BuyersStrike!

It Was Dark Over Westphalia

Christmas Eve Quick Take: Who Clearly Has No Clue What an Open Label Extension is? (CYDY)

Leave it to everyone's favorite reverse-merger pink sheet Coronacrapper, **Cytodyn (CYDY)**, its CEO **The NaDDir*** and his klown krew, to gift the world an absolutely stunning Christmas Eve Surprise (https://www.cytodyn.com/investors/news-events/press-releases/detail/493/fda-provides-guidance-for-adding-an-open-label-extension-to) in the form of a 7:45pm press release even more insane than their previous (https://buyersstrike.wordpress.com/2020/12/22/christmas-week-quick-take-what-misleading-bs-is-cytodyn-spewing-today-cydy/) holiday stunners (https://buyersstrike.wordpress.com/2020/12/23/christmas-week-quick-take-what-nasdaq-listing-nonsense-are-the-cytodyn-shills-spewing-today-cydy/). The press release, like many, is designed to draw attention away from the real news, and instead focus the attention of inexperienced retail investors on some truly misleading hype. First the "shiny object" to distract:

> VANCOUVER, Washington, Dec. 24, 2020 (GLOBE NEWSWIRE) -- **CytoDyn Inc. (OTC.QB: CYDY)**, ("CytoDyn" or the "Company"), a late-stage biotechnology company developing Vyrologix™ (leronlimab-PRO 140), a CCR5 antagonist with the potential for multiple therapeutic indications, announced today the U.S. Food and Drug Administration ("FDA") provided guidance to the Company to add an open-label extension to its Phase 3 trial ("CD12") and specific criteria for the continuation of eINDs for patients meeting the inclusion/exclusion criteria of CD12.
>
> The CD12 protocol will be amended for adding the open-label arm extension and submitted to the FDA on Monday, December 28, 2020. Upon clearance, each CD12 participating clinical trial site will have the option of enrolling additional qualified patients, with all patients receiving leronlimab. Treatment of qualified patients will continue until the trial's data is unblinded.

(https://buyersstrike.files.wordpress.com/2020/12/dec24pr-ole.png)

Sadly, these morons have absolutely no clue what an **Open Label Extension** (OLE) is, and neither do their investors that are being pumped, dumped and chumped. The Klown Krew are claiming that the Open Label Extension will allow the company to enroll **additional** patients who will all receive **loserlimab (https://buyersstrike.wordpress.com/2020/08/28/but-teh-science-be-so-gud-part-1-a-brief-history-of-loserlimab-cydy/)**. This is NOT what an OLE is, nor what it allows. Here is some background reading on Open Label Extensions. From the British Medical Journal (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1200598/):

> Open label extension studies Go to:
>
> Open label extension studies typically follow a double blind randomised placebo controlled trial of a new drug. At the end of the double blind phase, participants are invited to enrol in an extension study. The study will normally be longer than the randomised trial (two years is not uncommon but they often continue until the drug is licensed). All participants in the extension study are given the study drug, and both they and the investigators know this. The objective is primarily to gather information about safety and tolerability of the new drug in long term, day to day use.

(https://buyersstrike.files.wordpress.com/2020/12/bmj-ole1.png)

Given that **CYDY** constantly declares loserlimab is safe, why would they choose to do an OLE, when OLEs are meant to collect even more safety data? The article continues:

> Properly designed and conducted open label extension studies can provide rigorous information on long term safety and tolerability of potential new drugs. This in turn can benefit the licensing application for the drug by providing longer term data that would otherwise not be available until after the licence was approved. Nevertheless, the conduct of such studies raises several ethical and scientific concerns.[1,2] As

(https://buyersstrike.files.wordpress.com/2020/12/bmj-ole2.png)

More from the **Journal of Medical Ethics** here (https://jme.bmj.com/content/28/6/373). And since the extension is open label, the data is almost certainly useless, as explained by Applied Clinical Trials (https://www.appliedclinicaltrialsonline.com/view/spotlight-open-label-extension-studies), here:

> For OLE studies, it is difficult to envision what analyses would be applicable without a control arm. A summary of the OLE study safety results is not easily interpretable without a comparator group. Even if some unexpected adverse events are seen, an epidemiological case is difficult to make against the active treatment since adverse events reported might be related to the long-term consequences of the disease under investigation, a separate disease or condition, or concomitant therapies rather than the active treatment.

