BuyersStrike!

It Was Dark Over Westphalia

Reader Mailbag – Breakthrough Therapy Edition (CYDY)

Commenter **Tom** recently asked (https://buyersstrike.wordpress.com/2020/09/24/who-else-is-suing-cytodyn-now-cydy/#comment-4483) a very good question. To paraphrase, "everyone's favorite reverse-merger pink sheet Coronacrapper, **Cytodyn** (**CYDY**) had bad news from the FDA but I can not find it on the FDA site. Can you help?" Certainly.

The answer to Tom's question should be quite illuminating to readers unfamiliar with the FDA, clinical trials, and the drug approval process. Before we begin, it would be helpful to review the Maxims (https://buyersstrike.wordpress.com/buyersstrike-maxims/), especially Maxims **19** and **20**.

Cytodyn often talks about "**Breakthrough Therapy Designation**" for loserlimab (https://buyersstrike.wordpress.com/2020/08/28/but-teh-science-be-so-gud-part-1-a-brief-history-of-loserlimab-cydy/). Like in this press release (https://www.cytodyn.com/investors/news-events/press-releases/detail/372/cytodyn-files-for-breakthrough-therapy-designation-with-the) from the 13th of January 2020:

CytoDyn Files for Breakthrough Therapy Designation with the FDA for the Use of Leronlimab for the Treatment of Metastatic Triple-Negative Breast Cancer

January 13, 2020 5:00am EST

Download as PDF

VANCOUVER, Washington, Jan. 13, 2020 (GLOBE NEWSWIRE) -- **CytoDyn Inc. (OTC.QB: CYDY)**, ("CytoDyn" or the "Company"), a late-stage biotechnology company developing leronlimab (PRO 140), a CCR5 antagonist with the potential for multiple therapeutic indications, announced today that the Company has filed for Breakthrough Therapy designation (BTD) with the U.S. Food and Drug Administration (FDA) for the use of leronlimab as an adjuvant therapy for the treatment of metastatic triple-negative breast cancer (mTNBC).

So just what is **Breakthrough Therapy Designation** (**BTD**)? You can read all about it here (https://www.fda.gov/regulatory-information/food-and-drug-administration-safety-and-innovation-act-fdasia/frequently-asked-questions-breakthrough-therapies). To briefly summarize, it is a stack of forms that a company fills out and sends to the **FDA** along with preliminary clinical evidence. The evidence must back up the company's belief that the treatment may show a substantial improvement, on at least one clinically significant endpoint, over available therapies.

Receiving **BTD** does confer certain benefits to the company developing the drug. It does not, in any way, mean the FDA "likes" a drug, or "wants" a drug to succeed. Getting **BTD** only means that the company filled out the forms correctly and had shown compelling preliminary clinical evidence. (Spoiler alert! Clinical evidence, unfortunately for **Cytodyn**, is not stories about **The NaDDir's*** mother-in-law.)

The existence of a filing for **BTD** status is actually confidential. A company applying for **BTD** is **not required to disclose** it to anyone, let alone the shareholders, but almost always do, in order to create hype and serve up a dose or two of that sweet sweet stock pimpin'. A company **is not required to disclose** if the request was granted or denied, either.

Furthermore, the FDA is forbidden from divulging this information as well.

> 18. **Will FDA announce when a drug has been granted breakthrough therapy designation?**
>
> FDA will not disclose information regarding sponsors who submitted requests for or who have been granted or denied breakthrough therapy designation. Breakthrough therapy designation requests are typically submitted to an IND, and the FDA cannot disclose the existence of an IND, or any submissions that have been submitted to the IND, unless it has previously been publicly disclosed or acknowledged per 21 CFR 312.130(a).

How can we tell what happened to that January request? Easy. The FDA responds to **BTD** requests within **60 days.**

22. What are the timelines for FDA to respond to a breakthrough therapy designation request?

FDA will respond to breakthrough therapy designation requests within 60 days of receipt of the request.

So, let's see what happened with **Cytodyn's BTD** request following the January submission. A month after that first press release the company mentioned it was awaiting a **BTD** decision from the FDA. See this press release (https://www.cytodyn.com/investors/news-events/press-releases/detail/385/cytodyn-reports-continued-positive-clinical-data-on-its).

CytoDyn Reports Continued Positive Clinical Data on its Phase 1b/2 mTNBC and Expanded Access Studies for MBC Ahead of Breakthrough Therapy Designation Decision From the FDA

February 14, 2020 6:00am EST

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Fast forwarding to March, what did the company say about the **BTD** application after the 60 day window had passed? A quick perusal of the **Cytodyn** website shows no press releases in mid-March (https://www.cytodyn.com/investors/news-events/press-releases?year=2020&page=8) about the **BTD** application.

