BuyersStrike!

It Was Dark Over Westphalia

What Is Cytodyn (Not)Curing Now? A Guest Post from B4UConsent (CYDY)

[Editors Note – The following is a guest post about everyone's favorite reverse-merger pink sheet Coronacrapper, Cytodyn (CYDY) from @B4UConsent, a real life patient with tremendous insight into drug development from both the patient and the clinical trial management perspectives. Follow her blog (http://b4uconsent.com/) and on Twitter (https://twitter.com/b4uconsent/).]

BuyersStrike has generously invited me – patient, investor, blogger at B4UConsent (https://b4uconsent.com/) – back to do a guest post on CytoDyn's TNBC delusions. Happy to help!

Today we sink from the height of scientific rigor and strategic foresight we witnessed with Roche's IMpassion program (https://b4uconsent.com/2020/08/10/impassion131-what-happened/) to the sewage ditch that is **CytoDyn's** attempt to take on -- wait for it – triple-negative breast cancer (**TNBC**). TNBC is, for the uninitiated, the rarest breast cancer subtype, exhibiting no hormone receptors nor overexpressing the HER2 protein, which make patients ineligible for anti-hormonal agents or HER2-targeted agents. Further, this tends to be an aggressive subtype that occurs in younger patients, and it's associated with the poorest outcomes.

Historically, while **TNBC** patients have had few treatment options beyond chemo, there have been advances, particularly with immunotherapy. **Roche** received an accelerated approval for the combination of atezolizumab plus the chemo drug **Abraxane**, to be used in the first line. **Sacituzumab govitecan**, from **Immunomedics (IMMU)** more recently received accelerated approval in third line. **Atezo/Abraxane** is the standout here, and I have my reservations about sac gov, but there's no disputing that these accelerated approvals were hard-won on **PFS** (progression free survival) data. **Roche** and **Immunomedics** are now just left to sweat out the wait on those **OS** (overall survival) numbers.

In contrast, **CytoDyn** got rid of a fake tumor engrafted on a mouse (https://www.cytodyn.com/newsroom/press-releases/detail/356/cytodyn-treats-first-patient-in-phase-1b2-clinical-trial) that one time.

And since in the fever dreams of its retail fanbase, and delusional (at best) management team, **leronlimab** has already "cured" **COVID** and **HIV**, with **GvHD** and **NASH** (and **MS** and **Alzheimers**, and on and on and on) on deck, why not throw **TNBC** in the mix? It's not like it's hard to design, recruit and run a cancer trial. **CytoDyn** is generously "keep[ing] the FDA current (https://www.cytodyn.com/newsroom/press-releases/detail/407/cytodyn-files-request-with-fda-for-preliminary-meeting-for)" on their miracle outcomes, which seem largely limited to meaningless, outdated lab markers (**CTCs**, really?) and **not the more meaningful outcomes** we in cancer are all familiar with, things like, "Tumor in lung got 31% smaller." I'm sure our friends at the Agency are eagerly anticipating these updates and sending them straight to voicemail.

The most telling press release (https://www.cytodyn.com/newsroom/press-releases/detail/372/cytodyn-files-for-breakthrough-therapy-designation-with-the) about the garbage this company is peddling is from January 13.

They reference two patients, one of whom is apparently enrolled in the company's phase 1b/2 study (https://clinicaltrials.gov/ct2/show/NCT03838367) which enrolls *previously untreated* metastatic breast cancer patients. You can tell a patient to drink more water in the first-line setting and get at least a modest response, which is why it should be a **GCP violation** to enroll subjects first-line for completely unproven drugs. You get one shot at first-line, one chance to maximize response and the duration of response. We know response rates get lower with each line of treatment.

In this case, the company felt compelled to announce that their first **TNBC** subject had a reduction in circulating tumor cells (CTCs). This is a) **not an endpoint** and b) **not clinically relevant**. No one does CTC tests, and they were never adopted widely because they were useless. They were **never sensitive enough**; you could be a walking tumor and have a CTC of 0. **Plenty of metastatic patients have CTCs of 0**, and a CTC result higher than 5 would signal full-on death watch. A more modern and useful marker would be ctDNA, which are small fragments of tumor that are used in the liquid biopsy tests we have from **Guardant** and **Foundation Medicine**.

Guess what else? "This patient's data also demonstrated tumor shrinkage of >20% after just a few weeks of treatment." Greater than 20%, that sounds good, right? **It's actually not**. It means the disease has remained stable. In cancer, we use one guideline to interpret tumor size and response on scans: it's called RECIST 1.1, and the rules are very clear. As a former medical writer on oncology trials, I can recite them in my sleep: a complete disappearance of disease is a Complete Response, or CR; reduction in disease >25% is a partial response, or PR; change in tumor measurement <25% but not increasing in size by more than 25% is defined as stable disease, which is NOT considered a response; and increase in tumor measurements by >25% is progressive disease, or PD.

So by the accepted laws of oncology, **this patient is an SD**. The CTCs are meaningless.

