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ATNM - Actinium Pharmaceuticals Inc Pivotal Phase 3 SIERRA Trial Call

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PRESENTATION

Operator

Welcome to the Actinium Pharmaceuticals conference call. (Operator Instructions). As a reminder, this conference is being recorded Monday, August (sic - October) 28, 2019. I would now like to turn the conference over to your host, Mr. Steve O'Loughlin, Actinium's Principal Financial Officer. Please go ahead.

Steve O'Loughlin - *Actinium Pharmaceuticals, Inc. - Principal Financial Officer*

Thank you, operator. Before we begin I would like to go over the disclaimer and Safe Harbor statement. Some of the information presented herein may contain projections or other forward-looking statements regarding future events or the future financial performance of the Company, which the Company undertakes no obligation to update.

These statements are based on management's current expectations and are subject to risks and uncertainties that may cause actual results to differ materially from the anticipated or estimated future results, including the risks and uncertainties associated with preliminary study results varying from final results; estimates of potential markets for drugs under development; clinical trials; actions by the FDA and other governmental agencies; regulatory clearances; responses to regulatory matters; the market demand for and acceptance of Actinium's products and services; performance of clinical research organizations; and other risks detailed from time to time in Actinium's filings with the Securities and Exchange Commission, including without limitation its most recent annual report on Form 10-K, subsequent quarterly reports on Forms 10-Q and Forms 8-K, each as amended and supplemented from time to time.

With that I would now like to hand the call over to Actinium's Chairman and CEO, Sandesh Seth.

Sandesh Seth - *Actinium Pharmaceuticals, Inc. - CEO & Chairman*

Good afternoon, everyone, and thank you for joining us today. We are very excited to share with you today the positive findings from 50% enrollment in the pivotal Phase 3 SIERRA trial for our lead drug candidate, Iomab-B. Full results were detailed in a press release that we issued this morning.

We are highly encouraged that all patients in the study arm receiving a therapeutic dose of Iomab-B were successfully transplanted. The patients in the control arm, however, continued to not farewell with just 18% of them being able to achieve complete remission, or seen another way, with an 82% failure rate for purposes of the primary endpoint.

These results, while heartening for SIERRA, occurred despite the addition of the newly approved targeted therapies including FLT3s, IDH inhibitors and venetoclax combinations to the control arm. We believe the data from the 50% enrollment will enable us to reshape perceptions of BMT as a viable alternative for older patients with active relapsed or refractory AML, as this is a population that is not considered viable to endure a transplant today.

As a company Actinium is committed to bringing this potentially transformative therapy to patients with active AML to enable them to receive a potentially curative BMT. I would now like to turn the call over to Dr. Giralt for an overview of Iomab-B and his perspectives on the findings from this data from the SIERRA trial. Dr. Giralt, over to you.

Sergio Giralt - *Memorial Sloan-Kettering - Chief Attending Physician*

Good morning. Thank you, Sandesh, for the kind introduction. And thank you all for taking the time to listen to our update of the SIERRA trial. I am Sergio Giralt, I am the Melvin Berlin Family Chair in multiple myeloma research and a Professor of Medicine at Weill Cornell Medical College and the Chief Attending Physician of the adult BMT service at Memorial Sloan-Kettering.

So, why are we here today? We are here today because we are addressing the issue of acute myelogenous leukemia an older patients. As you can see in this slide, patients who are over the age of 60 with acute leukemia that have failed to respond to primary therapy have a dismal prognosis with current available combination chemotherapy, which is primarily cytarabine based.

We know for a fact that high-dose therapy, or reduced intensity conditioning with an [algoneic] transplant, can cure a small fraction of these patients. However, as we try to get better disease control with bio ablative conditioning, older patients do not tolerate these treatments well and have significant non-relapse mortality. As we do very reduced intensity conditioning regimens, the disease tends to relapse and allogeneic transplant does not work.

Now when we think about 170,000 patients who are diagnosed with acute leukemia and the fact that only one in five get transplanted, some of the problems that are happening are: one, that patients many patients are not being able to get to transplant because primary therapy does not work; or two, when they're viewed as candidates for transplant their current medical condition, either by the disease being not in remission or their health condition does not allow them to go through current available conditioning regimens.

This is because current available chemotherapies are non-targeted and many of them are highly toxic. This means that there's limited access and, even for patients undergoing transplant, relapse remains the most important cause of treatment failure, many patients just fail to have long-term disease control.

Iomab-B CD45 targeting antibody is a radiation conjugate. Several factors contribute towards potential use in transplant. One, CD45 is a highly relevant target. It is expressed in most acute myelogenous leukemia and it is only found in the blood system, thus on-target soft tissue effect is very rare.

Two, there's already extensive Iomab-B clinical experience with more than 300 patients, 12 clinical trials in six different disease entities. And in retrospective analysis performed by Dr. [Kagle] and his group when he was in Seattle, there was a demonstration of improved survival and curative outcomes that actually led to the development of this Phase 3 trial.

