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CytoDyn CEO claims Covid-19 drug success while describing data suggesting study failure

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Nader Pourhassan, the chief executive officer of CytoDyn.

CytoDyn CEO Nader Pourhassan used a conference call on Thursday evening to claim success with the company's experimental Covid-19 drug — but his description of the clinical data, if true, suggests the drug didn't meet the study's primary goal.

In disjointed comments to investors, Pourhassan insisted that leronlimab delivered "positive efficacy results" in the Covid-19 study. CytoDyn intended to quickly submit the "strong results" to the Food and Drug Administration and expected to win approval for leronlimab as a new treatment for Covid-19, he added.

But in describing the leronlimab data, Pourhassan only said the drug improved symptoms after three days, not the 14 days set as the study's endpoint. If that's the case, it would suggest the 75-person trial failed to achieve its primary goal. Generally, the FDA does not approve drugs which cannot prove a benefit for patients, even those with Covid-19.

In another unusual departure from normal disclosure, CytoDyn provided no documentation, whether by press release or SEC filing, to back up the statements made by Pourhassan on Thursday evening's conference call.

Since early July, CytoDyn has promised to disclose the full results[7] from the clinical trial it calls CD-10, which is investigating weekly injections of leronlimab, a repurposed and still-experimental HIV drug, to treat Covid-19. But those data are still missing.

On July 21, CytoDyn issued a press release claiming "impressive" safety data[8] from the CD-10 study, while also disclosing the death of a Covid-19 patient following treatment with leronlimab. The company said the death was unrelated to its drug, but declined to offer any corroborating details.

CytoDyn's Phase 2 study enrolled 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.

The primary efficacy goal of the study measured "clinical improvement" across four symptoms — fever, muscle ache, shortness of breath, and cough — after 14 days of treatment, according to a description of the study[9] on the U.S. government's ClinicalTrials.gov website.

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 set the efficacy bar for leronlimab's study so low that even a positive outcome versus placebo would have been considered medically irrelevant.

On Thursday's conference call, Pourhassan claimed leronlimab achieved the primary efficacy goal of the study. "We have seen improvement in day 3 vs. day zero in the leronlimab arm as compared to the placebo arm," he said.

But this is not the primary efficacy goal of the study, which is required to show a statistically significant clinical improvement at day 14. Pourhassan also didn't indicate if the comparison of leronlimab and placebo was statistically significant after three days.

Similarly, Pourhassan described two secondary efficacy goals of the study where leronlimab "beat" placebo. But the study lists 16 different secondary outcomes, which raises questions about whether leronlimab failed all the others.

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. Pourhassan and CytoDyn Chairman Scott Kelly have both personally profited from these promotional efforts[12], 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.

But time and again, statements made by CytoDyn and Pourhassan turn out to be false or misleading.

In late June, CytoDyn said it had reached an agreement with the "NIH of Mexico" to conduct a clinical trial of leronlimab in Covid-19 patients. "Leronlimab could receive approval in Mexico very quickly," Pourhassan said at the time.

Asked for an update on the Mexico clinical trial during Thursday's call, Pourhassan said it was on hold. Similarly, a clinical combining leronlimab and remdesivir, which CytoDyn said in May would be starting soon,

has also been shelved.

Pourhassan further claimed on Thursday that the FDA might approve leronlimab for Covid-19 based on safety data alone, even if the efficacy results showed no benefit for patients. To support this statement, Pourhassan cited Regeneron Pharmaceuticals, which he said had altered its own Covid-19 clinical trials to use safety and not efficacy as the primary outcome goals.

Regeneron is conducting five clinical trials of experimental antibody treatments for Covid-19, none of which will rely solely on safety data as their primary goals, according to ClinicalTrials.gov.

CytoDyn pitches leronlimab to investors as a wonder-drug with the potential to cure patients with HIV, Covid-19, multiple types of cancer, the fatty liver disease known as NASH, Alzheimer's disease, multiple sclerosis, and graft-versus-host disease.

But in almost all these diseases, promised clinical trials of leronlimab have failed to materialize. On Thursday's call, for instance, Pourhassan said the first NASH patient would be injected with leronlimab in September, yet there is no independent listing for a NASH clinical trial involving leronlimab.

Two weeks ago, the FDA refused to accept an application[10] from CytoDyn seeking the approval of leronlimab to treat patients with HIV. The company is scheduled to meet with FDA officials next week in an attempt to get the HIV submission back on track, Pourhassan said.

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