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Daewoong pharma partners with Tufts medical center for Ph 2 trial with Niclosamide

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Entering phase 2 clinical trial in the United States based on trial results in South Korea, India, and Australia



Daewoong Pharmaceutical announced on 26 Oct 2020 that the collaborative clinical research agreement between Daewoong and Tufts Medical Center was signed to prepare for the phase 2 clinical study of DWRX2003 (active ingredient: niclosamide) in the United States. DWRX2003 is an investigational drug under development by Daewoong Pharmaceutical as a COVID-19 treatment.

Tufts Medical Center is a renowned academic medical center located in Boston. Harry Selker, MD, MSPH, of Tufts Medical Center, agreed to be Daewoong's principal investigator along with his Tufts Niclosamide Team's current work in a separate phase 2 clinical trial evaluating the efficacy of oral niclosamide for COVID-19.

Niclosamide is an inexpensive medication that has been used worldwide for 50 years for tapeworm, which has been shown to have potent anti-viral activity. A clinical trial of niclosamide for COVID-19 is now underway at Tufts Medical Center to investigate niclosamide's ability to prevent progression to serious disease. The study is also examining niclosamide's potential to prevent viral shedding of the SARS-CoV-2, the virus that causes COVID-19, which would help prevent spreading of the disease.

Daewoong Pharmaceutical is planning a pre-IND meeting with the U.S. FDA to apply for a phase 2 clinical trial once obtaining the ethnicity-based safety data sorted from phase 1 clinical studies in South Korea, India, and Australia. The company expressed confidence in working with Tufts Medical Center and its extensive experience with niclosamide for the upcoming clinical trial.

Daewoong Pharmaceutical employed its proprietary delivery technology to repurpose oral niclosamide into a long-acting intramuscular injection, DWRX2003. The new formulation is expected to (1) overcome the low absorption rate of oral niclosamide, (2) maintain plasma concentration high enough to treat viral infection upon a single injection, and (3) prevent gastrointestinal adverse events (i.e. nausea, vomiting, etc.) that are known to occur by oral pathway.