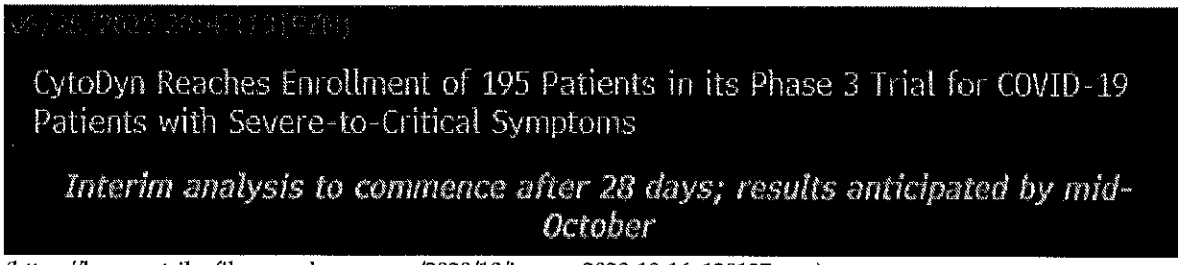
BuyersStrike!

It Was Dark Over Westphalia

Who's STILL Not Participating in CYTODYN'S Ridiculous Loserlimab Trial? (CYDY)

While we wait for everyone's favorite reverse-merger pink sheet Coronacrapper, **Cytodyn (CYDY)**, to finally release the much hyped, and delayed-yet-again (see last night's press release from the Cytocrew here (https://www.cytodyn.com/newsroom/press-releases/detail/475/cytodyn-to-hold-webcast-on-october-20-to-discuss-dsmcs) and an absolute howler of stock promoting stupidity here (https://insiderfinancial.com/handicapping-cytodyns-otcmkts-cydy-interim-readout/180558/)), interim results from their latest trial (https://clinicaltrials.gov/ct2/show/NCT04347239#contactlocation) (sometimes called **CD12**) of loserlimab (https://buyersstrike.wordpress.com/2020/08/28/but-teh-science-be-so-gud-part-1-a-brief-history-of-loserlimab-cydy/) (sometimes called PRO140 or leronlimab) in Severe-To-Critical Covid-19, let's catch up on what the company has been up to the last few weeks.

Since announcing that the interim enrollment milestone was reached on August 25th the company has had several arduous tasks in front of it:



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First, **The NaDDer*** and his trusty clinical trial wizard, **Kooosh Doody** had to remember that August has 31 days, so they needed to check on whether the last patient was dead or alive on **September 22nd**. Then they needed to tally up all the mortality events. It took these geniuses eight days, but they did it, and on **September 30th** they announced to the world that there were, supposedly, **45 deaths** in the trial.

Regulatory agency	Update
FDA	~220/390 Patients enrolled/total patients for trial Safety look after 100 **was positive** Interim after 195 (total death ~ 45) Interim analysis in October 2020
MHRA	Five sites are ready to initiate trial

(https://buyersstrike.files.wordpress.com/2020/10/image_2020-10-16_121003.png)

Supposedly? Because it seems they weren't exactly sure, that's why that little tilde is hanging out there before the '45'. Those complicated ordinal numbers. The rigors of higher math. After the deaths are counted, the **Data Safety Monitoring Committee** (DSMC) is usually the team tasked with seeing if the deaths occurred in Group A or Group B, putting those numbers into a spreadsheet (one so simple any 1st semester or AP Stats student could do it in under 5 minutes), determining if there is a statistically significant difference between the groups, making a recommendation, and finally reporting the results.

What should have taken 15 extra minutes on the 30th of September, takes an additional 20 days in Cytoworld.

While all this has been going on, of course, **Cytodyn** and the **CD12** trial have not been standing still, or have they?

Recall that in late August two sites, Eisenhower Health in California and **Yale-New Haven** in Connecticut, dropped out of the CD12 trial (read more about that here (https://buyersstrike.wordpress.com/2020/09/08/quick-take-whos-not-participating-in-cytodyns-ridiculous-loserlimab-trial-cydy/)). One might also recall that on August 20th **Cytodyn** claimed they would start enrolling patients in the UK "immediately"

After Several Months of Providing Requested Information About Manufacturing and Safety of Leronlimab, U.K.'s MHRA Accepts CytoDyn's Request to Enroll in its Current Phase 3 Trial for COVID-19 Patients with Severe-to-Critical Symptoms

August 20, 2020 4:51am EDT

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Patient enrollment to commence immediately

On September 2nd they backtracked on that claim, but insisted that UK study could now be "officially initiated":

09/02/2020 17:11:16 [BT]

That takes us to CD12 trial. First, let me explain CD4 -- I'm sorry CD12 enrollment in UK. So I am ready now -- I'm going to read to you the email that the Regulatory Director at Amarex, Dr.Ahmed Bayat sent me in regards to that. This is what he said. "We received great news today. UK ethical committee approved CD12 study to be conducted in the UK. Now, the study can officially be initiated. Please also see our MHRA comments below". They have recommended, CytoDyn to resubmit the CytoDyn CD12 COVID-19 study to the urgent public health, UPH scheme. If UPH scheme

