ENDPOINTS NEWS

InflaRx plans to launch Covid antibody with five-figure price tag

by **Nicole DeFeudis** on April 5th, 2023

A day after winning emergency use authorization for its Covid-19 antibody, InflaRx said it has enough supply ready to treat several thousand patients. However, the drug will likely have a five-figure price tag.

InflaRx is aiming to make vilobelimab available as soon as possible, CEO Niels Riedemann said in a call with analysts on Wednesday. The drug, to be launched under the name Gohibic, was cleared for use in critically ill adults within 48 hours of receiving invasive mechanical ventilation or extracorporeal membrane oxygenation.

That's a much smaller patient population than Gilead's antiviral Veklury, which launched at $2,340 per course for developed governments and is now approved for both hospitalized and non-hospitalized patients, Riedemann said. Following talks with payers, the chief executive said Gohibic's list price will likely be a five-digit figure, "and it will not have a 1 as first figure," he added.

InflaRx wins FDA emergency use authorization for Covid antibody

The drug was approved roughly a year after failing a topline readout based on a site-stratified analysis

of 28-day all-cause deaths. While the original protocol did not call for site stratification, Riedemann said the company changed the protocol about two weeks before unblinding based on recommendations from regulators. That method led to 61 patients at smaller sites being "factually ignored," he said.

Without site stratification, InflaRx reported that vilobelimab did show a statistically significant reduction in all-cause mortality. InflaRx said it had "encouraging interactions" with the FDA, and announced plans to file an NDA back in July.

D erval O'Carroll

InflaRx execs said they're currently in discussions with the FDA about filing for a full approval, but it remains unclear whether that will require further studies. Gohibic targets a protein called complement factor C5a in an effort to rein in the body's inflammatory response.

"I think you'll see from the authorization that the data that we have is fairly solid, but we haven't had

those discussions yet," VP and head of regulatory affairs Derval O'Carroll said on the call.

When asked whether the company would consider a commercial partner, Riedemann said all options are on the table.

"We must be relatively opportunistic as a small biotech company. Again, if the idea is to get the drug to patients ASAP, that would not exclude a partner who can do that faster than we do," he said.

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