BuyersStrike!

It Was Dark Over Westphalia

What Other Disease Won't Cytodyn Be Curing Today? (CYDY)

For years now, everyone's favorite reverse-merger pink sheet Coronacrapper, **Cytodyn (CYDY)**, has been hyping up the potential for its only product, affectionately referred to as loserlimab (https://buyersstrike.wordpress.com/2020/08/28/but-teh-science-be-so-gud-part-1-a-brief-history-of-loserlimab-cydy/), as a treatment for **Graft versus Host Disease** (GvHD). And as with all things **Cytodyn**, this has been only a string of ridiculous hype and broken promises.

The status of the GvHD trial is one of the topics in the company's upcoming webcast (https://www.cytodyn.com/investors/news-events/press-releases/detail/494/cytodyn-to-hold-webcast-on-january-6-to-provide-timelines) on January 6, 2021:

1) BLA submissions to Health Canada, MHRA, EMA, and US FDA
2) HIV prevention trial/monotherapy trial
3) Potential revenue from HIV and manufacturing forecast
4) HIV Cure - amfAR
5) EUA submission timelines to same four agencies for COVID-19
6) Long-hauler clinical trial and potential data readout timelines
7) NASH trial and potential interim analysis timeline
8) Cancer trial Breakthrough Therapy designation potential timelines
9) GvHD trial status
10) Stroke/MS new trials in 2021
11) NASDAQ uplisting status

(https://buyersstrike.files.wordpress.com/2020/12/jan6-confcalltopics.png)

[It should also be noted that there is no mention of the Philippines in this list, which is odd considering all of the hype in recent months. Unless, of course, one knows that all of that hype was easily disproven nonsense (https://buyersstrike.wordpress.com/2020/12/29/which-country-will-not-be-granting-cytodyn-an-eua-anytime-soon-cydy/).]

As a preview of next week's circus, let's take a look at the history of the **GvHD** trial, and where it actually stands today.

As early as Fall 2015 the company began to hype up **GvHD** as a potential indication. Press releases (https://www.cytodyn.com/newsroom/press-releases/detail/212/cytodyn-files-an-ind-and-full-protocol-for-phase-2-study-in)were issued in October 2015:

CytoDyn Files an IND and Full Protocol for Phase 2 Study in GvHD

October 20, 2015 6:30am EDT

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Orphan Drug Designation Application to be Filed

VANCOUVER, Wash., Oct. 20, 2015 (GLOBE NEWSWIRE) -- **CytoDyn Inc.** (OTCQB:CYDY), a biotechnology company focused on the development of new therapies for combating human immunodeficiency virus (HIV) infection, today announced that recent Company research has produced data to expand the potential clinical indications for PRO 140 for autoimmune diseases. Accordingly, the Company recently filed with the FDA a new IND (Investigational New Drug) application and a full protocol for a Phase 2 clinical trial. Furthermore, CytoDyn intends to file for Orphan Drug Designation for a Graft versus Host Disease ("GvHD") indication for patients requiring bone marrow transplants in the near future. CytoDyn (https://buyersstrike.files.wordpress.com/2020/12/oct15-gvhd.png)

And in mid December 2015 (https://www.cytodyn.com/newsroom/press-releases/detail/217/cytodyn-receives-fda-clearance-for-its-first-non-hiv):

CytoDyn Receives FDA Clearance for Its First Non-HIV Indication for PRO 140

December 14, 2015 8:30am EST

Download as PDF

Phase 2 Protocol for a Transplantation Indication Cleared for Patient Enrollment

VANCOUVER, Wash., Dec. 14, 2015 (GLOBE NEWSWIRE) -- **CytoDyn Inc.** (OTCQB:CYDY), a biotechnology company focused on the development of new therapies for combating human immunodeficiency virus (HIV) infection, today announced that it has been cleared by the FDA to conduct a Phase 2 trial for Graft versus Host Disease (GvHD), which is a life-threatening complication for patients undergoing stem cell transplants. CytoDyn currently is conducting a Phase 3 pivotal trial with its lead product candidate, (https://buyersstrike.files.wordpress.com/2020/12/dec15-1-gvhd.png)