As already stated, AML is a high unmet need. There is a strong proof of principle in the current available data. There are more than 20,000 patients diagnosed each year and BMT remains the only curative option for these patients.

So, why do we think that Iomab-B is worthwhile exploring? In this slide you can see that, again, as stated previously, transplant is currently the only option for long-term disease control. For patients with active disease, many centers are refusing to proceed to transplant. Now this means that many patients -- older patients with acute leukemia who get currently available anthracycline cytarabine based conditioning -- I mean induction treatment, are unlikely to achieve a remission.

And since they are unlikely to achieve a remission they are unlikely to go to transplant because most centers are not offering transplants in patients who are not in remission. This results in very suboptimal outcomes. And services that do allow patients not in remission to go to transplant, the current one-year or two-year survival is somewhere between 10% and 20%.

Historical controls using Iomab-B BMT conditioning suggest that one-year survival can be up to 30% and two-year survival is up to 20%, significantly higher than what has been historically mentioned with chemo and BMT in very selective agents.

So, what is the SIERRA trial? In this slide you see the current design of the ongoing pivotal Phase 3 SIERRA trial for Iomab-B. This is the only randomized Phase 3 trial investigating a BMT option for older patients above the age of 55 with active relapse or refractory disease. The trial is planned for 150 patients, 75 in each arm, and the primary endpoint is durable complete remission at six months, with a secondary endpoint of one year overall survival.

The plan is to recruit 150 patients with active refractory relapse acute myelogenous leukemia and randomize them one-to-one to either Iomab-B or physician choice. Patients who go -- are randomized to physician choice, if not achieving a CR in a failed primary endpoint, can be crossed over to the Iomab-B arm. Again as stated, the primary endpoint is six months durable CR and the secondary endpoint is one year overall survival.

We've already presented the primary results when we have achieved 25% enrollment in the SIERRA study. We showed that there were high rates of engraftment and engraftment without delay in patients randomized to the SIERRA arm. Interim results were similar to what were seen in the Phase 2 trials at the University of Washington Fred Hutchinson Cancer Research Center.

Initial findings also demonstrated that crossover was a viable option, that patients who crossed over had virtually, again, 100% engraftment without delay, which allowed physician investigators to encourage patients to participate in the study, recognizing that if they were randomized in a control arm they would still have the option of achieving -- or receiving the investigational therapy if their treatment failed to achieve a complete remission.

The trial has been accepted throughout the transplant community with now 20 leading BMT service centers participating in the SIERRA trial.

What have we learned now that we have 50% enrollment? Again, this was a patient population that expected to have four outcomes at minimal access to BMT based on age, risk and active disease. So, with 50% enrollment with 75 patients, the median age is 65 and 64 for patients randomized to conventional care.

And these were patients with intermediate or high risk cytogenetics. And at the time of randomization the average number or the median number of (inaudible) was 30% in the patients randomized to Iomab-B versus 26% in patients randomized to conventional care. So again, a large number of patients with active disease would have been unlikely candidates for current available transplant conditioning regiments in most centers across the United States.

Of note, 20 of the 38 patients who were randomized to conventional care crossed over to the transplant arm and actually underwent transplant. Median percent [blast] at the time of transplant was 35%.

Again, with a 50% enrollment we have seen an absolute neutrophil -- the median time to absolute neutrophil recovery of 15 days, all patients [engraftment], 31 out of the 31. Patients randomized to the conventional arm can receive standard of care transplant of which 18% of them were there; the median time to recovery was similar at around 18 days. And for those who crossed over from the conventional arm to Iomab the median days to neutrophil recovery was 13 days.

No differences were seen in platelet recovery and, as expected, the median time to transplant from randomization was 30 days for patients in the study arm and 64 days for patients who crossed over to the Iomab arm after having failed conventional care.

I think it's important to note, and these are very important highlights -- and once again, this is only 50% enrollment -- is that 92% of the patients -- there was a significant number of patients who have received venetoclax or hypomethylating agents, and all these patients engrafted and did as well as the other patients who received more traditional anti-leukemic therapy. That only 18% of patients who achieved CR in the control arm went

on to receive a BMT. That all the patients who underwent transplant after Iomab conditioning regimen engrafted. And there seemed to be no delay of transplant when patients were crossed over to the Iomab arm.

What else have we learned after the 50% enrollment? Again, similar to what we saw when we had 25% enrollment, there is a very low 100-day non-relapse mortality rate, about 3% in the Iomab arm and 13% for patients who were crossed over to Iomab after having failed conventional treatment.

Now the number of patients is small, that was only two patients out of the 16 that were crossed over, which is, again, very important for the physicians and investigators who are offering this trial to patients, once again encouraging them that even if they are randomized to the control arm, that if they fail to achieve a CR they can go to Iomab treatment.

