Ocugen Statement Regarding Publication of COVAXIN™ (BBV152) Phase 3 Study Results in The Lancet

November 11, 2021

We are pleased that *The Lancet*, a trusted source of clinical, public health and global health knowledge, published Phase 3 data showing the COVID-19 vaccine candidate, COVAXIN™ (BBV152), has 93.4% efficacy against severe COVID-19 disease. COVAXIN™ (BBV152), a whole virion inactivated COVID-19 vaccine candidate, uses the same technology that is safely and effectively applied in the production of Bharat Biotech's polio vaccine. These data were critical in the World Health Organization's recent decision to place this vaccine on its global Emergency Use List (EUL), which now applies to more than 96 countries.

COVAXIN™ (BBV152) demonstrated 77.8% overall efficacy, 63.6% efficacy against asymptomatic disease and 65.2% efficacy against the Delta variant in the Phase 3 clinical trial of nearly 25,800 participants. 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, which is consistent with data from other vaccines that apply whole-virion technology. Both adverse events and serious adverse events reported in the vaccine group were reported at similar rates to the placebo group. The trial was conducted in India and sponsored by Bharat Biopharma. More than 150 million doses of COVAXIN™ (BBV152) have already been manufactured and administered.

These results make it the only vaccine to show efficacy against the COVID-19 Delta variant in a controlled Phase 3 clinical trial. The rapid spread of the Delta variant makes it clear that expanding protection against this variant is critically important. With vaccination rates still significantly below those needed for herd immunity, there is an urgent need for additional vaccine options.

We look forward to bringing COVAXIN™ (BBV152) to Canada and the United States. We recently submitted an Investigational New Drug application to the U.S. Food and Drug Administration an Investigational New Drug application to initiate a Phase 3 clinical trial evaluating COVAXIN™ (BBV152) for the prevention of COVID-19 in adults as well as a submission for an Emergency Use Authorization request for the use of COVAXIN™ (BBV152) in children, 2-18 years of age. Our rolling submission for emergency use authorization for COVAXIN™ (BBV152) with Health Canada is proceeding. We are confident that upon its approval, this vaccine's positive safety and efficacy data, along with its established technology platform, will make it a strong tool in the fight against this pandemic and may help to overcome vaccine hesitancy for many.