Two Additional Coronavirus Patients Treated at Leading New York Hospital with CytoDyn's Leronlimab, Bringing the Total to Four Patients
Mar 23, 2020 6:00am EDT

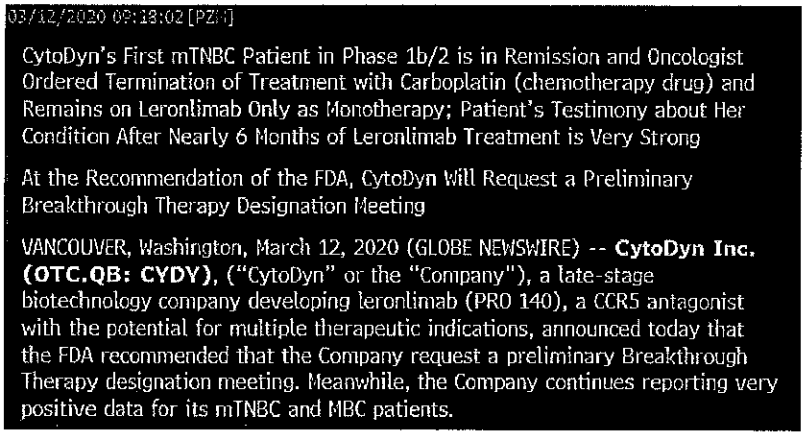
U.S. Food and Drug Administration (FDA) Grants Emergency IND for Two Coronavirus Patients Treated in New York with CytoDyn's Leronlimab
Mar 19, 2020 6:00am EDT

CytoDyn to Present at Wall Street Reporter's NEXT SUPER STOCK - Live Stream Event on March 19, 2020
Mar 18, 2020 3:52pm EDT

CytoDyn Files Modified IND and Protocol for Phase 2 Clinical Trial for Treatment of Patients with Coronavirus with Leronlimab (PRO 140) and Advises Correction to Press Release Issued on March 12, 2020
Mar 16, 2020 6:00am EDT

CytoDyn Appoints Jacob Lalezari, M.D. as Interim Chief Medical Officer
Mar 13, 2020 6:00am EDT

However, there WAS a press release from the 12th of March 2020 that **Cytodyn** appears to have **removed from their website.** It is still available on Bloomberg.



03/12/2020 09:18:02 [PZN]

CytoDyn's First mTNBC Patient in Phase 1b/2 is in Remission and Oncologist Ordered Termination of Treatment with Carboplatin (chemotherapy drug) and Remains on Leronlimab Only as Monotherapy; Patient's Testimony about Her Condition After Nearly 6 Months of Leronlimab Treatment is Very Strong

At the Recommendation of the FDA, CytoDyn Will Request a Preliminary Breakthrough Therapy Designation Meeting

VANCOUVER, Washington, March 12, 2020 (GLOBE NEWSWIRE) -- **CytoDyn Inc. (OTC.QB: CYDY)**, ("CytoDyn" or the "Company"), a late-stage biotechnology company developing leronlimab (PRO 140), a CCR5 antagonist with the potential for multiple therapeutic indications, announced today that the FDA recommended that the Company request a preliminary Breakthrough Therapy designation meeting. Meanwhile, the Company continues reporting very positive data for its mTNBC and MBC patients.

Instead of getting its BTD request approved, the BTD request was **denied**, and the **Cytodyn** clowns spun the rejection as a recommendation for a "request for a meeting".

What retail and generalist investors do not know, but every professional does know, is that these "preliminary BTD" meetings are supposed to be held before a company makes a **BTD** request, to avoid wasting everyone's time and potentially embarrassing the company. Con artists and stock promoters hope that retail investors never learn the truth about these things, they expect people to be lazy and not do the most basic research on these processes. The truth is easy to find, however. Says the FDA:

> 23. **Can a sponsor get preliminary breakthrough therapy designation (BTD) advice from the review division prior to the submission of a formal BTD request?**
>
> A sponsor can contact the regulatory project manager (RPM) in the division to which the active IND is assigned and request the "Preliminary Breakthrough Therapy Designation Request Advice" template. This template should then be submitted as a formal amendment to the IND and a subsequent teleconference between the sponsor and the review division will be set-up by the RPM. The review division will make a recommendation as to whether a request for a BTD is appropriate, may be too preliminary, or does not currently meet the criteria for a BTD. The Agency's recommendation is advisory and is not to be interpreted to predict the Agency's decision on the BTD request.

"How can you be so sure it was rejected?", a bull might ask. Time for another quick lesson. Scams and shady companies will lie in press releases all the time. Sometimes outright lies, sometimes sins of omission. SEC filings, 10Ks in particular, are usually more truthful. So instead of believing anything in a press release, the rule at **BuyersStrike! HQ** is to **believe nothing in press releases**, and instead **rely on the filings**.

