Galectin Therapeutics, Inc. (NASDAQ:GALT)

Conference Call Transcript

September 27, 2016 05:30 ET

Operator:

Welcome to the Galectin Therapeutics Business Update Conference Call. At this time, all participants are in listen-only mode. Following management's prepared remarks, we'll hold a Q&A session.

As a reminder, this conference is being recorded. I would now like to turn the conference over to Jack Callicutt, CFO of Galectin Therapeutics. Please go ahead.

Jack Callicutt

Thank you all for participating in today's call. Speaking today from Galectin Therapeutics will be Dr. Peter Traber, President, Chief Executive Officer, and Chief Medical Officer; we also have Dr. Stephen Harrison, the principal investigator of our NASH-FX clinical trial and the co-principal investigator of the NASH-CX clinical trial.

Earlier this afternoon, Galectin Therapeutics announced results of the NASH-FX trial. If you have not received this news release or if you would like to be added to the company's distribution list, please call 610-228-2110 and ask to be added to the Company’s distribution list.

Before we begin, I would like to caution that comments made during this conference call by management and presenters will contain forward-looking statements regarding the operations and future results of Galectin Therapeutics. These statements include those regarding the aspirations that its lead compound will be successful in treating liver cirrhosis and fibrosis due to fatty liver disease. Regardless of the results of any of its development programs Galectin may not be successful in developing partnerships with other companies or raising additional capital that would allow it to further develop and/or fund any studies or trials.

For discussion of additional factors impacting Galectin's business, please see the company's Annual Report on Form 10-K for the year ended December 31, 2015 and other filings made with the SEC. You should not place undue reliance on forward-looking statements. All forward-looking statements speak only as of today's date, September 27, 2016, and as except required by law, the company assumes no obligation to update these forward-looking statements whether as a result of any new information, future events, changed circumstances or otherwise.

With that, I would like to turn the call over to Dr. Peter Traber. Peter?

Peter Traber

Thank you very much, Jack, and good afternoon to everyone who has called in.

Earlier this afternoon, Galectin Therapeutics announced three important developments.

- First, the results of our pilot NASH-FX trial, which will be described by Dr. Stephen A. Harrison, the principal investigator of the trial.

- Second, we announced completion of enrollment of our much larger and longer treatment trial which is called NASH-CX. This trial is in our lead indication for GR-MD-02, NASH cirrhosis.
- And finally, we announced an investment from a single major shareholder as well as his commitment to help ensure funding for the completion of the NASH-CX trial.

The NASH FX trial was designed in collaboration with, and conducted by Dr. Stephen Harrison, a leading investigator in NASH and liver disease. Dr. Harrison is the principal investigator of the NASH-FX trial, medical director of Pinnacle Clinical Research in San Antonio, TX, and Visiting Professor of Hepatology, at the Radcliffe Department of Medicine at the University of Oxford, in the United Kingdom. I will now turn it over to Dr. Harrison for reporting on the results of the NASH-FX trial.

Stephen?

Dr. Stephen Harrison

Thank you Peter. The design of the NASH-FX trial evolved from the results of a Phase 1 study in NASH patients with advanced fibrosis. The results of this phase 1 study have been accepted for publication in the peer reviewed medical journal, *Alimentary Pharmacology and Therapeutics*. Preliminary indications based on limited data from the phase 1 trial suggested that FibroScan® measurements improved in three patients with just four doses of drug. While most experts, including myself, feel that liver fibrosis trials should have treatment phases for at least a year in duration, the results from the phase 1 study provided a rationale for

studying a larger group of patients with shorter therapy and exploring non-invasive technologies for assessing liver disease, liver stiffness and fibrosis with a goal of using these technologies in later trials.

Therefore, the NASH-FX trial was designed as a pilot study at a single site with four months of treatment with GR-MD-02. All patients enrolled in the trial had liver-biopsy proven nonalcoholic steatohepatitis with advanced fibrosis, which was performed within 6 months of beginning treatment. Liver biopsies were not performed at the end of the study following treatment due to safety considerations involved with liver biopsy-related risk in a short duration trial such as this.

