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A moment of truth arrives for CytoDyn's Covid-19 drug. Don't let spin obscure it

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CytoDyn chief executive Nader Pourhassan

CytoDyn is nearing the completion of a clinical trial investigating the use of leronlimab, its repurposed and still experimental HIV drug, to treat patients with Covid-19. When results of the study read out in the next few weeks, leronlimab is unlikely to show meaningful benefit.

Should CytoDyn be trusted to offer an honest summary of its clinical trial? I have doubts. What investors may get instead is a spin job that tries to portray objectively negative study outcomes in a more positive light. Expect to see a lot of handwaving to distract from bad data.

I wanted to ask CytoDyn and CEO Nader Pourhassan about their expectations, but they did not respond to questions or requests for an interview. But, for now, we can still look at the trial design and more.

CytoDyn's Phase 2 study sought to enroll 75 patients with mild to moderate symptoms of Covid-19 without need for oxygen support. Hospitalization was not an eligibility requirement, unlike other studies involving Covid-19 patients with moderate disease like Gilead Sciences' remdesivir.

Recruitment of patients started in April, but by early June, CytoDyn admitted publicly that enrollment stalled at 58 patients — 39 treated with leronlimab injections and 19 offered matching placebo injections. Days later, however, CytoDyn said it had managed to recruit, enroll and treat the full allotment of 75 patients with mild to moderate Covid-19.

CytoDyn credited the quick boost in patient enrollment to Chris Recknor, a physician and clinical trialist in Gainesville, Ga., who also was treated with leronlimab under a compassionate use protocol after being

diagnosed with a more serious case of Covid-19. Recknor eventually recovered, although what role, if any, that leronlimab played is not known.

Recknor was "very grateful for CytoDyn's efforts" and agreed to work for the company to recruit patients, said Scott Kelly, CytoDyn's chairman and chief medical officer, on a June 11 conference call. "He has been a tremendous asset in enrolling our mild to moderate Covid-19 trial."

The exact nature of Recknor's patient recruitment work for CytoDyn is not clear. Recknor's medical practice is called the Center for Advanced Research and Education. Recknor and his practice have participated in 10 clinical trials, mostly focused on treatments for osteoporosis and other bone disorders, his medical specialty, according to the government's ClinicalTrials.gov database.

The primary efficacy goal of the Phase 2 study measures "clinical improvement" across four symptoms — fever, muscle ache, shortness of breath and cough — after 14 days of treatment. This is a relatively weak and imprecise way to measure the benefit of a drug for Covid-19. Among the four symptoms, fever can be measured most objectively, but fever reduction alone has not been considered a clinically meaningful primary endpoint in any other Covid-19 clinical trial.

Gilead's remdesivir study in moderate Covid-19 patients, by comparison, defined clinical improvement based on a scale that assessed death, intubation, use of supplemental oxygen and hospitalization status.

CytoDyn has set the efficacy bar for leronlimab's Phase 2 study so low that even a positive outcome versus placebo looks medically irrelevant. This is particularly true for a drug that requires patients with relatively mild Covid-19 symptoms to visit a doctor's office or hospital for multiple injections.

The leronlimab study is also measuring more definitive outcomes like intubation, oxygen use and hospitalization as secondary endpoints, but showing statistically significant results will be difficult given the small number of patients enrolled and their relatively mild symptoms at baseline.

Separately, CytoDyn is conducting a Phase 3 study of leronlimab in patients with severe Covid-19, although it has also been delayed by slower-than-expected enrollment and its status is uncertain.

In June, CytoDyn CEO Pourhassan told investors the severe study would be stopped early so the company could conduct an interim mortality analysis. In an interview posted to YouTube on July 4, Pourhassan reversed himself, stating that an interim analysis was not happening even though he wanted to do one. The company would ask the FDA if an interim analysis could be conducted and maybe it would take place at the end of July. Recknor, the Gainesville doctor, is also working to recruit severe Covid-19 patients into the CytoDyn study, Pourhassan said.

From the earliest days of the coronavirus epidemic, Pourhassan has been unabashedly promotional about leronlimab and its potential to treat and save the lives of patients with Covid-19. In May, Pourhassan told investors that "you may sue us, hate us, or short our stock, but you can never deny that leronlimab is most likely saving some patients from the plague of coronavirus."

The tactics have been effective. CytoDyn's market value now tops $3 billion, despite being a penny stock that trades over the counter. CytoDyn CEO Nader Pourhassan and Chairman Scott Kelly have both personally profited from these promotional efforts[9], selling company shares for $12 million and $3 million, respectively.

Pourhassan has previously said he sold his company stock to pay for manufacturing of the drug and avoid delays.

It's a lot easier for Pourhassan to boast without having to cite actual clinical data. That's about to change, so how confident does he feel now about leronlimab and its chances for approval as a Covid-19 medicine?

"I just don't know," he said, when asked during his July 4th interview.

That's the biggest red flag of them all.

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