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Antares; My View of How Otrexup and Medac's New Product Rasuvo May Compete (ATRS, Buy, \$2.54)

Posted by Larry Smith on Jul 12, 2014 • (21)

Investors Are Concerned About Rasuvo's Impact on Otrexup

Investors have been concerned about the potential effect on Otrexup if the private company Medac gains approval for Rasuvo. Both products are device drug combinations that use highly engineered and proprietary auto injectors to administer methotrexate as a subcutaneous injection. These products were both developed under the 505 (b) 2 pathway which does not require clinical trials demonstrating efficacy to gain approval. The efficacy of methotrexate is well established. It is the gold standard drug for the treatment of rheumatoid arthritis and is also important in the treatment of psoriasis and some types of cancer. In order to gain approval Antares and Medac needed only to show that their drugs result in therapeutically effective levels of methotrexate in the blood.

Otrexup was approved in October 14, 2013 and has been marketed in the US since early this year. Otrexup is considered a new and novel dosage form of methotrexate which entitles it to three years of market exclusivity. There are additional patents on its Vibex auto injector that potentially could provide exclusivity for many years and means that any competitor cannot launch a product with an auto injector that infringes upon its Vibex auto injector patents. These patents do not protect against a product using a different type of auto injector that doesn't infringe. Medac uses an auto injector developed by Becton-Dickinson.

Antares is Attempting to Block FDA Approval of Rasuvo

Please keep in mind these dates. Medac announced on January 27, 2014 that the FDA had accepted its 505 (b) 2 application and had granted a PDUFA date of July 10, 2014. Because the FDA has to accept or reject the application within 60 days, this means that the application may have been filed on November 27, 2013 or later. However, there was no obligation for Medac (a privately owned company) to announce the FDA acceptance and it could have been filed much earlier. The PDUFA date is usually set by the FDA as ten months after the filing of the application. This suggests that the 505 (b) 2 application for Rasuvo was filed on or about September 27, 2013. This would be before the approval of the 505 (b) 2 application of Otrexup on October 14, 2014.

The timing of the 505 (b) 2 application is of critical importance. If it was filed after the approval of Otrexup on October 14, 2013, Medac would be required to submit a certification that it does not infringe several issued patents listed in the Orange Book pertaining to Otrexup and would have had to have listed Otrexup as a reference listed drug in their application. In this event, Medac would have been required to notify Antares of the filing. At this point, Antares could file for patent infringement. This would prevent approval of Rasuvo for either 30 months or the completion of a trial whichever comes first. It is almost always the case that the 30 month stay applies. So, if this is the case, Rasuvo could not come to market until April 14, 2016.

Antares filed a Citizen's petition to block the approval of Rasuvo in March. Antares appears to believe that Medac should have cited Otrexup as the reference listed drug for Rasuvo's application. This might have resulted in a 30 month stay on approval of Rasuvo. It is arguable that even if the 505 (b) 2 application of Rasuvo was filed before the approval of Otrexup on October 14 that the 30 month stay should still be applicable because Medac knew that Otrexup was the reference listed drug.

Following the filing of the Citizen's petition to block approval of Rasuvo in March, 2014 documents were exchanged and an injunction hearing was held on June 27. A mediation conference was then scheduled for July 9 which was the day before the July 10 PDUFA date. However, given the usual slow pace of these types of cases, it may be that this confrontation will continue beyond July 10.

There are also lawsuits by Antares against Medac alleging infringements of patents held by Antares. I believe that Medac and Becton Dickinson are counter suing Antares for patent infringement. I think it is next to impossible for investors to predict the outcome of many patent disputes and this is certainly the case here.

It is important to understand that any potential third competitor will be subject to a 30 months stay and could not be launched until April of 2016 at the absolute earliest. Also, any third competitor also has to defend against patents held on the Otrexup and Rasuvo devices.

Rasuvo Not Approved on July 14, but I Am Expecting That It Will Be

The July 10, 2014 PDUFA date has passed and I keep checking the Medac website for an announcement that Rasuvo was approved and as I write this on July 11, there has been no announcement. It could be the case that the mediation hearing has brought up some issue or decision that has delayed approval.

It is also possible the FDA is overworked and is just slow on completing its work; this is not unusual. It might find some issue to

prolong the review time or there could be a problem with the Medac filing although I doubt this. Perhaps the FDA is not be satisfied with Medac's user study, but this is just wild speculation on my part. These products are intended to be self-administered by rheumatoid arthritis patients who may have badly deformed hands. The FDA required Antares to do a user study that demonstrated that Otrexup could be self-administered by rheumatoid arthritis patients. Perhaps Medac's study was not as convincing but I doubt this.

