

「Antibody cocktail treatment for COVID-19 enters late-stage trials」

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When naturally infected with COVID-19, the body generates antibodies that latch onto the virus and mark it for destruction, or hinder its ability to infect healthy cells. These antibodies can be drawn from recovered COVID-19 patients and injected into sick patients to bolster their immune systems against the virus, a treatment known as convalescent plasma therapy. But plasma donations from different patients contain different mixtures of antibodies, and some antibodies may target COVID-19 more effectively than others.

[1] For instance, some antibodies directly prevent the virus from entering cells in the first place — so-called neutralizing antibodies — while others may not prevent infection, but instead direct other immune molecules to destroy infected cells. Therefore, it is difficult to evaluate the effeteness of convalescent plasma therapy.

To overcome this limitation, and avoid relying on a limited supply of plasma, several drug developers have turned to monoclonal antibodies — antibodies carefully selected for their ability to specifically target the virus to make a "antibody cocktail" as a treatment.

Recently, one such therapy REGN-COV2, from Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN), had entered Phase 3 clinical trials to evaluate whether the treatment can prevent COVID-19 infection among healthy people who have had close contact with an infected person, such as a housemate. 2,000 patients in the U.S. participated in this randomized, double-blind trial jointly run with the National Institute of Allergy and Infectious Diseases (NIAID) from July. [2]

Last week (Sep 29), Regeneron Pharmaceuticals, Inc. announced their antibody cocktail REGN-COV2 has been shown to reduce viral load and the time to alleviate symptoms in non-hospitalized patients with COVID-19. REGN-COV2 also showed positive trends in reducing medical visits. [3] And another 2,000 patients in the U.K. will be recruited to join the Phase 3 open-label trial. [4] REGN-COV2 is the first specifically designed COVID-19 therapy being evaluated by RECOVERY, a U.K. government-backed Randomised Evaluation of COVid-19 theRapY trials.

Experts said that it was selected in part based on its emerging safety profile in humans, pre-clinical data showing it could protect against viral escape mutations, and prevention and treatment studies in non-human primates showing it reduced the amount of virus and associated damage in the lungs. [4]

REGN-COV2 contains two antibodies that latch onto and help to neutralize the coronavirus, hampering its ability to infect healthy cells, according to the statement. The two antibodies bind to the virus's spike

protein, a structure that juts from the surface of the pathogen and plugs into cells to trigger infection. Regeneron scientists found the two antibodies by studying genetically modified mice with human-like immune systems and antibodies collected from human COVID-19 patients. [3]

Martin Landray, Professor of Medicine & Epidemiology, University of Oxford, said there are good reasons to be excited about the trials as it would provide a robust assessment of the effect the lab-manufactured monoclonal antibody combination treatment has on hospitalized patients. "Up to now, we have largely been studying whether existing drugs can be re-purposed to tackle this new disease, but we now have the opportunity to rigorously assess the impact of a drug specifically designed to target this coronavirus," he said. [4]

In addition to Regeneron, the pharmaceutical companies Eli Lilly and AbCellera are currently evaluating antibody treatments against COVID-19 in human trials. [5] If the FDA approves the drug at the end of Phase 3 trials, REGN-COV2 would then move on to the last phase called Phase 4, during which the drug could enter widespread use and its short- and long-term effects would be monitored in thousands of patients.

Reference:

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- 2. Nicoletta Lanese, July 08, 2020. "Antibody cocktail to prevent and treat COVID-19 enters late-stage trials" LiveScience
- 3. TARRYTOWN, N.Y., Sept. 29, 2020. "REGENERON'S REGN-COV2 ANTIBODY COCKTAIL REDUCED VIRAL LEVELS AND IMPROVED SYMPTOMS IN NON-HOSPITALIZED COVID-19 PATIENTS" Regeneron Pharmaceuticals Inc. news
- 4. Sep 14, 2020. "UK trials new antibody cocktail treatment for COVID-19" The Economic Times press.
- 5. Jacqueline Howard et al. July 7, 2020 "Regeneron starts Phase 3 trial of Covid antibody drug that might treat and prevent infection, company says" CNN Health press release.

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