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

As one now knows, an OLE is merely an, often shady, **continuation of an existing clinical trial** designed to collect safety data that allows all of the patients **already enrolled** in an existing trial the following:

1. Existing patients can choose to participate and thus are guaranteed to receive (or continue to receive) the study drug.
2. Existing patients can continue to be monitored past the study completion date.

Which of these two possibilities explains why **Cytodyn** would be asking the FDA for guidance on extending the much hyped **CD12** trial of loserlimab in severe-to-critical Covid-19? According to **The NaDDir*** patients are only given loserlimab on days 0 and 7, they do not continue to receive loserlimab. From the October 20, 2020 CONference call:

10/20/2020 21:32:12 [BT]

Arian Colachis, VP and General Counsel and Corporate Secretary:
In the -- with the new analysis of survival at 42 days now being included in the next interim work, have the treatment arm patients been provided with Leronlimab between day 28 and day 42, or was Leronlimab discontinued at day 28?

Nader Z. Pourhassan, Director, President and CEO:
So, Leronlimab was only given, as Dr. Jay Lalezari said, only on days zero and day seven and then you take a look at the data -- how that patient's dose reduced to two dose and that's it. Next please?

(https://buyersstrike.files.wordpress.com/2020/12/oct20dosing.png)

This eliminates the first reason. Existing patients who choose to continue will not receive any more loserlimab, since they already received their two doses. Which leaves us with the second reason. The company is trying to find a way to continue to monitor patients after the 28 day mark. Why?

Perhaps because the DSMC asked for an analysis at 42 days. Recall back in October, when **The NaDDir*** explained they had to get 42 day data:

10/20/2020 21:32:12 [BT]

Arian Colachis, VP and General Counsel and Corporate Secretary:
Have you been following patients today the 42 -- day 42 throughout the entirety of CD12 trial?

Nader Z. Pourhassan, Director, President and CEO:
Yes, we have. That's -- that's the follow update that we have to have even though the primary endpoint is 28 days. But 42 days was all -- had to be followed up. Next, please.

(https://buyersstrike.files.wordpress.com/2020/12/oct20-42day.png)

and then only a few weeks later, on December 10th, **The NaDDir*** abruptly changed his mind and announced that there would be no second interim analysis and no look at 42 days?

12/10/2020 17:03:31 (ET)

weekend hopefully, give or take a day or two. Very exciting indeed. In regards to our DSMC, we had finished the enrollment several days ago, a couple of weeks ago and we have to wait 42 days for the last patient before we can do the DSMC. We were talking about many different plans, but we finally decided that because the enrollment has peaked up so much that we actually had a 15-patient enrollment record in one day. So with that said, we're going to go ahead and finish the trial which we believe, if we finish in the next five days or so, it'll be December 15th, 28 days later, would be sooner than when we could have DSMC data ready and the 42 days done. So it doesn't make sense to do the interim analysis we just go

(https://buyersstrike.files.wordpress.com/2020/12/dec10confcall42days.png)

The OLE would allow for the company to continue to collect data past the 28 day mark. Our guess is that someone demanded the 42 day look and to save face **Cytodyn** is putting up a blatant smokescreen to distract people.

If that is the distraction, what is the real news that **Cytodyn** management is trying to bury? That is easy. Look at the bizarrely worded final statement from **The NaDDir***:

> Nader Pourhassan, Ph.D., President and Chief Executive Officer of CytoDyn, commented, "We are very thankful to the FDA for providing guidance on accessing our drug pending the results of CD12, especially during these unprecedented times. CytoDyn will provide the precise requirements for potential participation in the new CD12 open-label extension and physicians seeking eINDs, while we eagerly await the unblinding of the data. The results of our CD10 trial will not support an eIND request."

(https://buyersstrike.files.wordpress.com/2020/12/dec24pr-cd10.png)

Far from being the "amazing" trial that **The NaDDir*** announced, the **CD10** trial of loserlimab in mild-to-moderate Covid-19 failed. Obviously. And completely.

[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 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? Want to know why? See here (https://buyersstrike.wordpress.com/2020/10/23/quick-take-what-cytodelusion-actually-died-last-night-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. Learn more 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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