BuyersStrike!

It Was Dark Over Westphalia

Update: Guess Who is (yet again) still not participating in the Loserlimab Trial? (CYDY)

While we all anxiously await today's no-live-q&a CONference call by everyone's favorite reverse-merger pink sheet Coronacrapper, **Cytodyn (CYDY)**, let's take a look at the status of their much-hyped "CD12" trial of loserlimab (https://buyersstrike.wordpress.com/2020/08/28/but-teh-science-be-so-gud-part-1-a-brief-history-of-loserlimab-cydy/) in severe-to-critical Covid patients.

For many months now, **Cytodyn's CEO**, affectionately known in these parts as **The NaDDir*** and his Klown Krew have been talking up potential business in the **UK**. As early as **April 27th**, they made claims about starting the process for "Compassionate Use" of loserlimab, and starting trials, in the UK:

04/27/2020 14:38:40 (ET)

Nader Pourhassan, Director, President and Chief Executive Officer: Yes. So thank you for your question. New England Journal Medicine was published and I really want to bring everybody's attention to the cytokine storm data that was attached to that letter that was published. Dr. Bruce Patterson evaluated those numbers. And in regard to UK, we have already started the process of getting Compassionate Use Agreement and probably having our trial in road in the United Kingdom and we will update the whole shareholders as soon as we have more information about that.
Next question please.

(https://buyersstrike.files.wordpress.com/2020/11/april27uk.png)

Then without much more from the company, this bizarre press release (https://www.cytodyn.com/newsroom/press-releases/detail/457/cytodyn-seeks-uk-approval-of-leronlimab-for-hiv-and-covid-19) was issued on August 7th. No mention of the trials, and no mention of Compassionate Use, instead **Cytodyn claimed they would submit their BLA for HIV and request Emergency Approval** in the UK during August:

CytoDyn Seeks UK Approval of Leronlimab for HIV and COVID-19

August 07, 2020 12:36am EDT **Download as PDF**

- *BLA-type submission planned this month in U.K. for HIV combination therapy with 350 mg weekly dose*
- *COVID-19 Phase 2 topline report to be submitted for consideration of emergency approval of leronlimab for patients with mild-to-moderate symptoms to U.K. and other countries following submission to the U.S. FDA next week*

(https://buyersstrike.files.wordpress.com/2020/11/image_2020-11-05_055943.png)

Obviously neither of those things actually transpired (as of the 4th of November it appears no BLA for HIV has actually been filed in the UK, and there has been no emergency approval of loserlimab in the UK). On August 17th the company issued another press release (https://www.cytodyn.com/newsroom/press-releases/detail/460/cytodyn-submits-its-top-line-report-from-its-phase-2), reiterating the claim that they will be **requesting emergency approval in the UK** (and the EU) and additionally that they **have requested emergency approval in Mexico**:

CytoDyn Submits its Top-line Report from its Phase 2 COVID-19 Trial to the U.S. FDA and Requests Emergency Use Approval

August 17, 2020 6:00am EDT

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The Top-line Report has been sent to the regulatory authorities in Mexico, and will be provided to U.K. MHRA, and E.U. EMA, with requests for emergency use approval

(https://buyersstrike.files.wordpress.com/2020/11/uk-aug17pressrelease.png)

Yet again, it is obvious that none of these things have come to pass. **No EUA in the USA, no EUA in the EU, no EUA in the UK, and no EUA in Mexico.** If the Klown Krew at **Cytodyn** actually did submit for emergency approvals they were **rejected.**

As everyone must now be familiar, nothing stops **The NaDDir*** from that sweet sweet stock pimpin', and just **two days later** the company is back at it with a new press release:

CytoDyn Requests "Fast Track Approval" for COVID-19 Patients from U.K.'s Regulatory Agency MHRA based on its Top-line Report Showing Statistically Significant Endpoint, NEWS2 ($p < 0.023$) and Notable Safety Results

