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CytoDyn's Covid-19 drug troubles escalate: Efficacy data are missing from study

By Adam Feuerstein[2] @adamfeuerstein[3]

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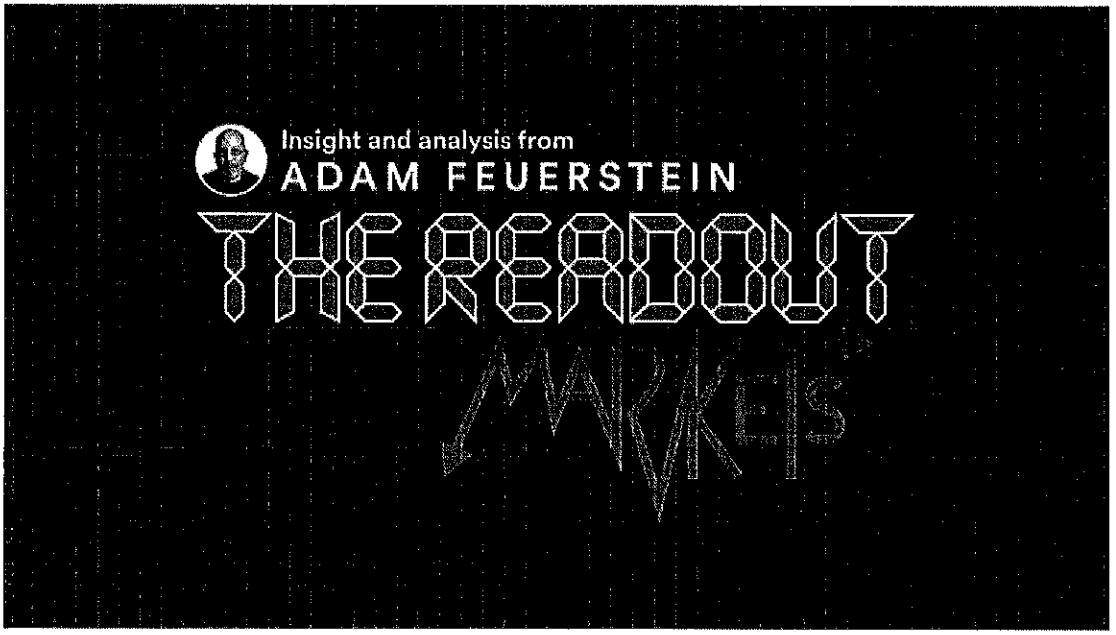

CytoDyn released safety data on its experimental drug for Covid-19 on Tuesday, but efficacy data were conspicuously absent, and the company disclosed that a patient had died following treatment with the therapy.

The cause of the patient's death was not disclosed, but CytoDyn said the fatality occurred 33 days after enrollment in the clinical trial due to an "event unrelated" to treatment with its drug, leronlimab. No other details about the patient were provided.

The company claimed the drug's safety profile was "impressive."

Over the past week, the company had teased investors with promises of full results from the completed study, which enrolled 84 patients with mild or moderate symptoms of Covid-19. On Saturday, CytoDyn CEO Nader Pourhassan gave an interview to a YouTube doctor in which he promised a press release on Tuesday morning with results from the Covid-19 clinical trial.

"We're just a couple of days away. As we said before, our optimism is through the roof. You have to hold me down with regards to my optimism," Pourhassan said.

But Tuesday morning came and went without the promised efficacy results, a red flag signaling CytoDyn was hiding a negative outcome.

In its statement, CytoDyn said an analysis of the study was incomplete. But that explanation makes little sense because the company was able to disclose unblinded safety data for the patients who received leronlimab injections or a matching placebo.

When a drug maker promises clinical trial results and then fails to deliver, the true reason is obvious: The study failed.

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. 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. That makes Tuesday's non-disclosure of any leronlimab efficacy data even more alarming.

About the Author

Adam Feuerstein[2]

Senior Writer, Biotech

Adam is STAT's national biotech columnist, reporting on the intersection of biotech and Wall Street.

adam.feuerstein@statnews.com [6]
@adamfeuerstein [3]

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