The evaluation of response to treatment was assessed using three of the leading non-invasive tests that are being evaluated and investigated by many investigators for NASH and fibrosis response to experimental therapy. The primary endpoint was assessed by the magnetic resonance imaging test called LiverMultiScan (or LMS), an FDA-cleared diagnostic test reported to evaluate inflammation and fibrosis in liver disease by the developers, Perspectum Diagnostics. While the patients in the trial had a LiverMultiScan that indicated advanced fibrosis, the primary endpoint of an improvement in LiverMultiScan was subsequently not met. The trial also did not meet secondary endpoints that measure liver stiffness as a surrogate for fibrosis, with FibroScan® and magnetic resonance elastography or MRE.

Although there was no apparent improvement in the three non-invasive tests for assessment of liver fibrosis in this four-month treatment pilot trial, inhibition of galectin-3 with GR-MD-02 remains promising for treatment of NASH fibrosis. In regard to the potential activity of GR-MD-02, it is encouraging that there was an

improved clinical effect in moderate-to-severe psoriasis, suggesting the compound has activity in a human disease that can occur in association with nonalcoholic steatohepatitis.

The trial also evaluated and correlated the non-invasive tests using the three different techniques in preparation for later trials. We found a positive significant correlation between FibroScan and MRE, both measures of liver stiffness. But, neither FibroScan nor MRE correlated well with LiverMultiScan, emphasizing the need to further investigate LiverMultiScan in this patient population before applying the assessment in our future trials.

It is critical that we complete the longer therapy, much larger NASH-CX trial in patients with NASH cirrhosis, which Dr. Traber will now provide an update.

Peter?

Dr. Traber

Thank you, Stephen, very much for that report and I thank you for your excellent work in completing the NASH-FX trial, and additionally thank all the patients and staff that contributed their time and effort in completing the NASH-FX trial.

The NASH-CX trial is a one-year, multi-center trial in patients with NASH Cirrhosis that is being conducted at 36 outstanding liver centers in the United States. The endpoints of the NASH-CX trial are invasive tests that are well-validated measures of disease severity. The primary endpoint is hepatic venous pressure gradient, or HVPG, which measures the blood pressure in the liver and is

well correlated with the clinical outcomes of patients. Liver biopsy is an important secondary endpoint in the NASH-CX trial, which evaluates the stage of liver fibrosis. Finally, there are also non-invasive tests as secondary endpoints including FibroScan and a breath test of liver function. These are important to correlate with the invasive tests.

Importantly, the U.S. Food and Drug Administration may view the NASH-CX endpoints as acceptable surrogates for outcomes for registration trials in this patient population. Now at this point, I am pleased to report additional information on the status of this most important clinical trial:

- The NASH-CX trial completed enrollment one month early with 162 total patients, exceeding the target of 156. This keeps us well on track for reporting of top-line results in December 2017.
- The 162 patients were enrolled at 36 sites in the United States following the screening of 290 patients to obtain a population with well-compensated NASH cirrhosis with elevated portal pressure.
- In determining the number of patients to meet statistical requirements, we planned for the possibility that as many as 25% of the patients may drop out of the study during the treatment phase. However, we are pleased that only 3 patients of the 162 enrolled have dropped out of the study thus far. This trend suggests that we will have a robust number of patients completing treatment for evaluation at the end of the trial.
- At this point, 4 patients have completed the entire protocol and 67 patients have already completed 6 months of dosing. The press release said 64, but this is a rapidly moving trial and so it’s now 67 patients completing 6 months of dosing.

- A total of 1,883 drug infusions have been given in this trial, representing nearly 45% of the total number of infusions in the entire study. So we are quite pleased that this study is well along in its development.

The safety and tolerance of GR-MD-02 in all of the trials is most encouraging and supports our commitment to pursue the lead indication of NASH Cirrhosis. In NASH-FX trial, GR-MD-02 was found to be safe and well tolerated among the patient population with no serious adverse events related to the study medication. Over all of the clinical trials, including the patients in the NASH-CX trial, over 1600 drug doses have been administered without serious adverse effects related to the drug. This highlights the superior safety profile of the therapy in a patient population with advanced stage disease, which is buttressed by the biological activity demonstrated in patients with moderate to severe plaque psoriasis.

Now as Dr. Harrison mentioned, as one of the two co-lead investigators in the NASH-CX trial, he believes that the inhibition of galectin-3 with GR-MD-02 remains a promising for treatment of NASH fibrosis, and it is important to complete the NASH-CX trial.