Interestingly, back in 2015 the company **used the proper language.** The FDA never "approves" studies, they only "clear" them. Another press release (https://www.cytodyn.com/newsroom/press-releases/detail/219/cytodyn-files-for-orphan-drug-designation-for-use-of-pro) appears in late December 2015:

CytoDyn Files for Orphan Drug Designation for Use of PRO 140 in Graft Versus Host Disease

December 22, 2015 8:30am EST

Download as PDF

Phase 2 Protocol Has Been Cleared by the FDA for Enrollment

VANCOUVER, Wash., Dec. 22, 2015 (GLOBE NEWSWIRE) -- **CytoDyn Inc.** (OTCQB:CYDY), a biotechnology company focused on the development of new therapies for combating human immunodeficiency virus (HIV) infection, today announced that it has filed for Orphan Drug Designation with the FDA for its first non-HIV indication, Graft versus Host Disease (GvHD). CytoDyn currently is conducting a Phase 3 pivotal trial with its lead product candidate, PRO 140, for the treatment of HIV infection.

(https://buyersstrike.files.wordpress.com/2020/12/dec15-2-gvhd.png)

Yet, in typical **Cytodyn** fashion, it took **The NaDDir*** and his klown krew a full four months, mid-April of 2016, to actually launch the study. You can look up the trial information for yourself, at the Clinicaltrials.gov (https://clinicaltrials.gov/ct2/show/NCT02737306) website, but here is the relevant section:

ClinicalTrials.gov Identifier: NCT02737306

Recruitment Status : Unknown
Verified August 2018 by CytoDyn, Inc..
Recruitment status was: Recruiting
First Posted : April 13, 2016
Last Update Posted : August 15, 2018

(https://buyersstrike.files.wordpress.com/2020/12/april16-gvhd.png)

It took them **13 more months to finally find and treat a patient**, in mid-May 2017. The company issued a press release (https://www.cytodyn.com/newsroom/press-releases/detail/259/cytodyn-treats-first-patient-with-pro-140-in-phase-2-trial) stating:

CytoDyn Treats First Patient with PRO 140 in Phase 2 Trial for Graft versus Host Disease

May 17, 2017 6:00am EDT

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VANCOUVER, Washington, May 17, 2017 (GLOBE NEWSWIRE) -- **CytoDyn Inc.** (OTC.QB:CYDY), a biotechnology company focused on the development of new therapies for combating human immunodeficiency virus (HIV) infection, announces the treatment of the first patient in its Phase 2 clinical trial for Graft versus Host Disease (GvHD), its leading immunologic indication for PRO 140.

(https://buyersstrike.files.wordpress.com/2020/12/may17-gvhd.png)

After that, the company was relatively silent about the indication, with the exception of two late 2017 press releases about routine paperwork submissions and trumpeting animal data (https://www.cytodyn.com/newsroom/press-releases/detail/269/cytodyns-pro-140-monoclonal-antibody-prevents). [**Cytodyn's** behavior around their HIV PrEP study in Thailand follows a similar pattern, big announcements of human trials then nothing but hype around animal data by an outside scientist to hide the fact that the PrEP study never even happened!]

In **March 2018**, after an interim analysis, the trial was **massively modified**. You can read the company's press release about it here (https://www.cytodyn.com/newsroom/press-releases/detail/272/cytodyn-to-amend-protocol-for-pro-140-phase-2-trial-in-gvhd).

The press release was scant on details, there was no mention of what the interim analysis actually showed, although we can make some educated guesses based upon the modifications. Naturally, the press release doesn't mention those specifically, the actual changes could only be found by digging on the clinicaltrials.gov (https://clinicaltrials.gov/ct2/history/NCT02737306?A=1&B=4&C=Side-by-Side#StudyPageTop) website.

