

Novartis backs hydroxychloroquine trial in COVID-19 fight

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3D print of a spike protein of SARS-CoV-2, the virus that causes COVID-19—in front of a 3D print of a SARS-CoV-2 virus particle. The spike protein (foreground) enables the virus to enter and infect human cells. On the virus model, the virus surface (blue) is covered with spike proteins (red) that enable the virus to enter and infect human cells. Credit: NIH

Swiss pharmaceutical giant Novartis said Monday it would sponsor a clinical trial in the US using hydroxychloroquine to treat patients hospitalised with COVID-19.

Novartis said it had reached an agreement with the US food and Drug Administration (FDA) to go ahead with a phase III clinical trial with around 440 patients to evaluate whether the drug is efficient in treating coronavirus, which has killed more than 164,000 people worldwide in a matter of months.

The company said its Sandoz division would supply the drugs needed for the trial, which would be conducted at more than a dozen sites in the United States starting within the next few weeks.

Hydroxychloroquine has been used for decades against malaria and is being tested worldwide against the virus along with another [anti-malarial drug](#), chloroquine.

Both have potentially [serious side effects](#), and a range of [clinical trials](#) are now underway to determine their efficacy and safety.

"We recognise the importance of answering the scientific question of whether hydroxychloroquine will be beneficial for patients with COVID-19 disease," John Tsai, Novartis Chief Medical Officer said in the statement.

"We mobilised quickly to address this question in a randomised, double-blind, placebo-controlled study," he added.

Hydroxychloroquine has shown early promise against COVID-19 in small-scale studies in France and China to reduce virus levels among people badly infected.

US President Donald Trump has touted it as a coronavirus treatment and in the US a limited emergency-use authorisation has been granted to the drug.

But many scientists are urging caution until larger [trials](#) show whether it is safe and effective.

Novartis said that patients in its trial would be randomised into three groups, with the first group receiving hydroxychloroquine, the second receiving the drug combined with an antibiotic therapy, and the third group receiving a placebo.

"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 company said.

Novartis said it would donate 130 million tablets of hydroxychloroquine to supply global clinical research efforts if the medicine is proven beneficial against COVID-19.

It also said it would open up its [intellectual property rights](#) relating to the use of hydroxychloroquine in a bid to facilitate access to the drug if it proves beneficial.

The company said it planned to sponsor or co-sponsor clinical trials to study the benefits of two other drugs, ruxolitinib, which is sold under the brand name Javaki, and canakinumab, commercialised as Ilaris, for patients hospitalised with COVID-19

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