What you see here is a graphical description of where we are with our 75 patients and that currently there is -- 31 patients were evaluable for engraftment, 30 patients are evaluable for the primary endpoint, which has not yet read out.

The importance of engraftment rates seen is consistent with past Iomab-B studies and that rapid engraftment suggests improved 100-day outcomes. And we are seeing similar observations with this trial, although, once again, we are only 50% enrolled.

At the 50% enrollment mark we again have seen that everybody randomized to Iomab-B was able to undergo transplant with a very low 3% non-relapse mortality rate. Patients on the control arm who then underwent transplant had a higher non-relapse mortality rate, but it is difficult to compare because we do not yet have all the characteristics of the transplant strategies that those patients underwent.

So, what's the relevance of Iomab-B considering that there are all these other therapies that are becoming available for acute myelogenous leukemia? So, it is true that over the last five years, we now have new agents that have been approved for refractory relapsed AML. For patients with FLT3 mutations, gilteritinib was approved in November of 2018.

For patients who are not fit and over the age of 75, venetoclax in combination with azacitidine or decitabine was approved. [Glastobig] was approved for patients 75 and over and not fit for conventional chemotherapy. Two IDH inhibitors have been approved as well as gemtuzumab ozogamicin for patients with relapsed refractory CD 33 positive AML and another FLT3 inhibitor has also been approved in combination with 7+3 midostaurin.

Current targeted agents are not curative and relapse remain a major issue. However, these targeted agencies can be considered good bridges to transplant. Since complete remissions in the control group has not necessarily been associated with long-term disease control, since many of these VRs go ahead and relapse and the average survival is less than a year for the whole group and a little bit over a year for patients achieving complete remission.

Despite this and the investigators and the scientific advisory board recommended to amend the SIERRA protocol to allow inclusion of patients getting a targeted therapy as bridging therapy or in the control arm. The control arms now include 32% of patients with targeted agents and 68% of patients with other salvage treatment.

We do not think that the availability of these targeted agents would actually detract from the efficacy of Iomab-B. If anything we think that this will allow for more patients to undergo transplant because they will be able to control the disease but not achieve complete remission, which allows them to get Iomab-B in a better circumstance. That however remains to be proven.

Again, just to underscore what was demonstrated in the Phase 2 trials and confirmed in this Phase 3 trial is the enormous activity of Iomab-B as a single agent with 100% reduction in peripheral blood blast by day eight, a [98%] reduction in peripheral blood blast by day three, as you can see in this slide.

So, what have we learned so far? With 50% of enrollment in SIERRA, Iomab-B has a potent single agent activity with a rapid and strong anti-leukemic effect. Targeted agents do not have a meaningful impact on BMT access for this patient population. Iomab-B still remains highly differentiated and SIERRA remains the only randomized Phase 3 trial to offer BMT.

At 50% Iomab-B is strongly tracking trends of high BMT engraftment and better outcomes previously shown in the 25% interim results and historical data from several Iomab-B trials.

So now I would like to introduce Dr. Mark Berger, the Chief Medical Officer of Actinium, who will update you on the trial status and outlook. Thank you very much for your attention and I will stay later on for questions and answers.

Mark Berger - *Actinium Pharmaceuticals, Inc. - Chief Medical Officer*

Thank you, Dr. Giralt. Your continued support of the SIERRA trial is greatly appreciated. I am proud of what we've achieved since I joined Actinium a couple of years ago. We have built an outstanding and committed team, partnered with leading bone marrow sites and with motivated investigators who share our strong desire to bring Iomab-B treatment to patients.

A key area of our focus has been the optimization of the study protocol. As you have heard Dr. Giralt say, physicians like him did not think that the study should have a control arm. Initially the control arm was a challenge to enrollment as physicians felt that randomization to the control arm would result in suboptimal outcomes for their patients, particularly as targeted therapies emerged and gained approval.

The decision to include these targeted therapies as options for the control arm was thus crucial and has had a positive impact on the trial. Investigators now can enroll their patients with confidence knowing that if their patients have, for instance, a FLT3 or an IDH mutation, they can receive the best available therapeutic options.

In addition, we've shortened the time for crossover valuation for from 28 days to 14 days for patients with disease that has progressed despite salvage therapy. This is an important way to assure investigators that their patients get quick access to Iomab-B and transplant if they did not respond to the salvage therapy.

Our strengthened team, which now includes two transplant physicians, a head of radiation sciences, a specialized oncology nurse, and a strong clinical operations group, has enabled to develop solutions that make SIERRA and Iomab-B more accessible.

As an example, Sloan Kettering, which is our highest enrolling site, does not use a lead-lined room but instead uses custom shielding solutions that we've developed that allow them to administer Iomab-B in a regular hospital room. A number of other sites do the same.