August 19, 2020 1:25am EDT

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(https://buyersstrike.files.wordpress.com/2020/11/image_2020-11-05_061923.png)

The company subtly changes its claim from "emergency" approval to "fast track" approval. **Loserlimab** yet again was still clearly **rejected.**

On the very next day **CYDY** keeps up the UK hype with yet another press release. In this one, the company announces that the **MHRA** (the **UK** equivalent of the US **FDA**) has given permission for the company to begin its study of loserlimab in the UK. **Cytodyn** claims that patient enrollment will begin **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

(https://buyersstrike.files.wordpress.com/2020/11/uk-aug20.png)

Strangely enough, as we noticed in early September (https://buyersstrike.wordpress.com/2020/09/08/quick-take-whos-not-participating-in-cytodyns-ridiculous-loserlimab-trial-cydy/), this statement by the company was **untrue.** The listing of clinical trial sites as of August 28th (https://clinicaltrials.gov/ct2/history/NCT04347239?V_10=View#StudyPageTop) included **zero sites in the UK.** In early September, **The NaDDir*** made some curious comments on one of his many CONference calls:

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

(https://buyersstrike.files.wordpress.com/2020/09/image.png)

The "UPH Scheme" is a program in the UK to provide financial support for clinical trials. The company elaborated on its plans in a press release that same day (https://www.cytodyn.com/newsroom/press-releases/detail/469/u-k-mhra-grants-meeting-to-cytodyn-to-discuss-fast-track):

U.K. MHRA Grants Meeting to CytoDyn to Discuss Fast Track Approval of Leronlimab for COVID-19 Patients

September 02, 2020 4:01pm EDT **Download as PDF**

U.S. FDA schedules Type A meeting with CytoDyn to discuss BLA filing for HIV

VANCOUVER, Washington, Sept. 02, 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 Medicines & Healthcare product Regulatory Agency (MHRA) of the U.K. government requested a meeting with CytoDyn on September 9, 2020 to discuss the Company's request for Fast Track approval of leronlimab to treat COVID-19 patients with mild-to-moderate symptoms based upon the trial's Top-line Report and additional eIND data. On the suggestion of the MHRA, CytoDyn will submit its current Phase 3 CD12 study for severe-to-critical COVID-19 patients in the UK to the Urgent Public Health (UPH) Research scheme to receive possible financial support from the trial sites and the government, if the UPH deems the Company's CD12 trial an urgent health issue.

(https://buyersstrike.files.wordpress.com/2020/11/uksept2-pressrelease.png)

Given that it is now early November, it seems clear that **Cytodyn's** requests for both "Fast Track Approval" of loserlimab in the UK and UPH designation for the CD12 trial were **rejected**.

Soon after some of **Cytodyn's** retail fans started to realize something wasn't kosher. The constant stream of CONference calls began to get angrier and angrier, and people started asking pointed questions. The company was more and more evasive. It is not a surprise that **CYDY** is no longer taking live questions on their calls.

In mid-September one caller pressed the company on their claim that the CD12 trial was supposed to begin enrolling August 20th. **Cytodyn's** Klown Krew management responded:

09/16/2020 17:13:03 [BT]

Yes, I can actually address both the aspects. So we are in the process of site selection and contract establishing for the selecting the investigators and sites in UK. So, the startup process is ongoing and we expect to start the enrollment very soon.

(https://buyersstrike.files.wordpress.com/2020/11/sept16ukenrollment.png)