Official Title:	~~A Phase II, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study of the Safety and Efficacy of PRO 140 for Prophylaxis of Acute Graft-Versus-Host Disease (GVHD) in Patients With Acute Myeloid Leukemia (AML) or Myelodysplastic Syndromes (MDS) Undergoing Allogeneic Hematopoietic Cell Transplantation (HCT).~~	*An Open-Label, Single-Arm, Phase II Multicenter Study of the Safety and Efficacy of PRO 140 for Prophylaxis of Acute Graft-Versus-Host Disease (GVHD) in Patients Undergoing Reduced Intensity Conditioning (RIC) Allogeneic Stem Cell Transplantation*

(https://buyersstrike.files.wordpress.com/2020/12/gvhdstudytitle.png)

Instead of a proper randomized, controlled, trial the study would now became an open label, unblinded, unrandomized, single arm, collection of anecdotes.

Study Design		
Study Type:	Interventional	Interventional
Primary Purpose:	Treatment	Treatment
Study Phase:	Phase 2	Phase 2
Interventional Study Model:	~~Parallel Assignment~~	*Single Group Assignment*
Number of Arms:	~~2~~	*1*
Masking:	~~Double (Participant, Care Provider)~~	*None (Open Label)*
Allocation:	~~Randomized~~	*N/A*
Enrollment:	60 [Anticipated]	60 [Anticipated]

(https://buyersstrike.files.wordpress.com/2020/12/gvhdstudydesign.png)

The placebo arm disappears, and the dosage of loserlimab (https://buyersstrike.wordpress.com/2020/08/28/but-teh-science-be-so-gud-part-1-a-brief-history-of-loserlimab-cydy/) given in the study would increase from 2 injections of 175mg, which would total to **350mg** of the drug, to **525mg** of loserlimab.

Arms	Assigned Interventions
Experimental: PRO 140 ~~60 subjects~~ *Up to 60 subjects will be enrolled. PRO 140 will be administered as a ~~525 mg~~ subcutaneous injection on Day -3 or Day -2 prior to stem cell infusion, on the day of stem cell infusion (Day 0), and then weekly for up to ~~100~~17 days. Subjects will return to the clinic for three Follow-up visits at 2 weeks after the last treatment visit, 30 days after the last treatment visit and one year after the first treatment visit.*	Drug: PRO 140 ~~Two~~ 1 mL injections, 175mg/ml each, of PRO 140 to opposite sides of the abdomen. Other Names: • Humanized monoclonal antibody to CCR5
Placebo Comparator: Placebo ~~60 subjects.~~	Drug: Placebo ~~Two 1 mL injections of the Placebo to opposite sides of the abdomen.~~ Other Names: • ~~Placebo Comparator~~

(https://buyersstrike.files.wordpress.com/2020/12/gvhdstudyarms.png)

Older, presumably sicker, patients were now being excluded:

Eligibility		
Minimum Age:	18 Years	18 Years
Maximum Age:	~~75~~ Years	*65* Years
Sex:	All	All

(https://buyersstrike.files.wordpress.com/2020/12/gvhdstudyeligib.png)

All of this **suggests that the 350mg dose was utterly ineffective** against placebo, so much so that a new, much higher, dose was selected, and the placebo group eliminated to avoid another embarrassment. The modifications were finally accepted in August 2018, and enrollment was able to continue.

It took another **19 months**, (a full **24 months** after the interim analysis) for **Cytodyn** to finally treat another GvHD patient (keep in mind this delay was before the convenient excuse of Covid-19 could possible come up.) The company announced (https://www.cytodyn.com/newsroom/press-releases/detail/390/cytodyn-treats-first-patient-with-leronlimab-in-phase-2) in a March 2020 trial update press release:

CytoDyn Treats First Patient with Leronlimab in Phase 2 Trial for GvHD under Modified Trial Protocol

March 04, 2020 6:00am EST

Download as PDF

VANCOUVER, Washington, March 04, 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 the treatment of the first patient in its Phase 2 clinical trial for graft-versus-host disease (GvHD) under the modified trial protocol.