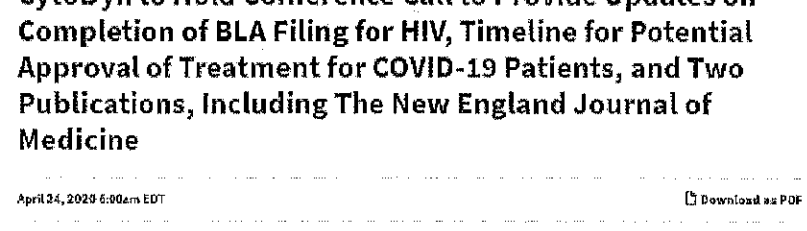
Let's examine the recent **Cytodyn** 10K filing (get it here (https://content.equisolve.net/sec/0001193125-20-220598/d923315d10k.htm)) from August, and see what it said about loserlimab getting **BTD** status from the FDA.

> On January 28, 2020, the Company awarded 11,650,000 performance shares to certain of its directors and executive officers outside of the 2012 Plan ("January 2020 Performance Shares"). The awards will vest and be settled in shares of common stock of the Company if the Company achieves FDA Breakthrough Therapy designation for cancer within 6 months of the award date and if certain other requirements have been met. The awards lapsed on July 28, 2020.

This section discloses that the **Cytodyn BTD** application from January was, in fact, **denied**! Otherwise, the clown crew would have awarded themselves 11.6mm free shares.

Moving on, let's examine the company's much hyped, but obviously doomed, **BLA** submission to get approval of loserlimab for HIV.

The company really started beating the drum about the BLA in late April with a series of press releases. Like this one (https://www.cytodyn.com/investors/news-events/press-releases/detail/420/cytodyn-to-hold-conference-call-to-provide-updates-on) from April 24th:



CytoDyn to Hold Conference Call to Provide Updates on Completion of BLA Filing for HIV, Timeline for Potential Approval of Treatment for COVID-19 Patients, and Two Publications, Including The New England Journal of Medicine

April 24, 2020 6:00am EDT Download as PDF

And this one (https://www.cytodyn.com/investors/news-events/press-releases/detail/421/cytodyn-submits-completed-biologics-license-application) claiming the BLA filing was complete and submitted just a few days later (spoiler alert: it wasn't true!):

CytoDyn Submits Completed Biologics License Application (BLA) to the FDA for Leronlimab as a Combination Therapy for Highly Treatment Experienced HIV Patients

April 27, 2020 9:12am EDT — Download as PDF

During the FDA's review period, the Company will dedicate all resources to ensure availability of leronlimab for COVID-19 patients; Cancer programs continue with positive results

VANCOUVER, Washington, April 27, 2020 (GLOBE NEWSWIRE) -- **CytoDyn Inc. (OTC.QB: CYDY)**, ("CytoDyn" or the "Company"), a late-stage biotechnology company developing leronlimab (PRO 140), a CCR5 antagonist with the potential for multiple therapeutic indications, today announced the Company has submitted the clinical, and the CMC (chemistry, manufacturing and controls) portions of its BLA to the U.S. Food and Drug Administration (FDA) for leronlimab as a combination therapy with HAART for highly treatment experienced HIV patients. The FDA previously granted both Fast Track designation for leronlimab and rolling review for the Company's BLA in HIV indication.

How can one tell that press release was false? Simple, just look at the press release (https://www.cytodyn.com/investors/news-events/press-releases/detail/428/cytodyn-clarifies-status-of-biologics-license-application) from May 8th:

CytoDyn Clarifies Status of Biologics License Application

May 08, 2020 7:58pm EDT — Download as PDF

Additional Data Required to Complete Application Expected to be Submitted on May 11, 2020

VANCOUVER, Washington, May 08, 2020 (GLOBE NEWSWIRE) -- **CytoDyn Inc. (OTC.QB: CYDY)**, ("CytoDyn" or the "Company"), a late-stage biotechnology company developing leronlimab (PRO 140), a CCR5 antagonist with the potential for multiple therapeutic indications, today further clarified the status of the Company's submission of its Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for leronlimab as a combination therapy with HAART for highly treatment experienced HIV patients, filed on April 27, 2020 with the FDA. The BLA will not be considered completed until the Company submits to the FDA clinical datasets required to address FDA comments it received in March 2020, as described in the Company's press releases on May 4 and May 6, 2020. CytoDyn expects to submit these clinical datasets on May 11, 2020.

Once submitted, the FDA will respond within 60 days if they will even accept the BLA for review. Only upon acceptance will the application be reviewed for possible approval. Based on this calendar, sometime in mid-July the company should have an answer from the FDA as to whether or not it will even evaluate loserlimab.