Dr. Naga Chalasani, the other co-lead principal investigator of the NASH-CX trial, provided his assessment in the press release, stating that, and I quote, “the results from the NASH-FX trial do not diminish the significance of the NASH-CX trial. Along with the safety and tolerability profile observed in the NASH-FX trial, the different patient population, much larger enrollment, rigorous study design and longer duration of therapy offer compelling rationale to complete the NASH-CX trial.” (end quote)

The company's attention has always been focused on completing the NASH-CX trial and reporting results in a timely fashion.

Now, the third and very important announcement made today regards new funding received by the company. I take this opportunity to thank Mr. Richard Uihlein, a prominent businessman and a name you may recognize, who has agreed to provide $1.5 million to the 10X Fund which has invested in Galectin as an expression of commitment to help the company progress through the completion of the NASH-CX trial. It should be noted that Mr. Uihlein already had a significant stake in Galectin, and we appreciate his continued confidence. Details of Mr. Uihlein's investment through the 10X Fund can be found in the 8K filed today. It is our intention to continue to pursue additional funding to support our clinical development program with the continued support of Mr. Uihlein.

With an outstanding safety profile, inhibition of galectin-3 with GR-MD-02 remains a potential treatment of NASH cirrhosis. Additionally, there is the longer therapy for one year, and endpoints that may serve as a surrogate for outcomes for registration trials in this patient population, provides us encouragement about our continuation of NASH-CX clinical trial.

So with that overview of our progress, operator, we are ready for questions from the callers.

Q & A Session

Operator

Thank you. We will now begin the question and answer session. To ask a question, you may press star then 1 on your touchtone phone. If you are using a speaker phone, please pick up your handset before pressing the keys. To withdraw your question, please press star then 2. At this time, we will pause for a moment to assemble our question roster.

Our first questioner today is Ed Arce, from HC Wainwright & Company, please go ahead, Sir.

Q:

Hi everyone.

Dr. Traber:

Hi Ed.

Q:

Hi Peter, hi Stephen. My first question on the results of the FX trial. Of the 15 subjects that were on study drug, were there any individual patients that showed and effect or perhaps trend toward significance?

Dr. Traber:

Ed, the endpoint was the baseline adjusted mean value of the corrected T1 value as ascertained from the LiverMultiScan in both groups. And there was not a

significant difference between placebo and GR-MD-02. Within the GR-MD-02 group, there were some patients that went down a little bit but none of it, as an aggregate, reached significance for a difference from placebo.

Q:

Okay, I guess next question is I know that you would like to continue to pursue fibrosis as indication at some point in the future if funding were to become available. I was just wondering if such a trial, if you were to get to that point, would be designed as a minimum one-year with start and end biopsies, sort of a full-fledged trial to really elucidate the effects in fibrosis.

Dr. Traber:

Yes, Ed, I think that at this point, and it has kind of always been our focus as a company, the lead indication for GR-MD-02 will be NASH cirrhosis, so our view is that we will complete the NASH-CX trial with the hope of showing an effect in that trial. We will not initiate additional trials in pre-cirrhotic NASH until we have the results of the NASH-CX trial.

Q:

Okay, understood. And then perhaps one final question before I jump back in the queue. Peter, you mentioned at the very beginning an investor and his commitment to help you reach the readout of the NASH-CX trial at the end of next year. I assume that Mr. Richard Uihlein, that you mentioned later. If you could

help us understand with any further specificity, what kind of commitment would be involved.

Dr. Traber:

Mr. Uihlein, as I mentioned, is a prominent businessman, who has a significant stake already in Galectin Therapeutics, and has expressed confidence in the approach that we're taking and really wants to see the science come to fruition through completion of the NASH-CX trial, which is why he wanted simultaneously, with the announcement of these results to have this tranche of funding be put into the company. Now beyond this $1.5 million that he, that we closed on already, he has committed to helping the company to raise additional funds. As you'll see through the 10X fund, there is a commitment to work towards additional funding, and he has committed to help do that. So there are no specific funds that have been put into the company at this point beyond the $1.5 million, but there is a commitment there to help the company raise the money needed for completing the NASH-CX trial.

Q:

Okay, understood. Thanks for taking the questions.

Dr. Traber:

Thank you, Ed.

Operator:

Again, if you would like to ask a question, please press star then 1 on your touchtone phone. Our next questioner is Sa'ar Yaniv from Roth Capital. Please go ahead.

