

With the FDA giving the go ahead to submit their Final Application for Final Approval for HIV for their humanized monoclonal antibody Leronlimab, CytoDyn Inc is positioned to make an impact in this area of unmet needs



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CEOCFO: Dr. Pourhassan PhD, what is the focus at CytoDyn Inc today?

Dr. Pourhassan: The focus is on our lead product, which is Leronlimab, which is also called PRO140. Leronlimab is a humanized monoclonal antibody. CytoDyn is focused on getting this product approved for HIV patients for two different populations, so hopefully two different labels. We are also developing this product for triple negative breast cancer and graft versus host disease. Both of those trials are in Phase 2 or Phase 1b/2. We are also exploring the use of leronlimab (PRO 140) for many other metastasizing cancers. We believe our product can help all the metastasis cancers that depend on the CCR5 gene (C-C chemokine receptor type 5, is a protein on the surface of white blood cells that is involved in the immune system as it acts as a receptor for chemokines). Therefore, we have initiated eight pre-clinical studies in Melanoma, Pancreatic, Breast, Prostate, Colon, Lung, Liver, and Stomach Cancers that could lead to Phase 2 program this year.

CEOCFO: What do HIV and cancer have in common?

Dr. Pourhassan: Dr Richard Pestell, MD, PhD, who has published over five hundred papers in peer reviewed journals, has discovered that the metastasis of cancer cells are happening through the cancer cells that have CCR5. Therefore, looking at a cancer tumor, only certain cancer cells have CCR5 and those are the only cells that metastasize and kill. This was a major discovery! Leronlimab binds to CCR5 on a T-Cell. Only T-Cells are used by HIV in order to replicate, so when it comes to T-Cells, leronlimab binds to the CCR5 on the T-Cells, which stops HIV from replicating. However, at the same time, because the CCR5 is also on the cancer cell that causes death, leronlimab binds to those CCR5s also and stops metastasizing. This discovery led Dr Pestell to approach CytoDyn and say to us, "Your product could have tremendous impact on the world of cancer for many years to come!" He had already started with Merck and Pfizer with their HIV products. Those HIV products are not humanizing monoclonal antibody. They are synthetic chemicals with side effects. All the humanized monoclonal antibodies have a different profile and he thinks that our leronlimab has tremendous potential in the world of cancer.

CEOCFO: In laymen's terms, how does it work?

Dr. Pourhassan: The way CCR5 works on a T-Cell is that it acts like a GPS. When there is a cut in the body there is a signal that goes to the CCR5 that calls the T-Cells to go to the site of the inflammation and fixes the problem. With cancer cells it is similar behavior. The cancer cells that have CCR5 want to move. The similarity is that they want to move to a

different site. However, those are the cells of cancer that cut through the walls of the vein, get into the blood stream and make a home in the lung, in the liver, in the brain, in the bone and so on. Therefore, when you stop these cancer cells from receiving a signal that causes them to move, then you interrupt that movement (the metastasis). Dr Pestell discovered that when the calcium signaling on CCR5, is turned off by leronlimab binding to the CCR5, the metastasis of cancer cells halts.

CEOCFO: *Is it a permanent situation? Do you need repeated doses? What have you learned so far?*

Dr. Pourhassan: There has been an animal study conducted in mice and we were able to almost completely stop the metastasis in mice for seven weeks so far and counting. The seven weeks in mice is equivalent to seven years in the human life. What we now need to do is use our leronlimab in humans for breast cancer indication. What has to happen is that we have to give this product to the patients every week in a clinical trial. Leronlimab is self-injectable at home. It is once a week. It only takes about thirty seconds to two minutes to administer. It is self-injectable like what diabetics do, one, two or three times a day, but this will only be once a week. Therefore, the difference between not having this product and having this product, if it works, is life expectancy for certain cancer patients. They will just be able to inject themselves with one dose of this product every week if it is approved. The product has shown in over seven hundred HIV patients to have hardly any side effects or toxicity. We even gave this product to normal HIV negative individuals, fifty four of them, and we had no problems with toxicity or side effects among these individuals.

“The FDA has just gave us the go ahead to submit our final application for final approval for HIV, this is a fact. We just announced that the FDA also granted us Rolling Review BLA (Biologic License Application), this is also a fact.”- Dr. Nader Z. Pourhassan, PhD

CEOCFO: *It seems almost too good to be true! Have similar concepts been tried?*

Dr. Pourhassan: The story is amazing from the very beginning! We had an event and the title of the event was, “Two Men with One Mission,” myself and Dr Pestell. Dr Pestell discovered the cause of cancer metastasis, which he had made his life time focus to come up with a solution. His father and mother died from cancer early in life and he wanted to find a product what his discovery could use to help cancer patients. It is funny that you said, “Too good to be true.” A seeking alpha author also just published an article about CytoDyn saying, “What do you do when it is too good to be true!” He indicated that what CytoDyn has publicly announced in the past is just too good to be true, so we are going to go and listen to the next shareholder conference that the CEO would conduct, which happened to be the next day. He said, “I am going to listen and see if he will be able to convince me that these are real.” In my conference call I indicated that when it is too good to be true, please check the facts. The FDA has just gave us the go ahead to submit our final application for final approval for HIV, this is a fact. We just announced that the FDA also granted us Rolling Review BLA (Biologic License Application), this is also a fact. Furthermore, we announced that the primary endpoint was hit more than a year ago! We then announced that the respondent’s rates for all the patients, some of them with unmet medical needs, were 81% at the end of twenty four weeks. Some of these patients were resistant to most of the current standards of care. Forty of these patients requested to go to rollover, from which some indicated they could not have suppressed viral load for many years (one of them was for 27 years without suppressed viral load).

