Trump-touted COVID-19 antibody treatments: what we know

October 8 2020

Credit: CC0 Public Domain

Two US companies have applied for emergency approval for their lab-produced antibodies against COVID-19—and President Donald Trump has signaled his strong backing based on the fact he was treated with one of them.

Here's what we know about the treatments and why the perception of political interference at the Food and Drug Administration may have eroded public trust.

What are they?

The therapies developed by Regeneron and Eli Lilly are called "monoclonal antibodies," a relatively new class of drugs that are best known for treating certain types of cancer and autoimmune disease.

Our own immune systems produce antibodies, which are infection-fighting molecules, and vaccines teach our bodies to be prepared to make the right ones for particular pathogens.

Another potential strategy is to give a patient fighting a disease the antibodies of someone who has already recovered. This is known as convalescent plasma, but it's hard to procure plasma on a big enough scale to use it very widely.

Regeneron and Lilly have developed "cocktails" of antibodies based on the most effective ones they have discovered. In the case of Regeneron, one of these came from a person and the other from a mouse with a genetically-modified human-like immune system.

They all work by binding to and distorting a surface structure of the SARS-CoV-2 virus called the "spike protein" that it uses to invade human cells.

The host immune cells that produce the antibodies can be cultured in a lab to produce the desired antibodies en masse.

Antibodies can't be ingested in a pill and instead have to be transfused using a drip. In theory they could be used to immunize people too, but

unlike vaccines the protection would be highly transient.

Are they safe and effective?

Both companies have released some early data based on a few hundred non-hospitalized patients in clinical trials, with both claiming their treatments reduced viral load and recovery time.

One particularly eye-catching figure came from Lilly's mid-stage trial, which showed the rate of COVID-related hospitalization and emergency visits was 0.9 percent for patients treated with its therapy versus 5.8 percent on placebo.

That result however was for Lilly's "combination" treatment of two antibodies, whereas it has so far only applied for emergency approval for a "monotherapy" of one antibody, because it has greater stocks of it and more safety data available.

Both companies said their trials haven't produced any serious safety concerns so far.

President Trump, who was diagnosed with COVID-19 last week and was treated with Regeneron's version, has made it clear he is a big fan.

In a video released Tuesday night, said: "It really did a fantastic job, I want to get for you what I got."

Can the regulatory body be trusted?

The president's comments, based on his personal experience rather than data, could heighten fears for the integrity of the regulatory process.

In theory, the FDA operates independently from the White House, but its decision to issue an emergency use approval (EUA) in March for the antimalarial drug hydroxychloroquine touted by Trump raised serious concerns.

No clinical trials have yet found in favor of using hydroxychloroquine against COVID-19, and the EUA was later withdrawn given safety fears.

The evidence standard used to grant emergency approval for the antiviral remdesivir was much greater—a late stage trial involving more than a 1,000 patients.

More than 6,000 patients were studied in a British trial that showed the steroid dexamethasone lowered mortality rates in hospitalized COVID-19 patients, which in turn led to US authorities recommending it.

But the FDA has also given an EUA for convalescent plasma, despite there being no trial data in its favor yet—so approval of monoclonal antibodies does seem likely.

What's more, FDA chief Stephen Hahn restored some independent experts' faith when his agency on Wednesday released its guidelines for approving a COVID-19 vaccine.

The document said that makers need at least two months of follow-up data from patients after receiving their final dose, which makes it unlikely there will be an injection on the market before the November 3 election.

Citation: Trump-touted COVID-19 antibody treatments: what we know (2020, October 8)