MedicalXpress

Regeneron suspends COVID-19 antibody trial among sickest patients

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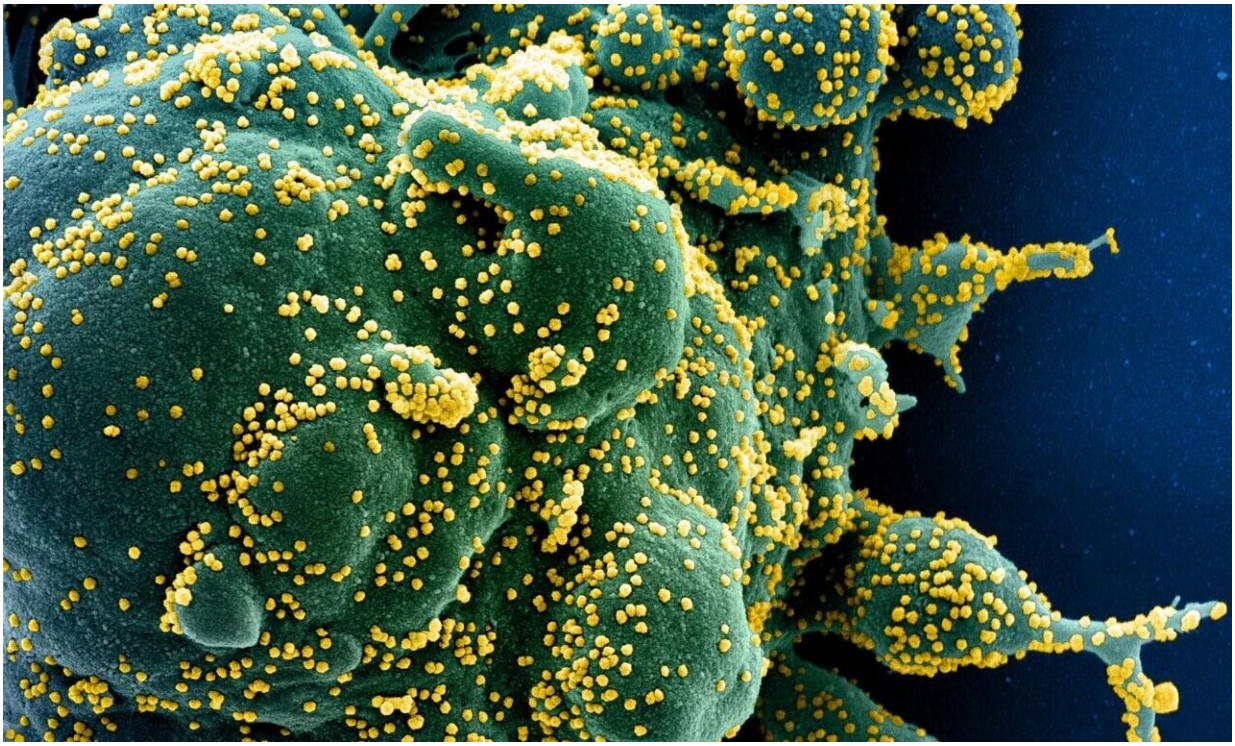

Colorized scanning electron micrograph of an apoptotic cell (green) heavily infected with SARS-COV-2 virus particles (yellow), isolated from a patient sample. Image captured at the NIAID Integrated Research Facility (IRF) in Fort Detrick, Maryland. Credit: NIH/NIAID

US biotech firm Regeneron on Friday said it was suspending enrollment for a study of its COVID-19 antibody treatment among the sickest

patients who require high-flow oxygen or are on ventilators.

The move follows a recommendation from an independent data monitoring committee (IDMC) which assesses the results and advises when it's necessary to halt a study.

"Based on a potential safety signal and an unfavorable risk/benefit profile at this time, the IDMC recommends further enrollment of patients requiring high-flow oxygen or mechanical ventilation be placed on hold pending collection and analysis of further data on patients already enrolled," the company said.

It added that the committee recommended that Regeneron continue to enroll hospitalized patients who either don't need oxygen or are on low-flow oxygen, and recommends the continuation of the outpatient trial.

Regeneron said it was informing the US Food and Drug Administration, which is currently evaluating the treatment, called REGN-COV2, for an emergency use authorization in mild-to-moderate outpatients at high risk for poor outcomes.

It is also sharing its recommendation with the committee monitoring a separate RECOVERY trial in the UK which is evaluating REGN-COV2 in hospitalized patients.

REGN-COV2 was recently used to treat President Donald Trump on a so-called "compassionate use" basis.

While there are no additional details about why the hospitalized trial for the sickest patients has been suspended, scientists have always believed that antibody treatments should work best when given early on in COVID-19.

This is because they work by preventing the virus from invading human cells and replicating.

But by the time a patient has progressed to late-stage COVID-19, the main factor driving their illness is not the virus itself but an abnormal immune response that causes severe inflammation and organ damage.

That's why current guidelines recommend treating late-stage patients with steroids, which dial down the immune system.

The human immune system itself develops antibodies, but because not everyone mounts an adequate response, companies like Regeneron are working on synthetic solutions.

They found two antibodies that were highly effective against the SARS-CoV-2 virus—one from a mouse with a human-like immune system, the other from a human—then harvested the cells that secreted them and grew them in a lab, to create a mass treatment combining the two.

The idea is seen as promising and the company recently received full regulatory approval for a similar treatment against the Ebola virus after it was proven to be safe and work well.

Regeneron has received more than $450 million from the US government for its COVID-19 drug development efforts.