STAT

Novartis steps up to study hydroxychloroquine in Covid-19

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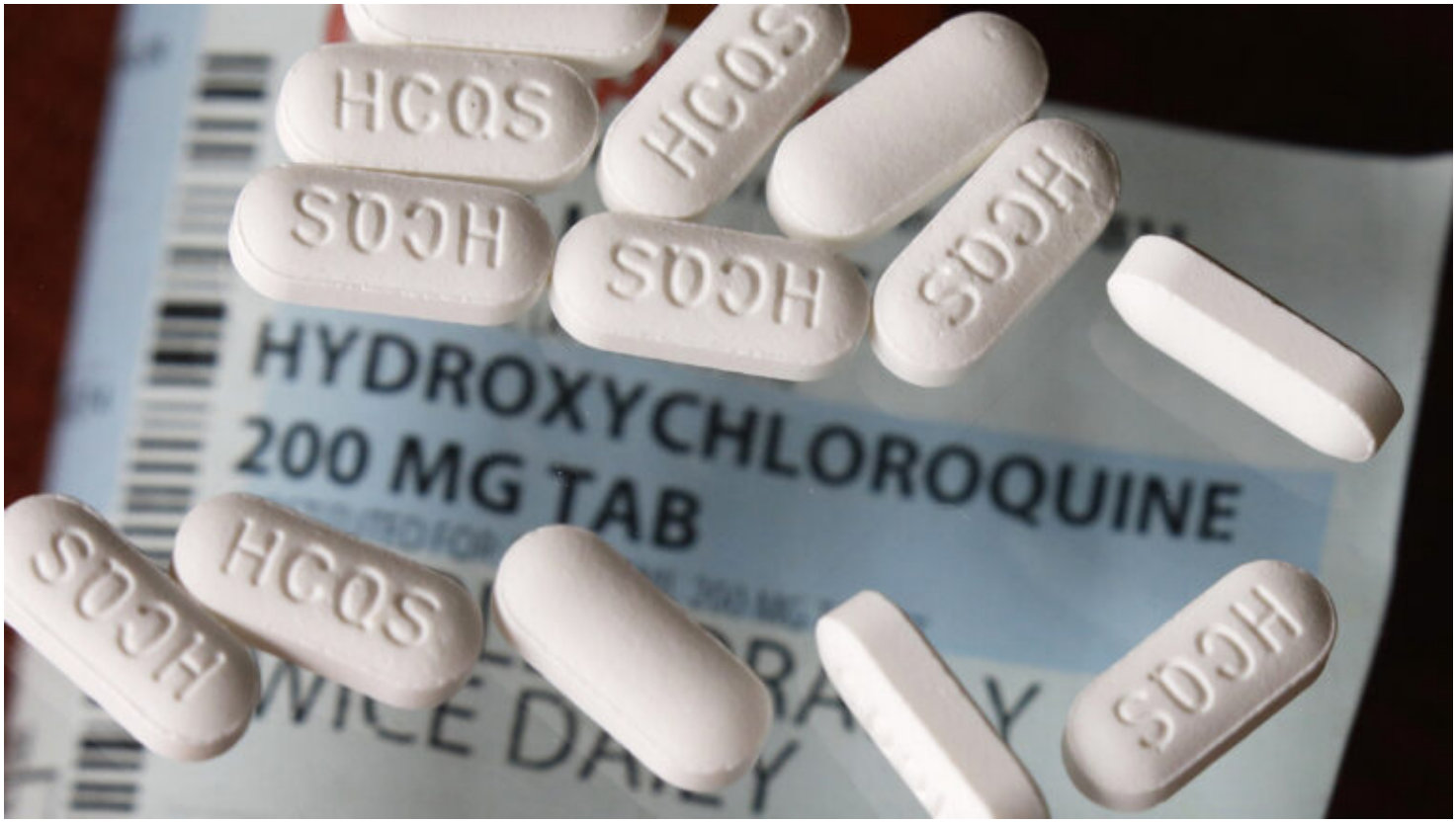

John Locher/AP

The drug giant Novartis said Monday it would conduct a 450-person study to determine if hydroxychloroquine, the malaria drug touted by many pundits and President Trump, can effectively treat Covid-19, the disease caused by the novel coronavirus.

The study will be a randomized, double-blind placebo-controlled study, the medical gold standard in which patients will be assigned one of three options: hydroxychloroquine, the combination of hydroxychloroquine and the antibiotic azithromycin, or placebo.

“We felt like there was just a lot of noise out there regarding whether it would be beneficial for this population of patients that [it] could really be helpful for,” said John Tsai, the chief medical officer of Novartis, in an interview. “So we wanted to embark on a rigorous, scientifically led approach to address the unanswered question, which is whether the use of hydroxychloroquine can help patients with Covid-19.”

The study will not include patients who are very sick and on ventilators. It will include adults who are hospitalized and are in what doctors call the moderate-to-severe population, for instance, those who need oxygen supplementation.

Patients will receive a loading dose of 600 milligrams of hydroxychloroquine, and then 200 mg three times a day. Tsai said that there is “a tight window” to get levels of the drug high enough that they might have antiviral activity without causing too many side effects, such as changes in heart rhythm that the drug can cause. The study will be conducted at more than a dozen sites in the U.S. and will begin within the next few weeks.

Hydroxychloroquine was originally approved by the Food and Drug Administration in April 1955. It was one of the first potential agents to show the ability to slow the SARS-CoV-2, the novel coronavirus, in a laboratory. Such results, while a useful scientific lead, still do not often translate into effectiveness in infected people.

A series of small studies, most of them not randomized (for instance, some compared patients who agreed to take the drug to those who didn’t) and not blinded (doctors and patients knew who got which drug) have shown conflicting results. One French study showed a dramatic reduction in blood levels of the SARS-CoV-2 virus with the combination of hydroxychloroquine and azithromycin, the antibiotic once sold by Pfizer as Zithromax.

Still, excitement about the drugs has meant that hydroxychloroquine is being used routinely in the sickest Covid-19 patients, and there have been concerns that patients with other diseases the drug is used to treat, such as lupus, have not been able to get it.

Most drug studies are conducted by pharmaceutical companies to increase the use of new medicines that are still protected by patents, which give them a monopoly on the drug's sales. For older, generic drugs like hydroxychloroquine, there are many manufacturers, none of whom are likely to make enough revenue to foot the bill.

But Tsai said that Novartis, which makes a generic version of hydroxychloroquine through its generic division, Sandoz, felt a responsibility to conduct the clinical trial.

"We felt like it was our obligation to embark on a study to understand the scientific question," Tsai said. "So that's why we pursued this study. There is not a financial incentive for us per se."

Novartis has already said it would donate 130 million doses of hydroxychloroquine to governments around the world, including 30 million that were given to the U.S.

The study will be led by Richard E. Chaisson, a professor of medicine, epidemiology and international health at Johns Hopkins University.

"While there has been a lot of enthusiasm about hydroxychloroquine, it is essential to put the compound through rigorous, science-based testing to determine its effectiveness and safety,"
Chaisson said in a statement.

About the Author

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