

COVID-19 Scoop: Epoch-Making GoldenBiotech's Oral COVID-19 New Drug Trial of Antroquinonol Got Green Light from the FDA to Extend Recruiting Severe COVID-19 Patients

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Golden Biotechnology Corp. →
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TAIPEI, Sept.16, 2021 /PRNewswire/ -- Golden Biotechnology Corp.(TPEX:4132) ("GoldenBiotech", GBC), a leading Taiwanese biopharmaceutical company, announces that its oral investigational new drug Antroquinonol (HOCENA®) has made headway with COVID-19 treatment development in more broader clinical trial patients permitted in inclusion severity as well as future marketing expansion by signing a new international MOU for cooperation and development of the new drugs in 23 European countries.



Golden Biotechnology Corp-Investigational new drug HOCENA®(Antroquinonol)

On Aug. 30, 2021, pursuant to clinical trial protocol amended following the recommendation of the approved second interim DMC (Data Monitoring Committee) review, GoldenBiotech was noticed by CRO that the Food and Drug Administration(FDA) agreed that its ongoing phase 2

trial of Antroquinonol for treating COVID-19 patients can be extended recruiting from the mild or moderate hospitalized patients to the severe hospitalized COVID-19 patients who need non-invasive oxygen support. The total trial subjects will remain the same, 174 patients in total.

The trial recruiting is expedited in full swing covering the USA, Peru and Argentina where the new upheaval pandemic is rampant with highly transmitted SARS-CoV2 variants. "So far, there is no oral drug approved or receives the EUA from the FDA for COVID-19 treatment. Our recent progress will help shorten the completion time of our phase 2 clinical trial and time to apply with the US FDA emergency use authorization (**EUA**) when the significant trial results are achieved," quoted by **Alex Liu**, the Chairman of Golden Biotechnology Corp.

Currently, Golden Biotechnology Corp. is the only Taiwanese company that undergoes the formal clinical trial for COVID-19 treatment in multi-national centers and follows the FDA guidance for COVID-19 trials to set the trial as randomized, double-blinded and placebo-controlled study.

Antroquinonol is a new small molecule drug (NCE) with convenient oral administration design and distinguished from other emerging oral treatment drugs for COVID-19 by its multi-functional effects on anti-viral, anti-inflammation and anti-fibrosis characteristics revealed by studies. The new permitted extensive enrollment from mild, moderate to severe patients in the trial will assess the efficacy of recovery rate and prevent the milder COVID-19 patients becoming more severe conditions which will ease the heavy loading of the medical systems.

Antoquinonl stands out from current many anti-viral drugs with its ingenious capability of anti-inflammation and liver protection effects which it recruits the COVID-19 confirmed patients consistent with pneumonia from their chest X-ray or computerized tomography (CT) scan. The sign of viral pneumonia indicates the inflammation and the tendency of severity which is lack of effective cure and with poor prognosis. People with liver disease are the vulnerable group to COVID-19 infection even the lower and slower antibody protection will produce after their receiving vaccination acc. to the recent studies.

GoldenBiotech signs MOU on Aug. 24 with Sanova Pharma GesmbH for cooperation and development of Antroquinonol in the 23 European countries including Austria, UK, Italy, Norway, Denmark and Switzerland. Sanova Pharma is a leading healthcare products and logistics provider in Austria and Europe with over 70 years of history in the healthcare sector. As integrated into the Herba Group in Austria and part of global McKesson group, Sanova Pharma

benefits from the knowledge and experience of the major local and global pharmaceutical wholesalers. "The MOU with Sanova Pharma will help boost the cooperation and expansion of the development for Antroquinonol in Europe," said Dr. **Today Su**, CEO of GoldenBiotech.

On Jan. 22, 2021, GoldenBiotech signed the licensing agreement with BNC Korea Co., Ltd, a leading South Korean company in medical device, biologicals and pharmaceuticals, for its COVID-19 new drug candidate Antroquinonol. BNC Korea is authorized for developing and commercialization of Antroquinonol for the treatment of COVID-19 in the territories of S. Korea, Russia, Ukraine and Turkey.

ClinicalTrials.gov Identifier: NCT04523181

<https://www.clinicaltrials.gov/ct2/show/NCT04523181>

About Antroquinonol (HOCENA®)

Antroquinonol®, a novel small molecule that was discovered in 2006 by Golden Biotechnology Corp. Its compound structure, preparation methods and applicable indications have been protected with patents worldwide. Embraced by its safety and multi-functional bioactive advantages, it has been applied in several clinical trials or research in oncology, coronavirus, liver metabolism symptoms, cardio-vascular, auto-immune and neuro-degenerative diseases. Other indications of clinical trials for Antroquinonol (HOCENA®) are pancreatic cancer, NSCLC (Lung cancer), AML(Leukemia), Hyperlipidemia, Atopic dermatitis and Hepatitis B etc. It has been granted the Orphan Drug Designation (ODD) by the U.S. FDA for the treatment of Pancreatic Cancer, Acute Myeloid Leukemia (AML) and HCC (Liver Cancer) in 2015. It also received the ODD for the treatment of Pancreatic Cancer from European EMA in 2017.

About Golden Biotechnology Corp. ("GoldenBiotech", GBC)

Golden Biotechnology Corporation, founded in 2002, is a Taiwanese based leading pharmaceutical company which dedicates to discovering novel compounds (NCE) and developing cutting-edge innovative therapeutics with breakthrough advantage against serious and rare diseases in hopes to improve and promote a lasting quality of life, health and longevity.

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