(https://buyersstrike.files.wordpress.com/2020/12/mar20-gvhdtrialupdate.png)

Throughout 2020 the company continued talking about the indication. Here are some slides from the most recent (October 2020) corporate presentation, available on Cytondyn's website (https://d1io3yog0oux5.cloudfront.net/_7b9e008c4a76d4778200dbb231eb2204/cytodyn/db/193/2912/pdf/CytoDyn+-+Investor+Presentation_Updated+10-14-2020+%28final%29.pdf).

Robust Pipeline

HIV, COVID-19, Cancer, NASH, MS, Stroke, and various Autoimmune Diseases

Designation	Program	Trial Status	Potential Timeline
FTD[1] - RR[2]	HIV - USA	BLA submission	2020
	HIV - UK	Pre-BLA meeting	October 26, 2020
	HIV - EU	Requested pre-BLA meeting	2020
	HIV - Canada	Requested pre-BLA meeting	November 9, 2020
	HIV- Monotherapy (Phase 3)	One dose/week	2020
	HIV - PrEP (Phase 2)	One dose/month	2021
	HIV – Cure (Phase 2)	5 patients/Timothy Brown model	2020-2021
	COVID-19 – Severe-to-Critical (Phase 3)	Interim Analysis	October 2020
	COVID-19 – Mild/Moderate(Phase 2)	Completed – Publication	2020
	COVID-19 - Moderate (Phase 3)	FDA discussions underway	Initiate 2020
	COVID-19 - Long Hauler (Phase 2)	File synopsis of the protocol w/FDA	October 2020
FTD[1]	Cancer - mTNBC (Phase 1b/2)	Enrolling-BTD discussions	2020
	Cancer - Basket trial (Phase 2)	Enrolling-BTD discussions	2020
ODD[3]	GvHD (Phase 2)	Enroll 5 more patients-BTD	2020

(https://buyersstrike.files.wordpress.com/2020/12/octpresgvhd-pipeline.png)

And the company went into greater detail here:

GvHD

Mechanism of Action – Phase 2 Update

Potential role of leronlimab in GVHD

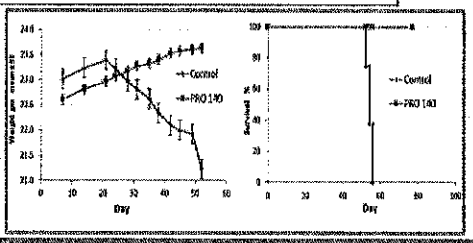
"Longer follow-up reveals a sustained reduction in acute GVHD incidence in maraviroc-treated patients compared with the control cohort, with a stronger effect on visceral vs skin GVHD and importantly no adverse impact on disease relapse, infections, or immune recovery. Thus, these data add further support that CCR5 blockade protects against GVHD."
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5314813/

"Importantly, although CCR5 deficiency affects lymphocyte trafficking to target tissues, T cells would still be able to recognize pathogen-derived antigens.[1] Furthermore, humans with CCR5 deficiency are not grossly susceptible to infections, and in fact, we observed no increase in infection rate with maraviroc in our study. This suggests that maraviroc can dampen alloreactive T-cell responses while not impairing immunity against infections."
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5314813/

"CCR5 is a marker for GVHD effector cells and that CCR5+ T cells are active participants in the pathogenesis of human acute GVHD."
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3182111/

GvHD (Graft vs. Host Disease)

- FDA granted Orphan Drug Designation (ODD)
- Xeno-GvHD Human BM transplanted into Immuno-Deficient mice
  Study was published in peer-reviewed publication:
  "Biology of Blood and Marrow Transplantation"
- Phase 2 trial initiated
- Amended protocol for Phase 2 trial received IRB approval
- Patient enrollment underway