Q:

Hi guys, thank you so much for taking my question, I appreciate it. I had a couple quick questions. The first one is, are you planning on following indications in the FX study for any length of time, perhaps maybe follow-up in about I guess it would be 8 months for a total of 12 months to see if maybe a liver biopsy would show any kind of improvement or stabilization of fibrosis.

Dr. Traber:

Sa'ar, we don't have any specific plans that have been put together in a protocol amendment at this point, but let me ask Dr. Harrison if he wants to make any comments about that.

Dr. Harrison:

Yeah, so I think that your question is a good one. Did we stabilize disease or even prevent progression of disease with 4 months of dosing? That's not something that we've contemplated doing or evaluating. But it raises an important point and one that ultimately we're aiming for in the whole space of advanced fibrosis in the setting of NASH and that is stabilizing disease and then improving it if possible. It may be something that we can look at and look into. It's not something that

Galectin and I have talked about up until this point, but that's an intriguing concept for sure.

Q:

Okay. Now,

Dr. Traber:

Sorry, let me just follow-up on that question for just a moment. One of the important things to take into account is that this was a very small study of 15 placebo and 15 treated, and it was done primarily because we saw this effect in phase 1 and we wanted to see whether we would see an effect after a short period of treatment. It was never designed to be a regulatory study with liver biopsy endpoints. So one of the things that we would have to think about in doing what you suggest is whether the numbers of patients in the study are really adequate to do repeat biopsies with a hope of seeing a difference because liver biopsies have a very high sampling error and a lot of variation from sample to sample. One of the reasons why we used LiverMultiScan at the primary endpoint in this study is because it has a demonstrated coefficient of variation which is less than 5% and therefore could be used in small study, so we would have to take some of those things into consideration before doing something like that with liver biopsies.

Q:

Would you consider doing additional measurements, perhaps LiverMultiScan or FibroScan or maybe even MRE at 6 months or 12 months?

Dr. Traber:

Yes, that's definitely a good suggestion and we can consider it.

Q:

Right, the only reason I was mentioning liver biopsy is because it was my understanding that most physicians are ambivalent about doing another liver biopsy within 12 months of the first one, that's why I was asking specifically about biopsy. Okay, that's very good. Let me ask you about the CX study. Are you at all planning now that you got the results from the FX study, and I know that they're different and I know you're using different measurements, are you at all looking potentially at an interim analysis and maybe a futility analysis at maybe half the patients reaching 12 months of treatment?

Dr. Traber:

An interim analysis is not currently in the NASH-CX protocol, but it is something that we can consider and we'll be looking into but no decision has been made about interim analysis at this point.

Q:

Okay, very good. Thank you so much.

Operator:

Our next questioner today is Vernon Bernardino with FBR & Company. Please go ahead.

Q:

Hi, thanks for taking my question.

Dr. Traber:

Hi Vernon.

Q:

Regarding the FX trial, so it's a study of duration of 4 months and just correct me if I'm wrong. There was FibroScan done at the beginning and at the end of the 4-month period?

Dr. Traber:

Yes, all 3 noninvasive tests, the LiverMultiScan, FibroScan, and MR elastography were done at the beginning of the study, prior to treatment and following treatment at the end of the study.

Q:

Okay, one of the intriguing results from the phase 1 study were the other biomarkers. Some of them were components of FibroTest. What kind of samples did you collect and when during the 4-month period for the FX trial?

Dr. Traber:

What we saw in the phase 1 study was reduction in FibroTest, which is a test of 6 serum markers. One of those serum markers was alpha 2 macroglobulin and that went down. We took serum at the beginning, in the middle, and at the end of the trial. The analysis of those is not completed because they are exploratory endpoints and weren't part of the topline data, so those are still under analysis. But we expect to have that type of analysis from this trial sometime in the future.

Q:

Terrific, because that's exactly what I wanted to get to because one of the most intriguing, perhaps strongest results in the phase 1 were the results on alpha 2 macroglobulin. When do you anticipate you'll have the results from that? Because perhaps if that is going in the right direction, that is to confirm the decrease that you saw in phase 1, then perhaps, GR-MD-02 still has a powerful effect in a short duration of time, even in the form of study.

Dr. Traber:

Yes, and I don't have a date on that as yet, Vernon.