Most importantly, the data presented at ASH and at TCT meetings and the data we've shared today demonstrate that crossover can rescue patients and, while the great majority of patients did not achieve a response in the control arm, all patients, including crossover patients, that have received a therapeutic dose of Iomab-B were able to successfully go to transplant.

The data we've observed to date from SIERRA has given us the ability to optimize our messaging to change the perception of transplant physicians and hematologists. The common perception was that older patients with active or relapsed refractory disease aren't candidates for transplant. That they basically couldn't tolerate the conditions necessary.

The data presented at ASH and PCT after 25% enrollment allowed us to show strong evidence to the contrary. Those data allowed us to demonstrate real evidence that patients did not receive -- that patients who did not receive a remission in the control arm could be rescued with Iomab-B. The present data of 50% of enrollment makes that case even stronger and we're very excited to take this messaging out to the PMT and hematology community.

In addition, we work with sites to develop a network of hematologists to refer patients to SIERRA sites. Our approach is data-driven using real-world AML claims data. We are able to identify the hematologists with practices with a high volume of older AML patients. And then through direct engagement we focus on connecting them with SIERRA investigators and sites.

As depicted on this map, we are well positioned as our SIERRA sites are in states that account for over 50% of the AML patient population. If you think of each SIERRA site as a hub, we partner with the PIs at these sites to create spokes within the region to reach hematologists and other hospitals that are not SIERRA sites that can drive referrals and enrollment.

Leveraging best practices adopted from our commercial team, we are deploying multiple strategies to increase awareness for the SIERRA trial and Iomab-B. This includes targeted web and social media events, hosting national teleconferences with SIERRA PIs and transplant thought leaders to educate the existing and prospective SIERRA trial investigators. We will continue to advance these efforts throughout the completion of the SIERRA trial.

With the SIERRA trial now optimized, I feel we are well positioned to drive the study to completion. The prominent visibility of our positive interim findings for the first 25% of patients at major medical meetings was a significant turning point for the study. Those important data showed to reinforce Iomab-B's highly differentiated profile in the AML therapeutic landscape.

We should note that the study's data monitoring committee has reviewed the data from the first 50% of patients and has recommended that SIERRA proceed as written, much as we'd expected. We are very pleased the data we presented today for the first 50% of patients are right in line with the findings for the first 25% of patients, as well as with the extensive data from Iomab-B's previous development.

I will now turn the call over to Sandesh to discuss our revision for becoming a leader in the field of targeted conditioning.

Sandesh Seth - *Actinium Pharmaceuticals, Inc. - CEO & Chairman*

Thank you, Mark. When we in-licensed Iomab we were struck by the extensive body of data that existed across several hematologic indications. Given the broad expression of CD45 we saw Iomab-B as a pipeline within a drug in multiple potential indications.

We are excited that the profile that first attracted us to Iomab-B, mainly the rapid time to BMT, high BMT engraftment rate, rapid engraftment and low non-relapse transplant-related mortality, has been consistent with prior clinical experience, as can be clearly seen by the table on this slide.

This consistency is evident in the proof of concept trial, the first data read, and now at the 50% mark of the Sierra trial. We believe this data is highly encouraging and supportive of our mission to bring this potentially transformative drug candidate to market.

The building blocks to supporting our objective are firmly in place. The data trends shown with the past clinical experience of Iomab-B, including key predictive metrics, are holding at the 50% mark of the SIERRA trial. The data from SIERRA was generated at some of the most prestigious transplant centers in the United States and Canada and assure us that this drug candidate can be utilized at some of the highest volume hospitals.

To aid with this adoption, the SIERRA team has focused not only on education but also on providing flexible logistical solutions to those sites, so lead lined rooms do not have to be used.

We are also encouraged and honored by the recognition Iomab-B has received from the BMT and heme communities at ASH last year, at TCT this year, as well as at the Soho meeting. This recognition is confirmative of Iomab-B's potential as a highly differentiated therapy for a patient population with a significant unmet medical need.

Based on unmet medical need and the potential for Iomab-B, we see a compelling market opportunity and targeted conditioning. The market is highly concentrated with the vast majority of transplants in the United States being done at over -- at just 50 centers. A similar dynamic exists in the other major markets, including Europe, which overall is a larger market than the United States.

In the US we have orphan drug designation, which could result in an accelerated review. We also have orphan drug designation in the EU. And the EMA, via their scientific advice program, has indicated that the SIERRA trial results could be the basis for filing a marketing authorization application.

With Iomab-B as the foundation we believe that the potential exists to create a leading franchise in targeted conditioning. Concentrated market dynamics in the US, EU and other markets, large addressable patient population with limited to no competition in many indications, and appealing projected market growth make for an exciting opportunity. With this in mind, we are strategically building a pipeline for this large underserved medical need not only in allo and auto transplants but also for cellular therapies.