My working assumption is that Rasuvo will be approved shortly and launched in the US before the end of 2014. I also think that the patent disputes on the devices will be settled by cross licensing patents between Antares and Becton Dickinson. This will make it more difficult for a third competitor to develop an auto injector that does not infringe on these patents.

How Will Rasuvo and Otrexup Compete in The Market?

There is some uncertainty on the part of investors on how Rasuvo and Otrexup will compete in the market. Let me make the point that Rasuvo is a unique product and has not been approved as a generic to Otrexup. Generics can be substituted by pharmacists for the brand name product and usually compete on price. This is not the case in the Otrexup/ Rasuvo competition.

So will Rasuvo still try to compete on price? I don't think so. I just don't see that Medac would compete on a price basis. If they come in at a significantly lower price than Otrexup that forced Antares to match the price, Medac would gain no advantage in unit market share and would suffer on sales because of the lower price. Based on experience with past launches of similar or me-too products, I would expect the Medac product to be priced at the same, a slightly lower or a slightly higher price. I would also add that two companies promoting similar products would accelerate acceptance and expand the market.

How Big Is The Opportunity for Otrexup and Rasuvo?

During a recent presentation, Antares presented a slide that showed the breakdown of the usage of anti-rheumatic drugs in the US. It showed that there are 700,000 patients in the US who have not progressed to a biologic and showed that of patients 420,000 were treated with methotrexate. It also showed that 590,000 patients had progressed to biologics and of these 280,000 were being prescribed methotrexate in addition to the biologic. There was a third population of 110,000 patients who were post biologic of whom 56,000 were being given methotrexate. Altogether, this indicates there are 756,000 patients using methotrexate for the treatment of rheumatoid arthritis in the US.

Otrexup and Rasuvo will not be used in mild to moderate rheumatoid arthritis patients if oral methotrexate or some other disease modifying agent is effective. They could be used when oral methotrexate is no longer controlling the disease or when patients can't tolerate oral methotrexate. Their primary use will be to keep patients on methotrexate longer before they have to move on to a biologic. The above table does not directly address how big this market might be, but it might be some part of the 280,000 patients now being prescribed methotrexate plus a biologic. At the Otrexup price of \$6,000 per year, this is a rather staggering \$1.6 billion. Let me hasten to add that I am not projecting sales potential of \$1.6 billion for Otrexup and Rasuvo; it will be some fraction of this and at this point it is very difficult to guess at a percentage. I am simply indicating that there seems to be a lot of potential.

The presentation also shows that there are 62,000 patients who are receiving subcutaneous methotrexate. There is no approved subcutaneous methotrexate product so this represents an off-label formulation that uses injectable methotrexate delivered with an insulin syringe. In addition it is estimated that there are about 38,000 patients receiving intramuscular injections of methotrexate. Altogether, this indicates that there are 100,000 patients currently receiving methotrexate injections. Otrexup and Rasuvo should replace a good deal of the off-label and much of the intramuscular methotrexate usage. These 100,000 patients represent an addressable market of \$600 million. Again, I am not suggesting that Otrexup and Rasuvo would replace all of this usage.

I do not have any good estimates on the size of the psoriasis market. Antares has indicated that there are 7 million psoriasis patients in the US of whom 1 million are in the moderate to severe status that will be the target for Otrexup and Rasuvo. I have heard estimates that 200,000 patients could potentially benefit from use of methotrexate, but I don't know how many are on methotrexate and how many of this number might be candidates for Otrexup or Rasuvo. However, it is likely to be a meaningful opportunity. In addition, methotrexate is also used in some cancer indications, but I can't even begin to hazard a guess as to the potential for Otrexup and Rasuvo in this therapeutic category.

Importance of Otrexup to Antares

At this point, you are probably waiting for me to give you an estimate of the addressable market for Otrexup and Rasuvo and what part of this market they will capture, but I can't with any degree of accuracy. Before, Rasuvo entered the picture, Antares was projecting that Otrexup had peak sales potential of \$200 million around 2019. My gut feel is that is quite low, but for the time being, let's assume that Otrexup and Rasuvo split the market and each reaches \$100 million at their peak in 2019. What does that mean for Antares and Otrexup?

Antares has estimated that Otrexup breaks even at about \$24 million of sales indicating that means that product and marketing costs are currently running at \$24 million. The current cost structure should not increase much as sales approach \$100 million. If costs were \$24 million with \$100 million of sales, pretax profits would be \$76 million. Assuming an effective tax rate of 35% and 130 million shares outstanding, I calculate that the contribution to EPS would be \$0.38. If we assume a modest P/E of 15 is placed on these EPS, Otrexup alone would be worth \$5.50 in the Antares stock price in 2019. Going through the same exercise using \$36 million of costs in 2019 results in a stock price due solely to Otrexup of \$4.80.