Q:

Okay. And the NASH-CX trial, what again is the first type of data that you will be announcing now that the enrollment has completed quickly?

Dr. Traber:

The protocol as it is written now and as are planned is it will be topline data in December of 2017.

Q:

Okay, thanks very much, Peter. Thanks for taking my questions.

Dr. Traber:

Thank you, Vernon.

Operator:

Our next questioner is Ed Arce from H.C. Wainwright & Company. Please go ahead.

Q:

Hi, thanks for taking the follow-up. I was just wondering about the NASH-CX trial. I know with HVPG and you had mentioned that this potentially could be viewed if the results are robust, as a potential registration trial. So I'm wondering,

have you preset for the mean baseline HVPG measurements to be below 10 or above 10 so that you could pursue one or the other of the two endpoints that are currently acceptable by the FDA.

Dr. Traber:

Yes, Ed, you bring up a very important point., What you're referring to is that an HVPG of 10 millimeters of mercury has been defined as clinically relevant portal hypertension. Portal hypertension occurs with a pressure of 6 or greater, but "clinically relevant" portal hypertension is 10 millimeters of mercury. We have targeted our patient population of well compensated cirrhotics, by from previous studies, to have an HVPG between 12 and 15. And that is the range in which we are seeing them in our trial. We're not, at this point, prepared the present the data on exactly what the starting mean HVPG is, but it's targeted to be greater than 10.

Q:

Right, so my point being that the results that would be significant or robust from a registration standpoint would be the get the overall mean effect of those patients in aggregate as a mean below 10.

Dr. Traber:

That has not been completely clarified by the FDA. Clearly, reducing the HVPG from above 10 to below 10 is likely to be viewed positively by FDA. I don't want to speak for the FDA, but is likely to be an endpoint that they would accept as clinically significant. However, there are data from Dr. Guadalupe Garcia-Tsao, at

Yale University, and others, that a 10% to 20% reduction in HVPG is also clinically significant. So for instance, in the Timolol trial, Dr. Garcia-Tsao showed that reducing portal pressure by 10% reduced the complications of variceal hemorrhage, ascites and progression of cirrhosis, using beta blockers. So the exact endpoints of that the FDA will accept as a registration endpoint has not been completely sorted out. However, our study is designed to have the opportunity to have the baseline above 10 and go below 10 or to show a 10 to 20% reduction, either or, or both. So there hasn't been a drug approved, based on HVPG as yet, but those are the type of endpoints that the FDA is talking about finding acceptable and we'll just have to wait 'til the end of the trial to see how the FDA is going to respond to a change in HVPG. Does that make sense, Ed?

Q

Yes, that's great.

Dr. Traber:

Stephen, I don't know if you want to add anything to that?

Dr. Harrison:

No, I think that you spelled it out very nicely. There are two different targets here; a percent reduction, not an absolute reduction, but a percent reduction, as illustrated in prior studies does have a clinically significant meaning as well as an absolute value change to less than 10. So I agree we don't really know what the FDA is going to accept at the end of the day. I think the important thing to see

from the CX trial is a reduction in overall HVPG that meets our endpoint and compared to placebo and we'll just have to see where we go from there.

Dr. Traber:

Great, thank you.

Q:

And if I may, just one other one on this CX trial. Given the patients that you've enrolled and the number of patients and especially the lower than expected drop-out rate, at least so far, question is, the study would then be powered to show significant effect in either one of those two potential surrogate endpoints.

Dr. Traber:

Yes, that's correct. The study was designed to be powered at 80% for 117 patients. Anything above 117 completed patients simply increases the power, and in fact it would be well over 95% if we ended up completing the full 162 that we've enrolled.

Q:

Okay, great, thanks again.

Operator:

There are no more questions at this time, so this will conclude our question and answer session. I would not like to turn the conference back over to Peter Traber for any closing remarks.

Dr. Traber:

Okay, thank you very much. I appreciate the time that you've all taken on this call. I want to end by saying that we presented the data on the NASH-FX trial and we presented the rationale and the case for the importance of completing the CX trial, and we are looking forward to the results of that CX trial in December of 2017. We appreciate your being on the call. I want to thank the analysts for their questions and thank Dr. Harrison for his time on this call as well. Thank you very much.

Upon Conclusion of Q & A Session

Operator

The conference has now concluded. Thank you all for attending today's presentation. You may all now disconnect your lines.