



Ocugen Statement Regarding WHO Emergency Use Listing Announcement

November 3, 2021

Malvern, Pa., – November 3, 2021 – We are pleased that WHO has recognized the potential value of COVAXIN™ (BBV152), a differentiated broad-spectrum vaccine candidate, developed by our partner, Bharat Biotech. The rapid spread of the COVID-19 Delta variant is making it clear that new vaccine options are needed in the North American COVID-19 arsenal to help reverse this negative trend.

Using a traditional advanced stage whole-virion inactivated vaccine development approach, COVAXIN™ (BBV152) induces the immune system to target the whole virus and broad antibody response against multiple antigens and cellular response. This is the same technology that has been successful in producing the polio vaccine for infants globally for decades. Other currently available COVID-19 vaccine options in the U.S. target just a spike antigen to elicit an antibody response.

COVAXIN™ (BBV152) is the only vaccine to demonstrate efficacy against the COVID-19 Delta variant with the first Phase 3 clinical trial to include Delta variant data. Phase 3 results demonstrated that COVAXIN™ (BBV152) has 93.4% efficacy against severe COVID-19 disease, 77.8% overall efficacy, 63.6% efficacy against asymptomatic disease and 65.2% efficacy against the Delta variant. Adverse events reported in the trial were low, with 12.4% of subjects experiencing commonly known side effects and less than 0.5% of subjects experiencing serious adverse events. Both adverse events and serious adverse events reported in the vaccine group were reported at similar rates to the placebo group. More than 100 million doses of COVAXIN™ (BBV152) have already been administered.

We are excited at the prospect of bringing COVAXIN™ (BBV152) to the U.S. and Canada, having submitted regulatory packages to the US FDA and Health Canada. Along with directly helping millions of people in those two countries, we believe it would be a strong addition to the United States' vaccine diplomacy program with developing nations, given its ability to be more easily transported and stored.

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