

Novartis update following WHO Solidarity trial announcement

May 27, 2020

On May 25, 2020 the World Health Organization (WHO) announced a temporary pause of the hydroxychloroquine (HCQ) arm within the Solidarity trial. The decision was based, in part, on publication in *The Lancet*¹ of an analysis of hydroxychloroquine and chloroquine and their effects on hospitalized COVID-19 patients. Novartis has taken note of this retrospective, observational study of existing multinational hospital registry data and our medical teams are evaluating the findings reported in the publication.

The medical evidence on hydroxychloroquine in COVID-19 patients at this point is preliminary. By design, retrospective observational studies cannot show causality, but only association. The medicine is currently under investigation in multiple large and small scale clinical trials. A full assessment of the benefits and risks of HCQ needs to single out the effects of the study medication versus other medications given concurrently, as well as placebo effects. It also needs to take into account patients' pre-existing medical conditions.

COVID-19 research efforts are about finding evidence-based solutions for the novel disease that will help patients get and stay well.

Similar to other diseases, we expect that there will be no 'one size fits all' treatment for exposed, mild, moderate and severe COVID-19 patients. Treatment may look different depending on the stage of the disease, co-morbid conditions, medicine availability and other factors. It is important to continue to add to the body of evidence and find the right treatment approaches for patients at each stage of the disease.

At Novartis, we remain committed to proceeding with the Novartis HCQ clinical trial to obtain much needed scientific data. We will continue to monitor other trials and review the medical information on the use of HCQ with a view to helping to identify the best treatment options for COVID-19 patients.

References:

1. The Lancet - Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis [https://doi.org/10.1016/S0140-6736\(20\)31180-6](https://doi.org/10.1016/S0140-6736(20)31180-6)

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