

# Novartis announces plan to initiate clinical trial of canakinumab for patients with COVID-19 pneumonia

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Novartis today announced plans to initiate a Phase III clinical trial to study canakinumab in patients with COVID-19 pneumonia. The CAN-COVID trial will examine the efficacy of utilizing canakinumab, an interleukin (IL)-1 $\beta$  blocker, to treat a type of severe immune overreaction called cytokine release syndrome (CRS) in people with COVID-19 pneumonia. CRS could lead to life-threatening complications in patients with COVID-19<sup>1-3</sup>.

The study builds on early evidence from lab tests of COVID-19 patients who showed elevated IL-1 $\beta$  levels, among other cytokines<sup>2,4</sup>.

Novartis aims to rapidly enroll 450 patients at multiple medical centers across France, Germany, Italy, Spain, UK and the US and randomize them to receive either canakinumab or placebo on top of standard of care (SoC). The primary objective of the study is to demonstrate the benefit of canakinumab in combination with SoC in increasing the chance of survival without the need for invasive mechanical ventilation among patients with COVID-19 pneumonia. Top-line results are anticipated late summer 2020.

This trial initiation is part of the overall Novartis approach to applying our best science to tackling the issues related to COVID-19 and further underscores Novartis commitment to quickly deploy R&D resources, medicines, clinical expertise and philanthropic aid to combat COVID-19.

1. National Cancer Institute. NCI Dictionary of Cancer Terms: cytokine release syndrome [online]. Available from: [www.cancer.gov/publications/dictionaries/cancer-terms/def/cytokine-release-syndrome](http://www.cancer.gov/publications/dictionaries/cancer-terms/def/cytokine-release-syndrome) [Last accessed: April 2020].
2. Mehta P, McAuley DF, Brown M, et al. COVID-19: consider cytokine storm syndromes and immunosuppression. *Lancet*. 2020;395(10229):1033-34.
3. Shimabukuro-Vornhagen A, Gödel P, Subklewe M, et al. Cytokine release syndrome. *J Immunother Cancer*. 2018;6(1):56.
4. Zhou F, Yu T, Du R, et al. Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study. *Lancet*. 2020. doi: [https://doi.org/10.1016/S0140-6736\(20\)30566-3](https://doi.org/10.1016/S0140-6736(20)30566-3) [Epub ahead of print].

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3. [https://doi.org/10.1016/S0140-6736\(20\)30566-3](https://doi.org/10.1016/S0140-6736(20)30566-3)