Tonight THERF announced info from their second presentation at the CROI conference regarding Ibalizumab, and once again it appears very good. Basically, the phase I/II study discussed during the presentation determined that once every two week and once every four week doses of Ibalizumab given via intramuscular (IM) injection produced similar results as the same doses given intravenously (IV) via earlier studies. I was under the impression the study would only be looking at the 2 week IM injection. The fact that they also had data on the four week version is a positive surprise. The two week version will expand the MDR market penetration for Ibalizumab nicely, but the four week version is one that could expand the market well beyond just the relatively small MDR HIV market. If THERF is able to advance the four week version faster than previously thought, this could be a big deal. However, it is still my understanding that it will take at least one large phase III test with the four week version before it can be marketed. So this is likely at least two years away from hitting the market. Still, if investors begin to realize there could be a market for Ibalizumab many times the size of the MDR market, the stock is certain to react very positively to that. I have joked in the past that the outlook for Ibalizumab falls somewhere between very good and Wow!. The ”Wow” is if the 4 week IM version makes it to market and greatly expands the number of Ibalizumab patients.

The other notable aspect of this study was that the drug was evidently given as a monotherapy to patients who had not had any form of treatment for at least one year prior to starting treatment with Ibalizumab. Ibalizumab is currently given in combination with other HIV drugs. If Ibalizumab can be shown to produce good results on its own with just a once every four week IM injection, the potential is mind-blowing. The information announced today indicates Ibalizumab had results that were similar to previous studies using the IV form of administration. Now, I am not a scientist so I need to check with the company before drawing any big conclusions about what the data actually tell us. But I do know this is very good data and it has the possibility of being really, really good. It sounds like the conference attendees might have had access to this data before the rest of us, so perhaps they were calling their brokers and buying the stock today. One way or another, it is clear other investors are now finally discovering what we have known for a while about THERF as the stock is under serious accumulation by buyers who just want to get into it as soon as they can. We thought Ibalizumab would leave the CROI conference with a buzz building about its attractive attributes and this seems to be coming to pass. If so, that is just what is needed in order to get Ibalizumab off to a fast marketing start once it is approved. What today’s data suggests, however, is that the two week IM version is likely to be available in mid to late 2018 and the very exciting four week version might also be available sooner than we thought as well. It will be very interesting to hear when Taimed might start the phase III test on the four week version and perhaps we will get some insight into that on the Investor Day in two weeks.

Here is a link to the press release covering today’s Ibalizumab presentation at the CROI conference:

https://ceo.ca/@newswire/theratechnologies-announces-comparative-pk-data-on

PRO 140 also had a presentation at the CROI conference today. While we do not believe this drug will develop into a direct competitor to Ibalizumab and CytoDyn has huge financial hurdles to overcome to complete testing of PRO 140, we are still keeping an eye on it. The company reported results from an phase II extension study of 16 patients which showed that five of these patients eventually faced a rebound in their viral load. Ten patients had virtually undetectable levels of HIV after two years of PRO 140 use. As discussed earlier, PRO 140 is an inferior drug to Ibalizumab in every meaningful aspect, but it may be able to find some use for HIV patients if it can figure out a way to survive and make it through FDA testing.

Gilead also reported phase II data for a monotherapy HIV drug that appeared promising. This is a big threat to PRO 140 as CytoDyn is pursuing PRO 140 as a monotherapy, but is not an issue for THERF. If the four week IM version of Ibalizumab becomes a reality, then the Gilead and CytoDyn drugs may turn out to be its competition. But we have not included anything in our models for Ibalizumab for the 4 week IM version at this point. THERF’s
stock should do very well just based on the MDR market where it essentially will not have any competition for some time.

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"So do not worry, saying 'What shall we eat?' or 'What shall we drink?' or 'What shall we wear?' for the pagans run after these things, and your heavenly father knows that you need them. But seek first His kingdom and His righteousness and all these things will be given to you as well." Matthew 6:31-35 (NIV)