And what of the second patient?

She was not enrolled in a trial. She received treatment under an "**emergency IND** protocol" and is described as having "HER2+ metastatic, stage 4, MBC" and "showed no sign of new metastatic spots in the liver, lung and brain during the treatment with leronlimab." Yeah, no new lesions is always nice, but what about the lesions she had at baseline? Subsequent press releases also suggest that this patient was receiving other treatment concurrently, so how could we attribute anything positive to the leronlimab?

This nonsense concludes with, "This **strong data** confirms the power of leronlimab as a CCR5 inhibitor for patients living with mTNBC, and is **clearly replicating early animal study results that demonstrated 98% elimination of metastases**." (Emphasis mine.)

What's that, now? That little mouse had what would probably be classed as a CR. These two patients didn't even respond.

But why stop at TNBC when the data are so compelling? That's a tiny little sliver of the cancer population. Aren't there a lot more cancers to cure and patients, shareholders and innocent bystanders to manipulate?

That brings us to the basket trial (https://clinicaltrials.gov/ct2/show/NCT04504942), open to all solid tumors, which seems to have just started enrolling a few days ago. "All solid tumors" will apparently be represented in a 30-subject phase 2 at one site, something called "**Quest Clinical Research**" in San Francisco. Just the name evokes the echelons of scientific development, no?

Let's review the primary endpoints for this "trial" together, shall we?

1. Number, frequency, and severity of adverse events (AEs)
2. Incidence of abnormal laboratory tests results
3. Changes in Eastern Cooperative Oncology Group (ECOG) performance status from baseline to subsequent scheduled visits

Are 1 and 2 not the same? And … what is 3 supposed to demonstrate? That is not an endpoint for approval in oncology. The enrollment criteria specify an ECOG status of 0-1 (that's fully active to slightly less active; by 2, patients are getting pretty debilitated). So we're looking at a phase 2 with no PFS endpoint. This study is exposed as **even more of a sham** by a line in the study description section:

Subjects participating in this study will be allowed to receive/continue standard-of-care chemotherapy or radotherapy [sic] as per the dosing schedule included on the package insert.

Let me get this straight. Subjects have the option of staying on therapies that are already working and just adding an experimental agent. **What exactly is being tested here?** Who would enroll in something like this, and why would anyone let them? Are they **trying to design a "study" that can't fail by deliberately rejecting the efficacy and enrollment standards by which a whole industry abides?**

Though we don't have answers, we do have a lesson: stay away from this bioturd. At least the mouse made it out.

Thanks again to BuyersStrike for having me.

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Posted in Bad Directors, Bio-Dreck, Bucket Shops, Reverse Mergers on August 11, 2020 by BuyersStrike!. 13 Comments

13 comments

1. **Michelle Mosley** says:
   August 12, 2020 at 2:04 pm
   I'm a stage four triple positive breast cancer patient. Kadcyla is no longer working and if nothing else effective becomes available I have less than one year left to live. I'm applying for the Leronlimab trial because I am very impressed with the science.

   REPLY

   1. BuyersStrike! says:
      August 12, 2020 at 2:15 pm
      Very sorry to hear about your diagnosis. Also very sorry to learn you are being conned. You are being sold false hope. Exactly what about "the science" impresses you? And I see you think Swiss scam **Relief Therapeutics (RLFTF)** is legit too….what other snake oil do you like?- **Editor**]

      REPLY

      1. **Jimmie** says:
         August 14, 2020 at 3:09 pm
         What scientific basis do you have to prove that leronlimab is a scam? Have tested the molecule to see if it works? Any new drug has to be tested. This is a blog and your opinion but your opinion doesn't count without proof. Show us the proof that it doesn't work. I'll wait because I have time

      2. **Mark** says:
         August 14, 2020 at 3:21 pm
         You people writing this column are sick assholes. This drug is working for many people without side effects and you gutless authors who can't even put your name on the byline and are acting on behalf of whomever paid your slimy ass to write these hit pieces are the lowest form of slime on earth. Who are you nameless hit squad? Who pays you? Gilead?

3. on the Mark says:
   August 14, 2020 at 4:01 pm
   It took all of 30 seconds for you to take my reply down. Truth scare you? Where's your name on the byline? Afraid of libel suits for spreading false info intentionally? This is criminal, you know! Who pays you to write this garbage? I bet you don't have the guts to come clean on anything, do you? Who evaluates a treatment based on messages posted on a chat site instead of actual results? Buyer's strike, that's who. Nobody else does. The E-ind results showed complete tumor eradication in all 10 patients treated, but you ignored that to claim the only positive result for the TNBC study was eradicating a tumor on a mouse? Nice research for the article, hack writer. The only thing in the sewer is your journalism ethics and practices as shown by the "intro" written by someone claiming to be the editor of this fine publication without the guts to put their name on it. That's one way to avoid a libel suit, for a few minutes at least. You're so eager to trash CyttoDyn you can't even wait for your guest author to write their piece of crap, you have to start the hacking in the intro. Another sign of bias and unethical journalism. Or at best you may be charged with manslaughter for steering someone away from life-saving treatment by publishing lies. Good luck in court hatchet man.