When Dr Pestell discovered that the cancer metastasis is through HIV pathway, he did not come to CytoDyn first. He went to Pfizer and Merck for their HIV product. What are the chances of HIV patient’s treatment may one day save mankind from cancer? After Dr. Pestell discovered this important finding, he had his work cut out for him. How are we going to make a product that can stop this,” and that must be an HIV product that binds to CCR5, which is only Maraviroc from Pfizer. And vicriviroc from Merck. He tried both of those products in animal studies and the results were great. Maraviroc was also used in human cancer trials in Germany and the results showed that some of the patients had their cancer tumors melted away! Some of those results are on our website www.cytodyn.com. In those patients, the cancer clearly melted away. Therefore, when we did our animal study we compared it to the animal study of the Pfizer product Maraviroc, and are results indicated that leronlimab is even better than them! The data speaks volumes! Is it too good to be true? Well, look at the data! If the data says so and it is good enough for the FDA then it is good enough for us. That is exactly what the outside people look at and say, “It is too good to be true.” I hear that all the time.

CEOCFO: *It is a bit unusual to be working on so many trials at once. How do you handle the logistics in overseeing so much rapid activity?*

Dr. Pourhassan: What we do not get credit for is that many public information indicates that to get one product from discovery to approval it costs about one to two billion dollars. We have raised about one hundred ninety million dollars in the last four and a half to five years and our product is about to submit its final application for its final approval. We

actually submitted the first one third of the application already and just a couple of days ago we announced it. Therefore, with less than two hundred million, we are about to get our final application for final approval. Starting in 2020, we could start having revenue if all goes according to plan. We also have a phase 2 in GvHD and a Phase 1b/2 in triple negative breast cancer. Now, the way we do this is that we outsource all these activities, so that our CRO has perhaps twenty five or thirty experts that are working on our project. We also have our own consultants, a group of about thirty individuals (some are thought leaders) who work with us in an ongoing bases and we have about eight or nine full time employees. The other major activity that we outsource is our manufacturing, very large outsourcing.

With our stock price not seeing the value that it should (in my opinion) and with many other daily challenges everything has been a big challenge for us. I got involved with CytoDyn in 2008 when they were one week away from bankruptcy. After about a few years I purchased leronlimab for CytoDyn, and all the scientist who work on this product believed that it would take about fifteen to twenty more years to get approval and it was not worth it. We purchased all the rights of PRO 140 and we did that with a down payment of about three and one half million dollars. My first task was to change the path to approval and I did that by first abandoning NIH funded Phase 2b and returned about six million dollar grant to NIH and brought new key opinion thought leaders, some of them key advisors to Gilead, and we paved a new path to approval for leronlimab that proved to be a game changer for leronlimab. I believe what we have done, people would later write books about it!

CEOCFO: *How do you deal with the frustrations of things not going quickly enough when people are dying and you have something that potentially could help?*

Dr. Pourhassan: One has to have a very clear focus in their mind of their own values and their own path of life and why they are living this life and what makes them happy and what makes them sad and how to be able to focus on a major part of life and not let daily life take that focus away from them. You have to be focused on the task at hand, but your own values for your life have to carry you through all the ups and downs. For me, I read quite a bit of the Bible every day, so that helps me. It keeps me going no matter how hard things get, and the most important person in my life, my wife, is the reason I got involved with CytoDyn so I am partner with her in this path and that helps a lot. As we went through many difficulties in CytoDyn, she has been a tremendous support! She actually saved the company with her own savings when I first joined CytoDyn! She took all of her credit cards and said, "I want you to go to this company, I will fund it as much as I can." Therefore, having a wife that will share the same values and having a focus and saying, "Hey, we are going to do our best and if it fails, we have done our best," and then be able to get to this point is very rewarding, but it has been very difficult. There were tremendous difficulties in the past ten years which we were fortunate to overcome, I believe the rest of the way is not going to be difficult at all.

CEOCFO: *Why pay attention to CytoDyn Inc today both from the healthcare and investment perspective?*

Dr. Pourhassan: I challenge anyone to find a single stock on Wall Street that is sitting at fifty cents level and has one Phase 3 clinical trial completed with excellent results and the FDA has granted permission to file their final application for final approval and they just filed one third of it. And that is not all; CytoDyn also has a second indication for a second population for HIV which could change the HIV paradigm according to all the thought leaders. This second indication is the first monotherapy with a self-injectable monoclonal antibody that is once a week.

Moreover, we now have an offer from a large manufacturing company who has agreed to make five hundred million dollars' worth of leronlimab without charging us till the end of 2020. Therefore, we have been able to proven our worth to at least one major company. Then we have triple negative breast cancer, in which patients die within nine months, and we are able to give some results of whether it is working or not within three to four months, which we believe it is going to work, because the animal data has been simply stunning! Then we have a phase 2 trial in graft versus host disease and on top of all these we have a prognostic test which we believe will be able to get a licensing agreement. Therefore, if you have all of these, and I would like to know if any company in the world right now is trading at fifty cents with even one tenth of what we have; I believe that if investors are serious about investing, you should check out our companies fundamental and see how accurate our information to public has been. Are we selling something and just trying to sell that or do we really have a good potential to save patients' lives in cancer and HIV and do we have the FDA green light to go forward with all of our activities? If we do, I think we are worth looking at!