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Golden Biotech receives FDA approval for COVID-19 drug trial

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Golden Biotechnology Corp., a leading Taiwanese biopharmaceutical company, announced that the FDA approved its investigational new drug (IND) application for a Phase II clinical trial of Antroquinonol (Hocena®) on COVID-19 patients in USA.

Future developmental planning of Antroquinonol in COVID-19 include joining the COVID-19 Candidate and Technologies Portal of the National Institutes of Health (NIH) and applying for the US emergency authorization (EUA) once it exhibits significant clinical results, all to expedite the meeting of the urgent market demand.

The Phase II trial will be a randomized, double-blinded, placebo-controlled study of Antroquinonol as a potential treatment option for mild-to-moderate pneumonia in COVID-19 patients, as measured by the proportion of patients alive and free of respiratory failure (i.e., need for invasive mechanical ventilation, non-invasive ventilation, high-flow oxygen, or extracorporeal membrane oxygenation [ECMO]) on Day 14.

Antroquinonol was found to reduce viral nucleic acid replication and viral protein synthesis in both cell and animal experiments. Prevention of organ and tissue damage was also observed with Antroquinonol when treating mice with excessive inflammation. The characteristic of multiple effects makes Antroquinonol more advantageous than other antiviral and/or anti-inflammatory drugs. GoldenBiotech is now actively promoting the Phase II study for COVID-19 in the hopes that Antroquinonol will not only improve the symptoms of COVID-19, but also minimize the possible side effects that may be induced during the treatment process.