I would like to thank everybody for their attention today. While Iomab-B is certainly our most important program and the center of attention, I wish to remind people of the other value opportunities that exist through your Actinium pipeline and platform. To that end I will note that several of these programs are progressing quite promisingly and we look forward to additional updates, some before year-end.

I would like to again thank Dr. Giralt for his contributions today. Our team would also like to thank all of the patients, their families, the investigators and staff that have made SIERRA possible to now. Operator, could you please open the call for questions? Thank you.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions). Jason McCarthy, Maxim Group.

Jason McCarthy - *Maxim Group - Analyst*

I have a couple of questions. Dr. Giralt, can you help us understand on slide 11 on the -- I'm looking at the breakdown of the trial. On the Iomab-B arm where it says no CR/CR or making that determination -- after their BMT, is that data that we should expect in the future part of this 50% enrollment?

Sergio Giralt - *Memorial Sloan-Kettering - Chief Attending Physician*

You're referring to slide 11, right?

Jason McCarthy - *Maxim Group - Analyst*

Yes, sir.

Sergio Giralt - *Memorial Sloan-Kettering - Chief Attending Physician*

So, the way that study is done is if the patients get Iomab and they did not achieve complete remission, means they did not meet the primary endpoint, they come off study as a treatment failure. If they achieve complete remission and that complete remission lasts six months, then they've achieved the primary endpoint and it's considered a success.

At this moment in time we haven't read out the primary endpoint, so all we can tell you is that everybody got transplanted, everybody got engrafted, and only one patient died from treatment-related toxicity.

If you go to slide 16 you will see that currently we have 30 patients that are evaluable, so that's 30 out of the 31 patients that are evaluable for that primary endpoint. And obviously the study hasn't read out, so we can't comment on it. But it's a good place to be. So, out of the 37 patients enrolled on Iomab-B, some of these patients are still undergoing -- at the time of this data cut we didn't have data on everybody.

Jason McCarthy - *Maxim Group - Analyst*

Okay, I see. Are the complete responses or complete remissions that are needed to go into the Iomab-B arm and then -- or then into transplant rather, predicated on peripheral blast counts and bone marrow blast counts right before the transplant?

Sergio Giralt - *Memorial Sloan-Kettering - Chief Attending Physician*

So, I think it's important, and thank you for the question, which is I think it's important to -- we are getting into -- if you just think about 100 patients over the age of 55 with acute leukemia, okay. Out of these 100 patients in a regular community hospital two-thirds of them will probably get an anthracycline (inaudible)-based regimen and another third now will get either venetoclax azacitidine or a FLT3 inhibitor -- let's say a targeted treatment.

Out of those 100 patients, with good luck maybe half of them will achieve a complete remission. The 50 of them that don't achieve a complete remission, in most small to intermediate size transplant programs they would not be considered for transplant because they are not in complete remission.

In the centers that are large that will consider doing patients with active disease, those patients would probably go on a reduced intensity conditioning regimen or a myeloablative treatment or in a clinical trial. And as you can see, the expectations, particularly for patients who are getting conventional reduced (inaudible) conditioning regimen, is that that two-year overall disease free survival rate is very, very, very low.

Of the 50 people who achieved a CR in that group, most of those patients will go on to relapse. So, what does Iomab-B do currently in this study? So, in this study it allows the 50 people who are not achieving a complete remission with primary therapy to get a transplant option and to be able to exploit the graft versus tumor effect in the context of a conditioning regimen that is not only well-tolerated but it is very effective in reducing tumor bulk. Does that answer your question?

Jason McCarthy - *Maxim Group - Analyst*

Yes, I also wanted to know just before -- so, in this study in particular, in the SIERRA study, are the blasts being measured right before transplants only peripheral? Or does it also include a bone marrow look at the blasts and if that's a factor after transplant?

Sergio Giralt - *Memorial Sloan-Kettering - Chief Attending Physician*

We look at it only -- you see about in the slide that -- in slide number 13, at the time of randomization to either Iomab or conventional care we do a bone marrow -- so think about that's the bone marrow you get pre-randomization, and that's a median of 30% for Iomab and 26% for conventional care.

The next bone marrow that is done is usually sometimes after the -- so, if you look at the design of the study, which is on slide 11, so that bone marrow that says CR or no CR, that usually happens at the 30-day mark from the treatment. So, that is 30 days after the transplant. So, people who get the Iomab, they then get the low dose -- the fludarabine TBI, and 30 days after the fludarabine TBI and the transplant is when we read out the CR.

In the physician's choice, patients that get a CR go to transplant and then their readout is at the six-month mark. But really the only important readout is the primary endpoint, which is the six-month CR.

Jason McCarthy - *Maxim Group - Analyst*

Okay, so the CR 30 days post-transplant in the Iomab arm is not a part of this data set, is that correct?

Sergio Giralt - *Memorial Sloan-Kettering - Chief Attending Physician*

That is correct.