I hope that you take these numbers for what they are intended to be, i.e. giving magnitude and trend and not being ball bearing precise. However, the bottom line is that Otrexup represents major potential for Antares. I am disappointed with the price performance of Antares, but this doesn't affect my positive opinion on the stock.

Tagged as **Antares**, **ATRS**, **Medac**, **otrexup**, **Rasuvo** + Categorized as **Company Reports**

21 Comments



1. **StefanClement** says:
July 12th, 2014 at 11:48 am

Dear Larry,

Rasuvo was approved on 10th July 2014.
<http://www.fda.gov/drugs/newsevents/ucm130961.htm>

As a private company Medac do not have to publish it immediately.
Overall the guys from Medac have had a perfect timing regarding the approval process of Rasuvo.

Like you i am very unhappy and disappointed with the Antares stock price.
I hope that we will see very quickly clearness and peace between the parties, because I also think that there is room for two drugs in this area.

When the storm is over we can concetrate us on the selling numbers and i hope they will be good for OTREXUP and with good sells the stock price will get updraft.

For stockholders nothing is as bad as uncertainty. So as well as the whole Medac situation is not perfect for Antares, they should close this chapter and look in the future.
And with a filled pipeline, attractive partnerships and profits on the horizon, the future is not as bad as it maybe seems today.

At last some words from an investors soul:
It never is easy to see decline the stockprice from a company you own and trust in. It needs really power and patience when the lights every day are in the red. But if the company is in good order and positioned well as Antares is, time will bring it back to fair value.

Investing is an marathon and a test of will to plagiarise you.
I am sure in one year your recommendation for Antares comes from an greatly higher stockprice level than today.

Greetings from Germany (the domicile from Medac)

Stefan



2. **Larry Smith** says:
July 13th, 2014 at 8:16 am

Thanks Stefan



3. **Al Marshall** says:
July 14th, 2014 at 4:15 pm

Mr. Smith: You mention that 62,000 patients are currently receiving subcutaneous methotrexate and that you expect a good number of these patients to switch over to Otrexup or Rasuvo.

Why is that? At \$6k per year Otrexup represents a significant cost which may be substantially higher than methotrexate and the insulin syringe (do you know the number?). Could insurance companies refuse to cover the additional costs for those patients who are physically able to perform the injections (which presumably many of these patients are already doing)?

Thank you.
Al Marshall



4. **Larry Smith** says:
July 16th, 2014 at 7:45 am

Otrexup has a cost advantage over the biologics which cost \$20,000 or more. Because the biologics have a greater effect on depressing the immune system, patients are more susceptible to infection

In regard to the insulin syringe dosed methotrexate, there are issues. First of all, this is not an approved product. Second of all the pharmacist must put a liquid dosage form of methotrexate in a syringe. For injectable products, the FDA for approved products requires production of the product in a sterile manufacturing facility to avoid the risk of bacterial contamination. Pharmacists filling syringes with liquid methotrexate may not have sterile facilities. While some doctors might opt to continue with the insulin syringes with approved products available, most will switch to approved products. Can you imagine the liability if a doctor prescribed an unapproved insulin syringe product and that patient suffered a severe bacterial blood infection.



5. *TDPeterson123* says:

July 16th, 2014 at 11:53 am

Hi Larry,

A peer provided the following info to me. I'm hoping you find this interesting and useful. It speaks to the differences between Antares and Medac "go to market", as well as specifics about each competitors device:

Antares has mentioned a 25 rep salesforce while Medac is recruiting 27 reps. But, Leo has a 75 rep salesforce for psoriasis, which gives an advantage to Otrexup.

Antares will have at least an 7-8 months head-start (mid-January Otrexup launch vs. Sep/ Oct Rasuvo launch, as Medac needs time to recruit and train its new salesforce).

Added to the differences in products characteristics, this should give an advantage to Otrexup.

The prescribing information is essentially the same boiler-plate for both, but some differences exist, in particular in the User Instructions part:

1 – shelf-life:

Rasuvo's is 17 months.

Otrexup's is 24 to 33 months (24 for 10/15 mg and 33 for 20/25 mg).

= At least 7 more months before need to be returned or thrown away.

2 – dose-strengths/ SKU:

Rasuvo has 10 going from 7.5 to 30 mg in 2.5 mg increments.

Otrexup has 4 going from 10 to 25 mg in 5 mg increments.

