

Novartis to sponsor HCQ clinical trial in COVID-19 patients

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Trial is designed and implemented quickly to address the need for science-based investigation following early preclinical and clinical evidence that hydroxychloroquine may help hospitalized patients with COVID-19 disease



Novartis has reached an agreement with the US Food and Drug Administration (FDA) to proceed with a Phase III clinical trial with approximately 440 patients to evaluate the use of hydroxychloroquine (HCQ) for the treatment of hospitalized patients with COVID-19 disease. The clinical trial drug supply will be provided by Sandoz, the generics and biosimilars division of Novartis.

The large trial sponsored by Novartis will be conducted at more than a dozen sites in the United States. Novartis plans to begin enrollment for this study within the next few weeks and is committed to reporting results as soon as possible.

To help achieve broad access to hydroxychloroquine as quickly as possible in these extraordinary circumstances, Novartis will make any intellectual property within our control that relates to the use of hydroxychloroquine to treat or prevent COVID-19 available through non-exclusive voluntary licenses, appropriate waivers, or similar mechanisms.

Patients in the trial will be randomized into three groups. The first group or arm will receive hydroxychloroquine. The second group will receive hydroxychloroquine in combination with azithromycin, which is an antibiotic therapy. The third group will receive placebo. Patients in all treatment groups are receiving standard of care for COVID-19. Researchers at the company compressed months of work into a few weeks to design the large clinical trial in order to rapidly respond to the need for COVID-19 disease treatments.

The clinical trial complements a commitment by Novartis, through Sandoz, to donate up to 130 million tablets of hydroxychloroquine to supply global clinical research efforts in the event the medicine is proven beneficial for treatment of COVID-19. Sandoz has already donated 30 million tablets to the US Department of Health and Human Services and is dispatching further shipments to countries based on requests from governments around the world.

As part of its research and development commitment, Novartis has formed a clinical investigation team to provide rapid access for approved clinical requests and support of clinical evaluation of its medicines to be repurposed and address the needs of patients with COVID-19 infections. In addition to hydroxychloroquine, Novartis plans to sponsor or co-sponsor clinical trials to study ruxolitinib and canakinumab for hospitalized patients with COVID-19 infections. Requests for investigator-initiated trials have been granted for COVID-19-related clinical studies of ruxolitinib, canakinumab, imatinib

mesylate, secukinumab, hydroxychloroquine and valsartan.