Jason McCarthy - *Maxim Group - Analyst*

Got you. Okay, that's what was confusing us a little bit. And also just a very broad question in general, just from clinical practice and what's been published in the literature. Can you give us a sense of what the median overall survival and a time to a relapse or a progression of any kind would be just in the general AML population that was able to get a transplant?

Sergio Giralt - *Memorial Sloan-Kettering - Chief Attending Physician*

So, in patients with active disease the median overall survival and patients going to transplant is eight to nine months. Most of them can get a remission, but those remissions last very shortly. Or they have serious life -- if you go into a more intense regimen the non-relapse mortality rate can be anywhere between 20% to 30% during the first year.

Jason McCarthy - *Maxim Group - Analyst*

And how quickly do they relapse -- and this is my last question quickly -- after the transplant?

Sergio Giralt - *Memorial Sloan-Kettering - Chief Attending Physician*

So, usually the median -- so, 80% of the relapses happen during the first two years of which more than half happen during the first year. So, the median time to relapse in somebody with active disease is somewhere between three to four months from the time of the transplant.

Mark Berger - *Actinium Pharmaceuticals, Inc. - Chief Medical Officer*

And Jason, this is Dr. Mark Berger, Chief Medical Officer. Just to add, all this has a lot to do with patient selection and the patient selection specifically for the SIERRA trial, the requirements require patients to be in very poor prognostic categories to start with. And that, of course, affects the survival and the ability to be transplanted by conventional means as well.

Jason McCarthy - *Maxim Group - Analyst*

Okay, great. Thank you, guys, for taking all the questions.

Operator

[Andy Shay], William Blair.

Andy Shay - *William Blair - Analyst*

I think this is kind of -- so, congrats on the progress. Thanks for taking my questions. So, since the SIERRA trial is an open label study, I'm just curious if you have the number of patients on Iomab-B arm that did not achieve an initial CR.

Sergio Giralt - *Memorial Sloan-Kettering - Chief Attending Physician*

No, we certainly don't. We are not following the trial for the primary endpoint. So, no, we don't. Obviously we'll be evaluating those data at the end of the trial or any time [we do] interim analysis.

Andy Shay - *William Blair - Analyst*

Okay. So, the reason why I'm asking is because in the presentation you made on slide 16, I think you made the comparison of 30 patients versus five patients. So, on the control arm those five patients were actually from a pool of patients who had initial CR. So, I would've thought that a more apples-to-apples comparison would be getting a pool of initial CR patients also from the Iomab-B arm.

Sergio Giralt - *Memorial Sloan-Kettering - Chief Attending Physician*

So, the patients on the Iomab-B arm clearly are potentially evaluable for the primary endpoint, and that's also true for those that are on the control arm. But the fact is for the control arm. The key piece of information is that patients who don't get a remission, and that's the case with 31 of the 38 patients on the control arm, those patients are obviously considered failures for the primary endpoint.

So, you already know that. What we have done here is take available information and put it together. But the fact is this information doesn't relate directly to the primary endpoint, but certainly can provide some indication. But since the primary endpoint is a durable complete remission of six months, that information is not being presented here.

Andy Shay - *William Blair - Analyst*

Right, exactly. No, that's right. So -- but you can't have durable CR without having an initial CR, is that correct?

Sergio Giralt - *Memorial Sloan-Kettering - Chief Attending Physician*

That's correct.

Mark Berger - *Actinium Pharmaceuticals, Inc. - Chief Medical Officer*

That is absolutely correct.

Andy Shay - *William Blair - Analyst*

Right, okay. So, the other question I have is there were patients on the Iomab-B who after randomization, due to various reasons, did not get a transplant. Based on calculation that's about 15%. So, just from a modeling perspective, do you estimate roughly in the real world setting that would probably be the same? Roughly 15% of the patients due to various reasons will not eventually get a transplant on the Iomab-B arm?

Sergio Giralt - *Memorial Sloan-Kettering - Chief Attending Physician*

Well, the fact is that these are very sick patients, they are to some extent medically unstable. They can get infections and deteriorate very quickly and that certainly happens to patients. That percentage will obviously vary depending on exactly which patients are put into the trial.

But certainly that's also essentially part of the reason that the salvage chemotherapy arm does poorly as well because, again, these are patients who can deteriorate very quickly and they are just not very stable. And particularly if you don't control the leukemia they up with all kinds of medical problems.

Andy Shay - *William Blair - Analyst*

Right, okay. So my next question has to do with your view on me interim analyses. I think the next one -- so, it seems like you passed the first one, which is 70 patients. And DSMB recommended the trial to continue. I believe the Company has complete control over whether to take that second interim or not. So, maybe, based on the 50% data, share with us your view on potentially taking that second interim.

