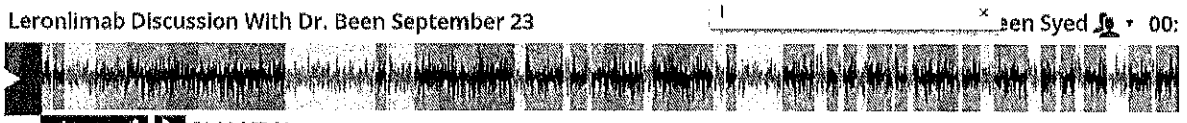
BuyersStrike!

It Was Dark Over Westphalia

Which Country Will Not Be Granting Cytodyn an EUA Anytime Soon? (CYDY)

For months now, everyone's favorite reverse-merger pink sheet Coronacrapper, **Cytodyn (CYDY)**, its CEO **The NaDDir*** and his klown krew, have 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/), in the **Philippines**. As with all things **Cytodyn**, this has been just more ridiculous hype.

Recall when **The NaDDir*** was making the rounds of every Youtube doctors' shows? Back on September 22, 2020, on something called the Dr. Been Show, **The NaDDir*** was not just positive, but VERY VERY positive about the Philippines:



Nader Pourhassan, CEO: Sure, Canada will be submitted soon. We have been in touch with them, and asked them for the application. It's going to be submitted very soon. With the Philippines we had gotten the news that they have asked for all this data on the emergency IND and CD10 and our company, the company that was working with us, had us sign a licensing agreement with a pharmaceutical over there for distribution before we could submit that to their FDA. They require that, so we signed that already, and now they're going to talk about that.

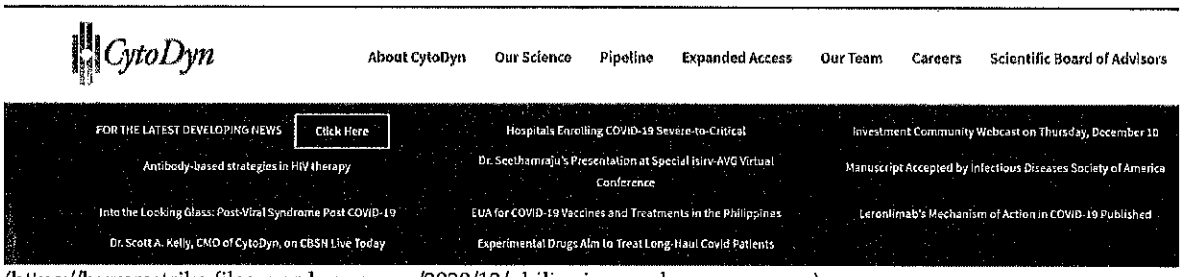
I'm very, very positive about the Philippines. We are also talking about the HIV project. But other than that, as we go forward, we will (https://buyersstrike.files.wordpress.com/2020/12/drbeensept23.png)

If you can possibly stand it, you can watch the video of that shitshow here (https://www.youtube.com/watch?v=8miCD7HE3bA).

The hype continued with a press release (https://www.cytodyn.com/investors/news-events/press-releases/detail/474/cytodyn-appoints-chiral-pharma-to-secure-leronlimab-for) on October 12, 2020 naming the company in the Philippines that was referred to weeks before:

> *CytoDyn Appoints Chiral Pharma to Secure Leronlimab for Local FDA Approval in Philippines*
>
> *VANCOUVER, Washington, Oct. 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 its appointment of Chiral Pharma Corporation, a subsidiary of Philippine New Marketlink Pharmaceutical Corporation (NMPC), to register leronlimab (PRO 140) for potential approval from the local Food and Drug Administration to treat patients with COVID-19 in the Philippines.*

In early December the company put up a link to an article (https://www.cnnphilippines.com/news/2020/12/2/Duterte-FDA-emergency-use-authorization-COVID-19.html) about EUAs in the Philippines right on their homepage:



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

The link leads to an article from CNN, dated December 2, 2020, which curiously enough, actually proves that **Cytodyn** has no chance for getting an EUA in the Philippines anytime soon.

"This can already be submitted to their FDA in their home country," Montoya told CNN Philippines' News Night, referring to the interim results of the Phase 3 trials. "After which, if they are given approval on EUA, then it can now be submitted for EUA also in other countries that have this mechanism in place, like the Philippines."

(https://buyersstrike.files.wordpress.com/2020/12/dec2cnn.png)

This means that the data must first be submitted in the home country, which in **Cytodyn's** case is the USA, and only AFTER the drug is given an EUA or approval in the home country can it then be submitted to the Philippines for an expedited EUA.

But that didn't stop **Cytodyn** from continuing to bamboozle investors about the prospects for an approval in the Philippines. On a December 10th conference call the company made the following claims. Firstly they teased investors with tales of all the revenues that could come in:

A - Nader Z. Pourhassan {BIO 16568801 <GO>}

So as everyone knows the COVID-19 is coming very, very close to some major results that we want to announce. We hope that Philippines takes advantage of what we are going to give them, because we only going to have 1.5 million vials, which is going to be about $2.5 billion or so worth of revenue to us. So whoever comes in first, we're going to give it to them first, if the result is positive enough for them. So the first approval could be, could be sometime in January.