Mid July comes around and the company issues a bizarre press release about their BLA submission, puzzling the retail cult, but surprising exactly zero professionals. Says the company (https://www.cytodyn.com/investors/news-events/press-releases/detail/449/update-on-hiv-bla-pdufa-fda-requested-more-information-to):

Update on HIV-BLA-PDUFA: FDA requested more information to complete a substantive review. No additional trials required. CytoDyn plans to submit the requested information and will ask for a Type A meeting with the FDA per the agency's suggestion

July 13, 2020 8:00am EDT — Download as PDF

Update on COVID-19: CytoDyn is planning to lock and unblind the Phase 2 COVID-19 trial data later this week. Periodic safety review by Data Safety Monitoring Committee (DSMC) for ongoing Phase 3 study (severe/critical population) is planned for next week. Both results to be announced in July

CytoDyn holds investment community call today, Monday, July 13 at 1:00 pm PT

VANCOUVER, Washington, July 13, 2020 (GLOBE NEWSWIRE) -- CytoDyn Inc. (OTC.QB: CYDY), ("CytoDyn" or the "Company"), a late-stage biotechnology company developing leronlimab (PRO 140), a CCR5 antagonist with the potential for multiple therapeutic indications, announced today it has received a Refusal to File letter from the U.S. Food and Drug Administration ("FDA") regarding its Biologics License Application ("BLA") for leronlimab as a combination therapy with HAART for highly treatment experienced HIV patients. CytoDyn is confident it can provide all information requested by the FDA.

Compare the company's soft-selling in the press release (and conference calls) to the stark disclosure in the 10K. Buried in the 10K, is this admission:

The preclinical and clinical development of PRO 140 was led by Progenics Pharmaceuticals, Inc. ("Progenics") through 2011. The Company acquired the asset from Progenics in October 2012, as described in "PRO 140 Acquisition and Licensing Arrangements" below. In February 2018, we announced we had met the primary endpoint in its Phase 3 trial for leronlimab as a combination therapy with HAART for highly treatment experienced HIV patients, and filed the non-clinical portion of our Biologics License Application ("BLA) on March 18, 2019. We filed with the FDA the clinical, along with the Chemistry, Manufacturing, and Controls ("CMC") portions of the BLA April and May of 2020. In July 2020, we received a Refusal to File letter from the FDA regarding the BLA filing, and requested a Type A meeting to discuss the FDA's request for additional information.

Notice compared to the press release there is not a word in the filing about the FDA "suggesting" anything. RTF letters are non-public, **you will not find them on the FDA website.** It is up to the company to disclose them to investors.

Hopefully Tom and some others have learned something today. Now for some homework. Do the same research and analysis on **Cytodyn's** pathetic attempts to get an **EUA** for Covid, additional **EINDs** for Covid, and **Expanded Access** for Covid.

Want to know why a NASDAQ listing is a **virtual impossibility** for Cytodyn? Read all about that here (https://buyersstrike.wordpress.com/2020/10/09/update-what-exchange-wont-cytodyn-be-listed-on-this-month-quarter-year-cydy/). Want to know why loserlimab is basically useless for anything except 1 (and only 1) strain of HIV? Read here (https://buyersstrike.wordpress.com/2020/08/28/but-teh-science-be-so-gud-part-1-a-brief-history-of-loserlimab-cydy/).

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Posted in Bad Directors, Bio-Dreck, Bucket Shops, CoronaCrap, Fail, Reverse Mergers on October 6, 2020 by BuyersStrike!. 4 Comments

4 comments

1. **Pg** says:
   October 7, 2020 at 10:25 pm
   I guess since Citronsfart cant publish bs reports anymore he's relegated to this site.

   [Can you point to a single error of fact? Disprove anything? Of course not. – **Editor**]

   REPLY
2. **David Marilley** says:
   October 8, 2020 at 12:35 pm
   This post exudes ignorance. Does the author even know what a virus strain is? And then we have the logic issues. OMG. NO POSITIONS.

   [OK David, here's your shot. Why don't you explain the different HIV strains to us all, and why you believe loserlimab will be effective against all of them? – **Editor]**

   REPLY
3. **Raymond Carlson** says:
   October 10, 2020 at 6:28 pm
   Hmm, no BTD available from the FDA? like this: https://www.fda.gov/media/95944/download

   [Ray, that is a common mistake. What you are seeing is a list of **drugs that received marketing approval** last quarter, that had **previously been granted BTD status.** It is easy to be confused, but that is not a list of drugs that were merely **granted** BTD status last quarter. The FDA does make drug **approvals public**, for obvious reasons. They do not make BTD decisions themselves public. The FDA does not announce whether or not a drug is granted BTD. Check for yourself right here, scroll down to Q18. – **Editor**]

   REPLY
4. Pingback: Cytodyn CONference Call Preview (CYDY) | BuyersStrike!