

CytoDyn says lead HIV drug was not filed for FDA approval, as previously claimed

By [Adam Feuerstein](#)² [@adamfeuerstein](#)³

May 7, 2020



CytoDyn CEO Nader Pourhassan is already under fire for the timing of [lucrative sales of company stock](#)⁵. On Thursday night, Pourhassan found himself with a new problem: An admission that CytoDyn misled investors about a completed drug marketing application to the Food and Drug Administration.

The biotech's lead drug, leronlimab, an investigational treatment for patients with HIV, has not been submitted for approval to the FDA, as the company previously claimed.

The admission was buried in a press release that Cytodyn issued at 6:24 pm EDT, ostensibly to update investors about an ongoing clinical trial involving leronlimab and patients with Covid-19.

But then CytoDyn offered this:

“We would like to provide an update that the Biologics License Application (BLA) for leronlimab as a combination therapy for highly treatment experienced HIV patients will be considered completed after the clinical datasets are submitted on May 11, 2020.”

This update contradicts an April 27 statement issued by the company, which said the approval submission for leronlimab as a treatment for HIV had been “completed.”

“The submission of the final two parts of the BLA is a significant milestone for the Company, and initiates its transition from a development-stage company to a commercial organization,” Pourhassan said in the release at the time.

Apparently not, based on CytoDyn's admission Thursday that "clinical datasets" still need to be submitted to the FDA. "The clinical datasets are updated to address FDA comments for mock datasets from March 12 and March 20, 2020," the company added.

CytoDyn does not explain why it submitted "mock datasets" to the FDA instead of real data.

"I'm not authorized to talk to you," said CytoDyn spokesman Dave Gentry, before hanging up the phone when contacted by STAT for further comment.

About the Author



Adam Feuerstein²

Senior Writer, Biotech

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

adam.feuerstein@statnews.com⁸

[@adamfeuerstein](#)³

Links

1. <https://www.statnews.com/stat-plus/latest/>
2. <https://www.statnews.com/staff/adam-feuerstein/>
3. <https://twitter.com/adamfeuerstein>
4. <https://www.parsintl.com/publication/stat/>
5. <https://www.statnews.com/2020/05/05/cytodyn-ceo-made-12m-from-his-stock-sale-and-his-explanation-raises-more-questions/>
6. <https://www.statnews.com/signup/>
7. <https://www.statnews.com/privacy/>
8. <https://www.statnews.com/2020/05/07/cytodyn-says-lead-hiv-drug-was-not-filed-for-fda-approval-as-previously-claimed/mailto:adam.feuerstein@statnews.com>
9. <https://www.statnews.com/topic/biotechnology/>
10. <https://www.statnews.com/topic/fda/>
11. <https://www.statnews.com/topic/stat-plus/>