(https://buyersstrike.files.wordpress.com/2020/12/dec10-philtakesadvrev.png)

Then they spun some nonsense that they will submit for an EUA in the Philippines without the data from the CD12 trial:

Nader Z. Pourhassan {BIO 16568801 <GO>}

Thank you, Scott. Third update is about the status of our application EUA that we are filing. We have not filed yet. We are filing that. And when we finished our -- completed our CD10 study, we told the world that three-day recovery is what happens between these patients three to seven days, but three-day recovery was 90% versus 70% in favor of leronlimab, that was the outcome of CD10. And there was also a much better result with the NEWS2 which is an indication of if the patient's going to get in trouble or not. We also have great safety record. But the number of the patient is very small. So when we applied for EUA with CD10, the Philippines pharmaceutical that we talked to and are representing us Chiral Pharmaceutical indicated that the Philippines gave one EUA to lenzilumab and that's all they would give. So they won't even consider.

Now there has been a Presidential order to consider other product as soon as possible, as long as they're safe and they show some kind of efficacy. We have got on the phone with all the Chiral Pharmaceutical team and our own team who's putting this together and Amarex folks and Dr.Rahman's team in our own internal team. And we feel very strongly that the application will be ready as soon as the FDA in Philippines is ready for this new order -- Presidential order to go in effect, which we hope to be in a couple of weeks. So we're very excited to see if we could actually get EUA without the data from CD12. We will give CD12 data as blinded data as what we have from the DSMC and we will update everybody in regards to this very, very exciting situation.

(https://buyersstrike.files.wordpress.com/2020/12/dec10-cd10eualies.png)

And finally that they will submit the application for an EUA the day the order is signed by Philippines President **Duterte**:

Operator

In light of the Philippines recent revision of EUA review timelines being reduced to 30 days, has there been any movement from the health agency regarding our submission?

A - Nader Z. Pourhassan {BIO 16568801 <GO>}

Yes. Well, we have three people that are working on this with Chiral Pharmaceutical and these three persons which we will tell name at the later time have done a fantastic job giving us situated with Chiral Pharmaceutical, you have to have a deal with the pharmaceutical over there and we made that deal and announced that several months ago where everybody tells what are they announcing these for. These are all planned ahead of time and we are right now in a position for them to file the EUA and they've been getting everything they need to from that application. So as soon as the Presidential order is in place with their FDA, we are submitting that day or submitting it immediately.

(https://buyersstrike.files.wordpress.com/2020/12/dec10-submitthatday.png)

As loserlimab does not have an EUA anywhere, let alone the USA, **it is impossible for them to get one** in the Philippines. This was further reinforced by the head of the Philippines' version of the FDA in an interview (https://cnnphilippines.com/news/2020/12/15/FDA-emergency-use-vaccine-inquiries.html) on December 15th:

"Hindi puwedeng sa Pilipinas unang kukuha ng EUA. Kailangan, meron na siyang EUA sa bansang pinagmulan niya o sa iba pang mga mature na regulatory agency," he added.

[Translation: We can rely on the evaluation and decisions of mature regulatory agencies and of the WHO. ***Companies cannot apply for an EUA for the first time in the Philippines. The product must be approved in their home country*** *or by any other mature regulator.]*

Keen readers already know that loserlimab (https://buyersstrike.wordpress.com/2020/08/28/but-teh-science-be-so-gud-part-1-a-brief-history-of-loserlimab-cydy/) has **virtually no chance** of ever getting an EUA in the United States? You don't know why? See here (https://buyersstrike.wordpress.com/2020/10/23/quick-take-what-cytodelusion-actually-died-last-night-cydy/).

But that is not the only reason why **Cytodyn's** delusions of an EUA in the Philippines are laughable. On December 14th the guidance documents (https://www.fda.gov.ph/?s=FDA+Circular+No.+2020-036+) were released, listing the requirements for the EUA.

4. List of Countries where the EUA is approved, with proof of approval for emergency use (or equivalent document) from the corresponding approving counterpart NRAs,
5. Reports on actual use from the issuance of EUA of approving counterpart NRA to the application for EUA in the Philippine FDA;
6. Complete assessment report including question and answer documents from the approving counterpart NRA,
7. Clinical trial data and results with the inclusion of racial distribution showing Filipino/Asians/ Pacific Islanders,
8. Currently available stability studies and list of ongoing studies,

(https://buyersstrike.files.wordpress.com/2020/12/dec14-eualist.png)

We already know **Cytodyn** fails conditions 4, 5, 6, and 7, but what about condition 8, **stability**? In recent conference calls **The NaDDir*** has been asked about stability:

A - Nader Z. Pourhassan {BIO 16568801 <GO>}

Yes. The product gets -- it gets the created in bulk. One since manufactured in bulk, you can store it at negative 80 degrees celsius for many years. The original product was stored for six years before the event and on saw some of those and vial them which is called fill and finish process. So the shelf life is very good when it's in the board position. But when you say shelf life, I'm assuming that you're talking about when it's finished fill and finish and it's in a vial, in that regard, we have more than two years of a stability for 1.4 milliliter vials with 2.4 million liter, we have over six months stability.

(https://buyersstrike.files.wordpress.com/2020/12/nov5stability.png)

It turns out that the current batches of loserlimab (actually 2.4ml vials) only have **~6 month** stability testing. Pity that the US FDA requires a minimum of 12 months (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q1ar2-stability-testing-new-drug-substances-and-products) stability testing:

e. Drug products intended for storage in a freezer (2.2.7.5)

Study	Storage condition	Minimum time period covered by data at submission
Long-term	-20°C ± 5°C	12 months

(https://buyersstrike.files.wordpress.com/2020/12/fda-stabilitytesting.png)

Failure to meet the stability criteria in the USA would be yet another reason why attempts to gain an approval, in any indication, anywhere, are foolish dreams. **This could also be another reason why the company has continually failed to actually refile its BLA for HIV in the USA, or file in the UK, Canada, or anywhere else** despite continued promises.

[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**

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2 comments

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