that it had asked authorities for emergency use authorization for COVID-19 vaccine Covaxin, which was developed in India, for ages 2 to 18.

Ocugen's data, gathered from clinical trials conducted outside of the United States with only a small group of children, may not be enough for the Food and Drug Administration (FDA) to grant the request.

Covaxin, developed in India by Ocugen's partner, Bharat Biotech, gained emergency approval from the World Health Organization on Wednesday and has already been cleared for use in 17 countries.

Tens of millions of doses have been administered to adults outside of the United States, notably in India.

The immunization uses inactivated virus technology, common in other childhood vaccines including polio shots.

The approval request is based on results from a study of 526 kids between ages 2 and 18 who received two doses of Covaxin 28 days apart.

The findings were compared with those from a group of 25,800 adults in India, which suggested "similar protection in children, ages 2-18, to that demonstrated in adults older than 18 years," the company said.

Ocugen co-founder Shankar Musunuri in a press release called the move "a significant step toward our hope to make our vaccine candidate available here."

In the clinical trial with 526 children, no serious adverse events or hospitalizations were observed, but the study's sample size may not have been large enough to detect rare side effects.

The FDA asked Pfizer and Moderna, whose COVID-19 vaccines have already been authorized in the United States, to conduct trials with thousands of children to have a better insight into any side effects.

Pfizer's shot is the only one approved in the United States for children under the age of 18, and health authorities cleared the way this week for 5 to 11-year-olds to receive the vaccine.