Sergio Giralt - *Memorial Sloan-Kettering - Chief Attending Physician*

So, as you mentioned, there are two ad hoc analyses built into the trial. We noted that the first 75 -- the first 50% of patients, which essentially provides the number for the first group -- we noted when they were enrolled. But the fact is the ad hoc requires they have six-month follow-up for the primary endpoint. That won't be available until first/second quarter next year.

So, basically at the time that these interim analyses are potentially possible we will evaluate a number of factors. And we will follow it very carefully and determine what's best for the trial and for the patients.

Andy Shay - *William Blair - Analyst*

Okay. So, two more just really quick housekeeping questions. One is on manufacturing. Maybe as we kind of think about potential commercialization in the future, any redundancies in place given that this is a personalized medicine, has to be manufactured on a per patient basis?

And the second question has to do with the EU regulatory pathway. Am I correct in saying that this SIERRA trial is a US only trial? So, no EU sites are being incorporated in the study?

Sandesh Seth - *Actinium Pharmaceuticals, Inc. - CEO & Chairman*

In terms of manufacturing redundancies we don't really comment on them. But look, we get plenty of notice. These doses that we make are usually able to -- each batch is able to serve a number of patients. We usually get a lead time of about a week or so at least.

Doctors tend to know a little bit in advance, sometimes a couple weeks in advance, as to when they want a patient to come in. So, there's -- that's the sort of failsafe mechanisms that have allowed us to consistently supply drug to patients and never miss a dose.

Mark Berger - *Actinium Pharmaceuticals, Inc. - Chief Medical Officer*

In terms of the EU, we (inaudible) with the European medicines agency who indicated they will accept the SIERRA trial for approval, obviously with piloted results. And we also have orphan drug in Europe as well. So, that's a requirement for European patients to be able to get European approval.

Andy Shay - *William Blair - Analyst*

Okay, got it, cool. Thanks for answering all my questions.

Operator

Matthew Cross, JonesTrading Institutional.

Matthew Cross - *JonesTrading Institutional - Analyst*

Congrats on the very positive data update and thanks for hosting the call today. A couple questions from me. Following up a little bit on something I think Andy was trying to uncover. In these results that you referred to, patients received a therapeutic dose of Iomab, and it looks like six patients didn't receive a therapeutic dose. So, could you explain why was that the case and provide a bit of clarity on the circumstances there?

I know you all have previously explained that dosing of Iomab is a very patient specific process with dose determination done prior to the actual therapeutic regimen. So, just wanted to get a better handle on why all 37 patients weren't treated at therapeutic levels. Thanks.

Mark Berger - *Actinium Pharmaceuticals, Inc. - Chief Medical Officer*

I can't get into the details of specific patients, but these patients are, as I said, sick people. They're medically unstable, they can easily get infections, they can easily have really a number of different medical problems.

I think the one thing I can say is there's no evidence that they have problems related to Iomab-B in any way. But there are instances where patients will deteriorate and that's just a part of really any trial in acute myeloid leukemia.

Matthew Cross - *JonesTrading Institutional - Analyst*

Okay, so just to clarify, these weren't patients who ultimately received a therapeutic dose of Iomab-B -- or that received a dose of Iomab-B for therapeutic treatment that was say sub therapeutic? They just weren't eligible to actually move forward with that process?

Mark Berger - *Actinium Pharmaceuticals, Inc. - Chief Medical Officer*

That's correct.

Matthew Cross - *JonesTrading Institutional - Analyst*

Got it. And then the second one is kind of a two-part question. Can you remind me how the patients who cross over to receive Iomab-B will be handled statistically and the discussions with regulators going forward? These are all kind of just [failures] obviously, but will you be assessing response rate and [NOS] for these patients?

And as a follow-up, assuming these crossover patients also outperform patients in the control arm that don't cross over, how significant do you think that data will be to the FDA relative to results in patients who receive Iomab from the get-go? Is one population or the other more indicative of how Iomab may ultimately be used by physicians?

Mark Berger - *Actinium Pharmaceuticals, Inc. - Chief Medical Officer*

Well, the primary endpoint of the study is durable complete remission based on an intent to treat analysis. So as you know, the crossover patients who are considered failures for the primary endpoint, we do follow them. We will provide information on them, but the fact is they don't contribute to the primary endpoint.

Sandesh Seth - *Actinium Pharmaceuticals, Inc. - CEO & Chairman*

So, to answer your question more directly, look, we don't comment on our regulatory plans, but certainly as the data mature, I think it's incumbent upon us to keep the regulators apprised of the progress of the trial and we will do what is appropriate.

Matthew Cross - *JonesTrading Institutional - Analyst*

Fair enough. And maybe to pose it to Dr. Giralt as well. I guess looking at this data and seeing the patients who have been exposed to a variety of different salvage or targeted therapies and then crossed over to receive Iomab performing similarly to those that get it outright from the beginning from randomization.

Which of these two groups is more relevant to a real-world setting in your view? Is this something where you would expect patients to go directly to Iomab-B? Or would they face salvage chemo and targeted therapies prior to moving on and (multiple speakers)?