Designation	Program
Orphan Drug Designation	GvHD (Phase 2) – Need 5 patients in this open label trial. With very positive results we can apply for breakthrough designation

(https://buyersstrike.files.wordpress.com/2020/12/octpresgvhdslide.png)

And throughout the year at the bottom of virtually every one of **CYDY's** multitude (over 120 year to date) of press releases was this little blurb buried in the boilerplate:

> The CCR5 receptor appears to play a central role in modulating immune cell trafficking to sites of inflammation. It may be crucial in the development of acute graft-versus-host disease (GvHD) and other inflammatory conditions. Clinical studies by others further support the concept that blocking CCR5 using a chemical inhibitor can reduce the clinical impact of acute GvHD without significantly affecting the engraftment of transplanted bone marrow stem cells. CytoDyn is currently conducting a Phase 2 clinical study with leronlimab to support further the concept that the CCR5 receptor on engrafted cells is critical for the development of acute GvHD, blocking the CCR5 receptor from recognizing specific immune signaling molecules is a viable approach to mitigating acute GvHD. The FDA has granted orphan drug designation to leronlimab for the prevention of GvHD.

(https://buyersstrike.files.wordpress.com/2020/12/dec2pr-gvhd-1.png)

That is, until the December 15th press release (https://www.cytodyn.com/newsroom/press-releases/detail/491/cytodyn-completes-enrollment-for-phase-3-registrational) when the boilerplate language suddenly changed, and a curious sentence was appended to the usual paragraph about GvHD:

(https://buyersstrike.files.wordpress.com/2020/12/dec15-20.png)

Funny that **The NaDDir's*** and his top notch team forgot to edit out the part of the paragraph that states they are currently conducting the study. Even funnier that this Klown Krew blame their failings on Covid-19 when the study has been a disaster, with delay after delay, since it was first announced over 5 years ago!

Happy New Year!

[Did you know **Cytodyn** is being sued by a group of former directors? What to know why? See here (https://buyersstrike.wordpress.com/2020/12/18/update-update-whos-suing-cytodyn-now-and-who-is-admitting-the-plaintiffs-are-right-cydy/) and here (https://buyersstrike.wordpress.com/2020/12/20/sunday-funday-what-else-doesnt-cytodyn-want-investors-to-learn-cydy/).]

[Did you know **Cytodyn's** claims of **non-dilutive** financings (with notorious penny stock player John M. Fife (https://www.sec.gov/litigation/litreleases/2020/lr24886.htm)) are complete bullshit? They are highly dilutive. Want to know why? See here (https://buyersstrike.wordpress.com/2020/12/21/what-did-cytodyne-bury-in-the-mid-december-s3-filing-cydy/).]

*** Spelled Thusly For A Double Dose of That Sweet Sweet Stock Pimping**

Posted in Bad Directors, Bio-Dreck, Bucket Shops, CoronaCrap, Fail, Reverse Mergers on December 30, 2020 by BuyersStrike!. 3 Comments

3 comments

1. **Kevin Hunt** says:
   December 30, 2020 at 5:20 pm
   Very promising Company. Looks as though Leronlimab will be very huge for the company and humanity. A lot of HIV and COVID-19 patients can benefit from this drug.

   [We'll just have to agree to disagree. Closer to 0 patients will benefit from this con. – Editor]

   REPLY
2. **S** says:
   December 30, 2020 at 5:42 pm
   This is a horrible article. I can't believe you won't even write an name behind your writings. As an RN, Leronlimab has saved lives and I'm praying fir it's approval for those fighting for their lives. So sad you would write such lies.

   [Can you point to a single factual error? Just one? Loserlimab is utterly useless for anything but one form of HIV, and has never been proven to save anything. It has not been approved for anything. Anywhere. As an RN, you should know better. – **Editor]**

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