Guess that wasn't true either, because on the 30th of September the company provided this update on clinical trial enrollment in the UK:

MHRA	Five sites are ready to initiate trial

(https://buyersstrike.files.wordpress.com/2020/10/image.png)

Fast forward to today, the 16th of October, and a peek at the list of trial locations on both Clinicaltrials.gov (https://clinicaltrials.gov/ct2/show/NCT04347239#contactlocation) and **Cytodyn's** own website (https://www.cytodyn.com/clinical-trial-enrollment/covid-19-severe-or-critical), show that the September 30th "update" was just another empty promise (polite term for bullshit) from the **Cytodyn Klown Krew**. There are **still no UK sites** for the CD12 trial. Both sources show 14 sites, and **not a single one in the UK**.

Even if progress in the UK has been stalled, the company surely must be chugging along in the USA, right? After all, as **The NaDDer*** constantly tells his loyal shareholder base "we are in pandemic!".

How is trial enrollment going? We know from the press release cited above that on August 25th there were 195 patients enrolled. From a depressing (for **Cytodyn** believers) presentation given by **Dr. Harish "Sad Sack" Seethamraju** (available here (https://d1io3yog0oux5.cloudfront.net/cytodyn/files/video/ISIRV+Harish_Seethamraju+Presentation.mp4)) it was revealed that on September 4th enrollment was up to **220** patients.

- **CD12 _COVID-19 :** Phase 2b/3, two-arm, randomized, double blind, placebo controlled, adaptive design multicenter study to evaluate the safety and efficacy of leronlimab (PRO 140) in patients with **severe or critical symptoms of respiratory illness caused by coronavirus 2019 infection.** Patients randomized to receive weekly doses of 700 mg leronlimab (PRO 140), or placebo. Leronlimab (PRO 140) and placebo will be administered via subcutaneous injection.
  - In progress: 220 enrolled as of Sep 4, 2020

(https://buyersstrike.files.wordpress.com/2020/10/image-1.png)

Which makes the trial update from the 30th of September from above all the more curious. Why? Look again:

Regulatory agency	Update
	~220/390 Patients enrolled/total patients for trial

(https://buyersstrike.files.wordpress.com/2020/10/image-2.png)

Why would there be no additional patients enrolled in almost a month? Want our guess?

Simple: "Pausing" a trial by stopping enrollment means never having to say it **failed**....the company can just pivot to the next pipe dream.

All is not lost, however, the **Klown Krew** has actually been hard at work. They did manage to get the shareholders to approve a huge, partially retroactive, options package for them on the 30th of September. They even filed an S-8 to register those shares later that same day (see here (https://www.cytodyn.com/investors/sec-filings/all-sec-filings/content/0001193125-20-259946/d25832ds8.htm?TB_iframe=true&height=auto&width=auto&preload=false))! And the next day filed a flurry of **Form 4s (https://www.cytodyn.com/investors/sec-filings/all-sec-filings?form_type=4&year=2020)**with the SEC to show where the goodies were distributed. Enrollment might be paused, the study might have failed, but **The NaDDer*** never stops cashing in while double-dosing the retail shareholder base with his sweet sweet stock pimping.

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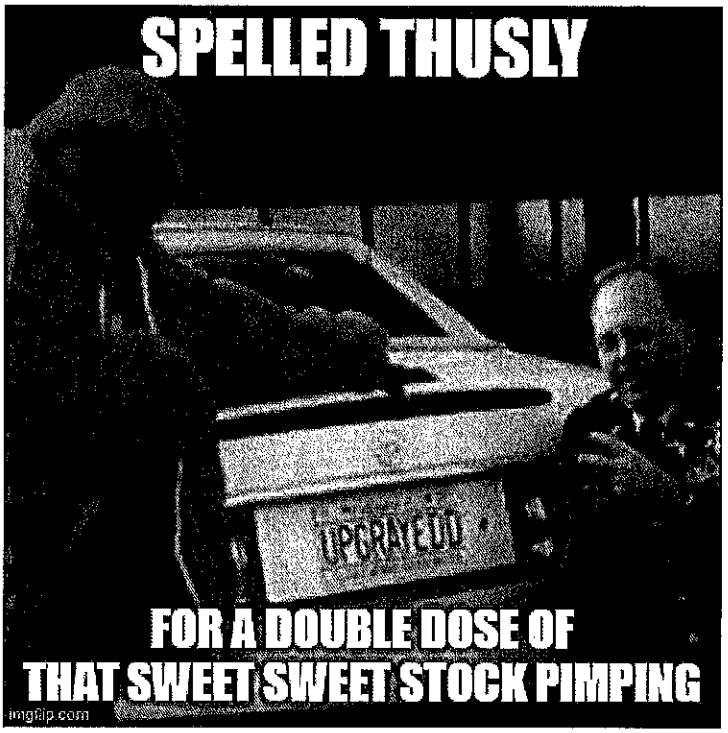

*The NaDDer

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