

December 5, 2017



## **Actinium Pharmaceuticals Unveils Actimab-MDS and Planned Phase 2 Trial in Myelodysplastic Syndromes Targeted at Patients with High-Risk p53+ Genetic Mutations**

- Phase 2 clinical trial planned for 2018, Actimab-MDS intended to be a bridge to a bone marrow transplant, the only curative treatment option for patients with myelodysplastic syndrome
- Trial principal investigator, Dr. Gail Roboz, Director of the Leukemia Program and Professor of Medicine at Weill Cornell New-York Presbyterian Hospital, to lead consortium of leading MDS focused medical centers that will conduct the trial
- Webcast to be held at 8 AM ET on December 5, 2017 to introduce Actimab-MDS and discuss the planned Phase 2 trial

NEW YORK, Dec. 05, 2017 (GLOBE NEWSWIRE) -- **Actinium Pharmaceuticals, Inc.** (NYSE American:ATNM) ("**Actinium**" or "**the Company**"), a clinical-stage biopharmaceutical company focused on developing and commercializing targeted therapies for safer myeloablation and conditioning of the bone marrow prior to a bone marrow transplant, and for the targeting and killing of cancer cells, announced Actimab-MDS, a new clinical initiative focused on myelodysplastic syndrome or MDS. Actimab-MDS is the latest clinical initiative from the Company's CD33-Alpha Program, which combines the CD33 targeting ability of the antibody lintuzumab with the cell killing power of the alpha-particle emitting radioisotope Actinium-225. Actimab-MDS builds on the Company's clinical development experience in over 100 patients and several clinical trials with Actimab-A for patients with acute myeloid leukemia (AML) and Actimab-M for patients with multiple myeloma (MM).

Actinium, together with Dr. Roboz, will conduct a webcast at 8 AM ET on December 5, 2017 to introduce Actimab-MDS and the planned Phase 2 trial. Participants can register and view the webcast through the following link:

<https://onecast.thinkpragmatic.com/ses/b9Fgmq01hWm-5D2yNB3B3w~~>

or via Actinium's Investor Relations Calendar <https://ir.actiniumpharma.com/ir-calendar>.

Participants may also participate by phone. The dial-in information is below:

Dial-in: U.S. (646) 402-9440

Dial-in: U.S./Canada (855) 698-6739

MDS occurs when the bone marrow produces stem cells that fail to mature to red blood cells, white blood cells or platelets. The only potentially curative treatment option for patients with MDS is a bone marrow transplant (BMT) also known as a hematopoietic stem cell transplant. Approximately 19% of MDS patients have a p53 genetic mutation. Data show that p53 mutation positive patients have shorter survival and poorer outcomes following a BMT as evidenced by shorter time to relapse and shorter Overall Survival (OS). The planned Phase 2 trial is intended to study Actimab-MDS as a conditioning regimen for patients with MDS and p53 mutations who will undergo a bone marrow transplant. Dr. Gail Roboz, Director of the Leukemia Program and Professor of Medicine at Weill Cornell New-York Presbyterian Hospital, will serve as principal investigator for the trial and lead a consortium of leading medical centers in the treatment of MDS that are expected to participate in the trial. The MDS Clinical Research Consortium members are the Cleveland Clinic, Dana-Farber Cancer Institute, Johns Hopkins, MD Andersen Cancer Center, Moffitt Cancer Center and Weill Cornell.

Dr. Mark Berger, Actinium's Chief Medical Officer said, "Actinium is delighted to be working with Dr. Roboz and the other members of the consortium. As our clinical experience using our CD33 antibody labelled with Actinium-225 has expanded, it has become evident that it has minimal extramedullary toxicities. We believe that this property would be beneficial in numerous indications as the broad expression of CD33 in various hematologic indications affords many opportunities for continued expansion of our CD33 program. Given the poor prognosis of MDS patients, particularly those with p53 mutations, we are committed to executing this trial for Actimab-MDS effectively in collaboration with Dr. Roboz and the consortium while forging an efficient regulatory pathway forward that will enable us to make this therapy available to patients as soon as possible."

Patients in the planned Phase 2 trial will receive 4.0  $\mu\text{Ci/Kg}$  administered via a single infusion 12 days prior to receiving their bone marrow transplant. Actinium has studied its CD33 antibody and Actinium-225 at this dose level in a previously completed Phase 1 clinical trial in acute myeloid leukemia. At this dose level the construct showed good tolerability with no extramedullary toxicities or side effects outside of the bone marrow. The myelosuppression effect of the construct at this dose level was strong and impacted all the treated subjects.

