

MEDIA & INVESTOR RELEASE

Novartis to sponsor large clinical trial of hydroxychloroquine in hospitalized COVID-19 patients

- *Novartis has reached an agreement with the US Food and Drug Administration (FDA) to proceed with a Phase III clinical trial of hydroxychloroquine in hospitalized patients with COVID-19 disease*
- *Trial is designed and implemented quickly to address the need for science-based investigation following early preclinical and clinical evidence^{1,2,3} that hydroxychloroquine may help hospitalized patients with COVID-19 disease*
- *Company will also make its hydroxychloroquine intellectual property available to support broad access if medicine is approved for COVID-19*
- *Study complements Novartis commitment to donate up to 130 million doses of hydroxychloroquine globally to support the COVID-19 pandemic response*
- *Novartis has a broad COVID-19 research and development commitment, including multiple large sponsored and investigator initiated clinical trials of its medicines*

Basel, April 20, 2020 — 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 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.

“We recognize the importance of answering the scientific question of whether hydroxychloroquine will be beneficial for patients with COVID-19 disease,” said John Tsai, Head of Global Drug Development and Chief Medical Officer at Novartis. “We mobilized quickly to address this question in a randomized, double-blind, placebo-controlled study.”

As the new virus continues to spread and claim lives around the globe, doctors and patients are eager for treatment options. In some cases, clinicians are evaluating drugs that have been approved for other diseases, hoping that these will also work against COVID-19.

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.

“We are donating hydroxychloroquine tablets for COVID-19 patients including for use in this and other clinical trials with the hope that researchers and healthcare workers can quickly and scientifically determine whether hydroxychloroquine can help patients around the world combat this disease,” said Richard Saynor, CEO of Sandoz. “We will continue to fulfill orders for existing customers to ensure the medicine remains available to US patients who rely on it for other indicated uses.”

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.

About hydroxychloroquine in COVID-19

The drug hydroxychloroquine has garnered interest in the medical community after showing preliminary promise in small clinical studies, including one with co-administration with the antibiotic azithromycin.¹ In addition, hydroxychloroquine has demonstrated antiviral activity against SARS-CoV-2 in laboratory tests.^{2,3} Hydroxychloroquine has long been used for the treatment of malaria and certain autoimmune diseases.⁴

Novartis commitment and response to COVID-19

Novartis is deeply dedicated to the global effort to combat COVID-19 and doing our part to support the stability of global healthcare systems. We announced a broad set of measures including the creation of a global fund of USD 20 million to support communities around the world impacted by the COVID-19 pandemic. Novartis also has committed 130 million doses of hydroxychloroquine to support pandemic response. In addition, Novartis joined two key cross-industry research initiatives, the COVID-19 Therapeutics Accelerator, coordinated by the Bill & Melinda Gates Foundation, Wellcome, and Mastercard, as well as a COVID-19 directed partnership organized by the Innovative Medicines Initiative (IMI). Novartis is separately supporting COVID-19 related clinical investigations of several Novartis medicines. To support access, the Novartis generics and biosimilars division Sandoz became the first company to commit to keeping stable prices for a basket of essential medicines that may help in the treatment of COVID-19. More information about the Novartis response to COVID-19 is available on [novartis.com/coronavirus](https://www.novartis.com/coronavirus).

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About Novartis

Novartis is reimagining medicine to improve and extend people's lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis products reach nearly 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 109,000 people of more than 145 nationalities work at Novartis around the world. Find out more at <https://www.novartis.com>.

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