Sergio Giralt - *Memorial Sloan-Kettering - Chief Attending Physician*

I think that's a great question. I think for the purposes of the trial the ones that have the primary endpoint are. But crossover patients are going to be very instructive for what we will call patterns of practice. So, you can imagine that Iomab-B will be available in specialized centers so that patients who are on centers in the periphery who now have failed their primary therapy, you can tell referring physicians very confident, look, based on the experience of the trial we were able to bridge them.

And in some circumstances you will probably get calls from referring physician saying I'm getting ready to put this patient on this combination of chemo. We like the idea of giving them Iomab-B. Could you be ready for them? And then you can say, yes, we would actually say this is what we recommend as a bridge, we'll be working to have a donor available. And don't worry, if he doesn't respond to bridge we were able to successfully bring people to transplant X% of the time, whatever that number will be.

And I think that part -- that point of information will be important to prevent patients from getting extensively pretreated before they get referred for the drug.

Matthew Cross - *JonesTrading Institutional - Analyst*

Perfect, okay. I appreciate that color, Dr. Giralt. And thanks for answering all my questions. Congrats again, guys.

Operator

Marcus Malkmus, Hestia Investments.

Marcus Malkmus - *Hestia Investments - Analyst*

Congratulations on a pretty fantastic read out so far. The first question that came up from another caller was that the therapy is not personalized, right? The production of Iomab-B is a standard (inaudible) chemical production without any patient specific customization, so there shouldn't be any issue about customizing that to individual patients, just to clarify?

Mark Berger - *Actinium Pharmaceuticals, Inc. - Chief Medical Officer*

No, the does is customized to each individual patient and we do that routinely on a weekly basis. So, for us it's a routine procedure. But that is correct that it is a customized dose.

Marcus Malkmus - *Hestia Investments - Analyst*

Yes, but it's not like a CAR-T where you have to take patient material and do a (inaudible) autologous (multiple speakers).

Mark Berger - *Actinium Pharmaceuticals, Inc. - Chief Medical Officer*

No, certainly not at all.

Marcus Malkmus - *Hestia Investments - Analyst*

(Multiple speakers) that's important.

Mark Berger - *Actinium Pharmaceuticals, Inc. - Chief Medical Officer*

No, it's a totally routine procedure, doesn't require any material from the patient and, as I say, we do it weekly.

Marcus Malkmus - *Hestia Investments - Analyst*

Just to clarify that. My second question is really when you look at your primary endpoint you've got five patients so far that would even have a chance of achieving the primary endpoint in the control group out of all 38.

And on the 30 patients in the Iomab part there should be -- it doesn't matter whether they had a CR before not because past transplant, they will have had all engraftment so they all stand a full chance irrespective whether they go into Iomab versus CR or not to achieve the primary endpoint just to clarify. Do I see that right?

Mark Berger - *Actinium Pharmaceuticals, Inc. - Chief Medical Officer*

Yes, that's correct. As we pointed out these are the groups of patients in each arm that at this point are eligible for evaluation for the primary endpoint.

Marcus Malkmus - *Hestia Investments - Analyst*

And I think that was in some of the questions quite unclear. But my understanding is when I transplant a patient when there is full engraftment, whether they are with a CR or before the transplant, doesn't change the outcome. The transplant is what resets the patient and from there on he has all the chance of any other transplant patients to achieve the primary endpoint.

Mark Berger - *Actinium Pharmaceuticals, Inc. - Chief Medical Officer*

That's exactly right.

Sergio Giralt - *Memorial Sloan-Kettering - Chief Attending Physician*

Correct.

Marcus Malkmus - *Hestia Investments - Analyst*

Okay great, yes, that was super helpful. Okay, and do you have any idea to share this data with the FDA prior to the completion of the trial or is this going to be only shared at the end?

Mark Berger - *Actinium Pharmaceuticals, Inc. - Chief Medical Officer*

We will evaluate the situation as we go along, just as I mentioned about the potential for ad hoc interims. And we will stay on top of that and make decisions based on the data that we have and what's best for the trial.

Marcus Malkmus - *Hestia Investments - Analyst*

Okay. So, could you potentially see if you hit the -- given the number 30 against five, if you hit the primary endpoint with significance already with half the patients, would there be a chance for even stopping the trial because you've already achieved the endpoint with significance?

Mark Berger - *Actinium Pharmaceuticals, Inc. - Chief Medical Officer*

Potentially. So -- and clearly we have a DSMB to assist us in making decisions as well. So again, I think it depends on the situation and we'll have to evaluate depending on what that is.

Marcus Malkmus - *Hestia Investments - Analyst*

Okay, that's great. That's very helpful. Thank you very much.

Operator

That is all the time we have today for questions today. This concludes today's call. As a reminder, a replay will be available for play back in a short while.