MDS or myelodysplastic syndrome is an Orphan Drug indication with an estimated prevalence of 60,000 patients in the US and 40,000 patients in the EU. Approximately nineteen percent of these patients test positive for a mutation of the p53 gene and these patients are considered high-risk in terms of their survival. Although bone marrow transplants can be curative or significantly extend survival for many MDS patients, those who are p53+ do not benefit as greatly and presence of the mutation is associated with significantly lower survival. It has been shown that approximately seventy-five percent of the MDS population expresses CD33 at expression levels greater than the twenty-five percent targeted in the Actimab-MDS trial. The addressable market for Actimab-MDS is expected to be in the neighborhood of fourteen thousand patients in the U.S. and EU combined with over eight thousand five hundred in the U.S.

Sandesh Seth, Actinium's Chairman and CEO said, "Actimab-MDS aligns perfectly with Actinium's strengths as we have significant expertise and know in the area of bone marrow transplant as a result of our experience with our pivotal Phase 3 program, lomab-B. Looking forward, we believe there exists for Actinium a compelling revenue opportunity in the 2020-2021 timeframe by launching not one but possibly two therapies that can provide safer myeloablation with the potential for increasing curative outcomes from bone marrow transplant. Due to the involvement of Dr. Roboz and the MDS Clinical Research Consortium, we expect that the Actimab-MDS trial will benefit from their significant expertise; high patient volumes treated and defrayed costs. Due to these factors and with sufficient drug supply on hand, we expect trial costs in the low single-digit millions over the life of the trial most of which would be incurred in 2019, and after the anticipated milestones from our other trials. Bone marrow transplant remains a highly concentrated market with the top fifty centers performing a majority of the transplants and via our clinical development programs, we have already established a supply chain and presence in over twenty such centers that account for over 33% of the market. Having two novel therapies, serving two patient populations with high, unmet needs, would allow us to achieve scale and efficiency that we believe will unlock significant value. Actimab-MDS indeed has the potential to transform the outlook for the Company in a very positive manner and we look forward to discussing this program."

### **About Actimab-MDS**

Actimab-MDS is Actinium's third CD33 program with expected initiation of a Phase 2 clinical trial in 2018 for patients with Myelodysplastic Syndromes that have a p53 genetic mutation.

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### **About Actinium Pharmaceuticals, Inc.**

Actinium Pharmaceuticals is a clinical-stage biopharmaceutical company focused on developing and commercializing targeted therapies for safer myeloablation and conditioning of the bone marrow prior to a bone marrow transplant and for the targeting and killing of cancer cells. We are currently conducting clinical trials for our four programs, lomab-B, Actimab-A Actimab-M and Actimab-MDS, as well as performing research on other potential drug candidates utilizing our proprietary actinium-225 technology platform. Our most advanced product candidate, lomab-B, is comprised of an anti-CD45 monoclonal antibody labeled with iodine-131. We are currently conducting a pivotal Phase 3 trial of lomab-B for myeloablation and conditioning of the bone marrow prior to a bone marrow transplant for patients with relapsed or refractory acute myeloid leukemia (AML) age 55 and older. A bone marrow transplant is a potentially curative treatment for patients with AML and other blood cancers including leukemias, lymphomas and multiple myeloma as well as certain blood disorders. Upon successful completion of our Phase 3 clinical trial for lomab-B we intend to submit this candidate for marketing approval in the U.S. and European Union. We are also developing our CD33 program that is based on our anti-CD33 monoclonal antibody labelled

with the alpha-particle actinium-225 (Ac-225). Our most advanced CD33 program, Actimab-A, is currently in a Phase 2 clinical trial for patients over the age of 60 who are newly diagnosed with AML and ineligible for standard induction chemotherapy. Actimab-M, our second CD33 program, is being studied in a Phase 1 trial for patients with refractory multiple myeloma. Actinium is planning a Phase 2 trial for Actimab-MDS, our third CD33 program, as a conditioning regimen prior to a bone marrow transplant for patients with MDS that have a p53 genetic mutation. Our Actinium Warhead Enabling (AWE) Technology Platform is focused on leveraging Actinium's know how and intellectual property to create additional drug candidates by labeling Actinium-225 to targeting moieties that we will either progress in clinical trials ourselves or out-license.

More information is available at [www.actiniumpharma.com](http://www.actiniumpharma.com) and our Twitter feed @ActiniumPharma, [www.twitter.com/actiniumpharma](https://www.twitter.com/actiniumpharma).

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Source: Actinium Pharmaceuticals