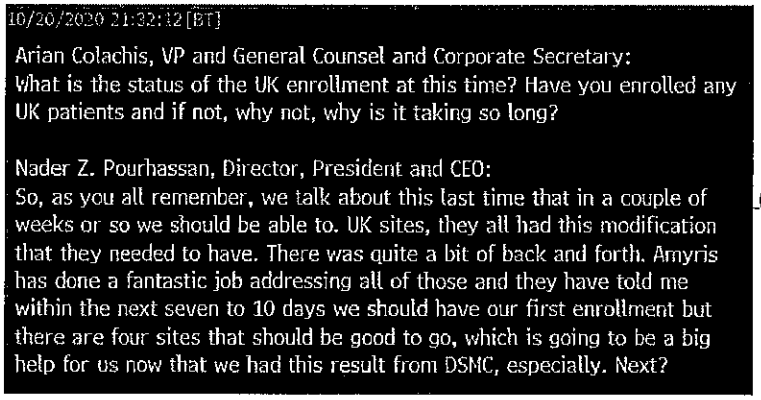
Weird, considering the company stated it was going to enroll UK patients starting August 20th, then again September 2nd, meanwhile it turns out they had not even selected any UK investigators or UK sites!

On the 30th of September the company provided this update on UK enrollment:

MHRA	Five sites are ready to initiate trial

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

Fast forward a few weeks later, and surprise, still no UK trial sites and no UK patient enrollment as of the 20th of October:

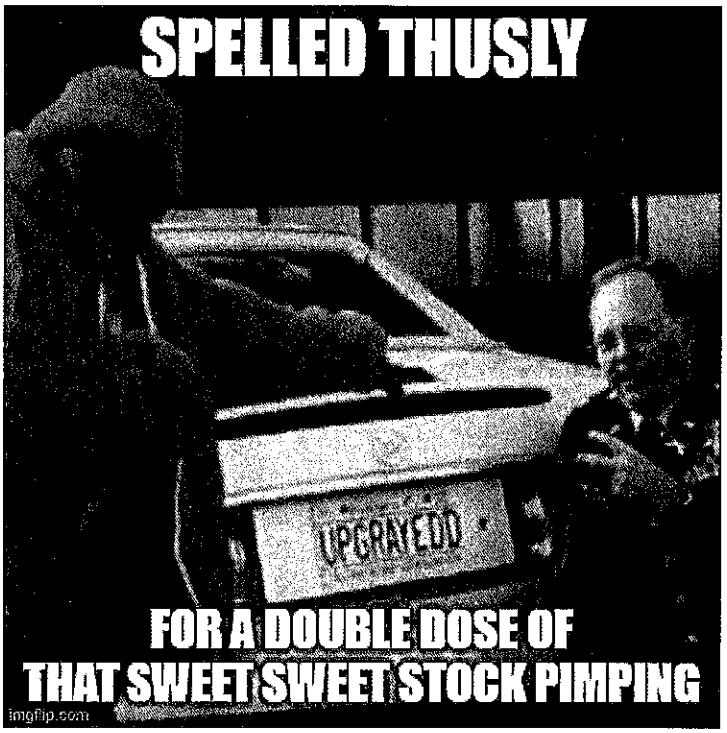


(https://buyersstrike.files.wordpress.com/2020/11/oct20uksites.png)

Yet as of the **29th of October**, at the list of trial locations on both Clinicaltrials.gov (https://clinicaltrials.gov/ct2/show/NCT04347239#contactlocation), **Cytodyn's** own website (https://www.cytodyn.com/clinical-trial-enrollment/covid-19-severe-or-critical), and in a PDF file available here (https://d1io3yog0oux5.cloudfront.net/cytodyn/files/pages/cytodyn/db/256/content/Phase+2b-3+Severe+or+Critical+10-29-20.pdf), show that there are **still no UK sites** for the CD12 trial. Not one.

Maybe we'll get to hear some new excuses this afternoon?

Keep in mind that because of the FDA's recent granting of a **full approval** for **Remdesivir** for hospitalized Covid patients, there is virtually no hope of **Cytodyn** receiving an **EUA** in this population, even if the drug is as amazing as its retail fanbase believes. **Section 564** has crushed those delusions. Don't know what **Section 564 of the FD&C Act** is? Better learn about it here (https://buyersstrike.wordpress.com/2020/10/23/quick-take-what-cytodelusion-actually-died-last-night-cydy/).



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