= Not sure if 2.5 mg increments would really change the life of rheumatologists and patients vs. 5 mg ones.

= Not sure if 27.5 and 30 mg doses critical vs. 25 mg.

3 – PK/ Bioavailability:

Rasuvo: healthy subjects, 7.5 to 30 mg exposure 35 to 68% higher than oral MTX; psoriasis, 30 mg exposure similar IM.

Otrexup: rheumatoid arthritis patients under oral MTX for at least 3 months, 10 to 25 mg exposure 13 to 36% higher than oral MTX, also similar abdomen or thigh.

= Not sure if one is better than the other in absolute. Still, I think a rheumatologist would find RA data in patients already under oral MTX more pertinent.

= Note "€œsignificantly enhanced bioavailability€œ" was highlighted by Medac in this morning's PR.

4 – Needle visibility:

Rasuvo has a visible needle.

Otrexup needle is hidden.

= Needlephobia could have influence in patients using a non-oral drug for the first time.

5 – Device activation:

Rasuvo: pull bottom cap straight (do not twist), push firmly against the skin to unlock safety.

Otrexup: twist bottom cap, flip top safety clip.

= Not sure if significant other than the two modus operandi are not exchangeable.

6 – Injection-site preparation:

Rasuvo: clean, "pinch a pad of skin with your thumb and forefinger of your free hand by gently squeezing. Patients with rheumatoid arthritis who are unable to pinch the skin can inject directly into the thigh without pinching if needed."

Otrexup: clean only.

= Otrexup simplest.

7 – Injection:

Rasuvo: press top button, once click heard count to 5.

Otrexup: push firmly till click heard, count to 3.

= Not sure if significant other than the two modus operandi are not fully exchangeable.

Taken together, 5- device activation and 7- injection seem easier for Otrexup.



6. *DAMIFINO* says:

AS I MENTIONED IN OTHER MEMO

MR HOWARTH HAS NOT TOLD THE STOCKHOLDERS ANYTHING. IN THE MEANTIME THE STOCK HIT A LOW OF ALMOST \$2.00 DONT YOU THINK SOMETING SHOULD COME FROM THE COMPANY REGARDING THE PLUNG IN THE STOCK? . I OWN 400000 SHARES AND I AM UNHAPPY WITH MR HOWARTH



7. **Larry Smith** says:
July 17th, 2014 at 6:50 am

The decline in the stock was started by the resignation of the CEO Paul Wotton. Mr. Howarth addressed questions on this and I wrote a blog on it. The approval of Rasuvo though expected continued the decline and other to acknowledge the approval, there was not much that can be said. However, the potential for Otrexup is very significant and we should see this become more apparent in 2H, 2014 and 2015. We will also begin to focus on QS T which has as much or more potential and then other products in thier 505 (b) 2 pipeline. A wild care would be approval of their ANDA for Epi Pen. I think the stock is attractive here. Warren Buffet says be greedy when others are fearful and fearful when others are greedy. People are fearful on Antares right now.



8. **Larry Smith** says:
July 29th, 2014 at 8:25 am

Small stocks like this often get involved in wild swings that are out of proportion on both the upside and the downside. This is part comes from the wide range of views on their fundamentals. It also comes from heavy hedge fund involvement on the short side. In the end, the issue is how Otrexup and other new products in the pipeline ultimately perform. I know it is tough, but we have to stay the course. There is no quick fix for the stock price.



9. **DAMIFINO** says:
July 19th, 2014 at 12:34 pm

I am a strong supporter of Antares. I feel time is in their favor I see no reason Jack does not tell whatever he can. Little of anything goes a long way. What is going on at Leo? It would make for good news to know if they are having any success. You guys are doing a great service. Keep it up...DAMIFINO



10. **daniellaidman** says:
July 21st, 2014 at 10:42 pm

Hi Larry, It's my understanding that Rasuvo will Be available in 10 different dosages. Oxetrup is only available in 4 dosages. Do you see this as a significant disadvantage for Oxetrup as the 2 products compete for market share?



11. **Larry Smith** says:
July 23rd, 2014 at 11:33 am

My preliminary view is that you probably don't have to titrate the dose that carefully. Otrexup can be dosed in mg increments whereas Rasuvo is dosed in 2.5 mg increments.



12. **DAMIFINO** says:
July 27th, 2014 at 9:13 pm

Larry,
When is Jack going to tell the stockholders what is going on at Antares?
You would think Antares would buy back some of its stock on the market
ATRS has plenty of cash. \$2.06 is surely a good buy for the Company.
I think they need a strong PR person to boost the Stock.
DAMIFINO



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