2. **Jimmie** says:
   August 14, 2020 at 3:13 pm
   Sorry about your diagnosis. Don't let a "blog" post discourage you from doing whatever you can to save your life.

   REPLY
3. **Mark** says:
   August 14, 2020 at 3:26 pm
   Don't listen to these paid shills doing hit jobs to protect other companies fearful of being left behind by better treatments. Do your research (these gutless toads haven't) before you commit to anything – personally, this treatment is the best I've seen, statistics-wise. Buyer's strikeout, on the other hand, is a journalistic sewer or reporting. As a former journalist I can tell you that a respectable writer would be proud to put his/her name on any article they wrote, unless it was a cheap hitjob with no journalistic merit like this piece of trash. Hope you heal quickly, Michelle.

   REPLY
   1. **hygrogroup** says:
      December 21, 2020 at 3:36 pm
      What part of this are you contesting? A good journalist would have gone point by point and presenting contradicting facts. Where are your's? Or you just a name caller. Bet you were a great journalist.

2. **Joe** says:
   August 14, 2020 at 3:18 pm
   Actually the author missed the March Update
   https://www.cytodyn.com/newsroom/press-releases/detail/389/cytodyn-reports-remarkable-outcomes-for-additional-cancer
   And missed that Dr. Hope Rugo has joined the scientific advisory committee.
   Ruth was a leader at ASCO this year, and is cutting edge on treatments.
   https://www.ucsfhealth.org/providers/dr-hope-rugo
   Dr. Hope Rugo is a hematologist-oncologist who specializes in breast cancer treatment.
   Rugo is co-director of UCSF's breast cancer clinical trials program. She is the principal investigator for several clinical trials of potential new therapies. She is also an investigator with the Bay Area's SPORE (Specialized Programs of Research Excellence) on breast cancer. The National Cancer Institute established SPORE to foster collaborative, interdisciplinary cancer research.
   So there is a lot more to this unfolding.
   Usually I would not comment, but the reader may be misled by this article so I did.
   As the author stated, there are few alternatives. What the author failed to state:
   Leronlimab in mTNBC can be used WITH and not in place of existing care. With no contraindications and with a stellar safety record in years of trial, the drug accompanies not replaces current chemotherapy.
   Of course, at doctor/patient discretion.

   REPLY
   1. b4uconsent says:
      August 14, 2020 at 8:22 pm
      Hi, blog author here. Rugo is indeed a towering presence in breast, and she's consulted with almost everyone, so I wouldn't read too much into that.

      There's a quote I pulled from the basket trial's CT.gov that describes how patients are permitted to enroll while undergoing concurrent systemic therapy and radiotherapy. The issue is that if a patient enrolls who is already stable or responding on their current treatment, or if they just started a new treatment, it would be impossible to measure treatment effect from leronlimab.

      I talked a lot about the "emergency IND" subjects, but the main issue is that these subjects don't seem to be undergoing assessment by anything close to industry-accepted (or FDA-approvable) endpoints. We would need to see conventional response measures (like PFS) for this to be a legit study. The CTC measurements, etc., would not be suitable for FDA submission. The expanded access process in general is irrelevant for drug approvals, and, regardless of the hype, CytoDyn is subject to the same regulatory oversight as anyone else.

      REPLY
3. **Joe** says:
   August 15, 2020 at 2:58 am
   Frankly PFS is Never an endpoint in a Phase I study,

   Honestly there are no endpoints such as you refer to them above, in Phase I studies.

This Cannot Be Refuted. There is NO Debate.

Your comment is factually incorrect and misleading to possible patients that follow your blog.
The trial you refer to in mTNBC is a Phase 1. Not a Phase III wherein you would be correct.

I do not desire to be rude, so forgive when I say, and I feel I am forced to correct you,

This information is really not valid and I hope no patient relies on this blog.

If you put yourself in a position of trust, such that patients may rely on your opinion, you really should be more careful.

I rarely comment and never would have if the information were anywhere near accurate, it simply isn't, and demanded correction.

[Well you should probably not be commenting then, **because you clearly read neither the post, nor the embedded links**. Take a minute and read it carefully and follow all of the links, and read them. Then go and look up the record of the clinical trial on clinicaltrials.gov. There you will find that the study is a combination 1b/2 study and **PFS is indeed the primary endpoint** of the P2 portion of the study. – **Editor**]

REPLY

1. **hygrogroup** says:
   December 21, 2020 at 3:43 pm
   Quest Clinical Research is owned and operated by Dr. Jacob (Jay) P. Lalezari, M.D., the Director of Quest Clinical Research. The name is probably familiar as the acting Chief Medical Officer of Cytodyn for a period of time. No conflict of interest there.

REPLY

4. Pingback: Sunday Funday – What Else Doesn't Cytodyn Want Investors To Learn? (CYDY) | BuyersStrike!

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