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FDA refuses application for HIV drug from CytoDyn, raising more questions about its credibility

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Andrew Harnik/AP

The Food and Drug Administration refused to accept an application seeking the approval of a drug to treat HIV from CytoDyn — a setback that could delay a decision for months, if not years.

The so-called Refuse-to-File letter, issued by the FDA against CytoDyn's drug called leronlimab, is also the most damning evidence yet that CEO Nader Pourhassan and other company executives might be misleading investors[5].

The price of CytoDyn shares have jumped tenfold this year based on unsubstantiated claims made by Pourhassan that leronlimab could become a blockbuster HIV drug, cure 22 different types of cancer, or save the lives of patients with Covid-19. In May, Pourhassan sold CytoDyn shares worth $12 million[6].

CytoDyn was seeking the approval of leronlimab, an injectable medicine, for use in combination with already approved antiretroviral pills, to treat patients with HIV that had grown resistant to standard therapy.

After years of delays, CytoDyn said it had submitted an application for leronlimab to the FDA in late April, only to admit in May that the submission was incomplete[7] because unspecified "mock datasets" had been sent to FDA instead of "clinical datasets."

In June, CytoDyn issued another statement claiming the leronlimab application was finally complete. Then came Monday's announcement admitting that the FDA refused to accept the leronlimab filing. Without offering specifics, CytoDyn said the leronlimab application "does not contain certain information needed to complete a substantive review." The FDA is also requesting "additional information."

CytoDyn offered no timeline for when it will meet with the FDA to discuss the Refuse-to-File letter, or when it will be able to resubmit the leronlimab application.

Under the best circumstances, delays caused by Refuse-to-File letters can linger for months, or even years if companies are forced to conduct new clinical trials. For CytoDyn, any delay is particularly costly because leronlimab is already facing formidable competition. Last week, the FDA approved a new HIV pill called Rukobia, marketed by ViiV Healthcare, a joint venture of GlaxoSmithKline and Pfizer, that will be used to treat advanced patients with limited options.

With its best shot at winning FDA approval now on indefinite hold, CytoDyn is now trying to shift investors' attention to the looming readout of a clinical trial investigating leronlimab as a treatment for Covid-19. But like most of what CytoDyn does these days, the results from this clinical trial are likely to be disappointing[10]. Expect to see a lot of spin and hand-waving to distract from bad data.

About the Author

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