

January 25, 2018



# Actinium Pharmaceuticals Issues Letter to Investors Providing Company Update and Outlook for 2018

- Strong finish to 2017 sets stage for series of value enhancing milestones in 2018

NEW YORK, Jan. 25, 2018 (GLOBE NEWSWIRE) -- **Actinium Pharmaceuticals, Inc.** (NYSE American:ATNM) ("**Actinium**" or "**the Company**") announced today that it has issued a letter to investors providing a company update and outlook for 2018. The letter to investors is available on the Company's investor relations page of its website <https://ir.actiniumpharma.com/shareholder-letters>. In addition, an 8-K has been filed with the SEC.

Sandesh Seth, Actinium's Chairman and CEO said, "In December 2017, we announced several exciting developments that exemplify Actinium's functionality, enhanced capabilities, and most importantly, a focus on execution. We finished 2017 with strong momentum in our lomab-B and Actimab-A clinical programs, added to our CD33 program and growing bone marrow transplant franchise with the announcement of Actimab-MDS and reinvigorated our research and development efforts with the launch of our AWE Program. This momentum gives our team phenomenal energy for 2018 and we look forward to continued strong execution on the numerous clinical milestones that we expect can unlock significant value for investors."

## Year End 2017 Highlights:

- Announced Actimab-MDS, a new clinical initiative focused on improving transplant outcomes as measured by 1-year overall survival for patients with high-risk myelodysplastic syndrome with a p53 genetic mutation. We intend to begin a Phase 2 trial with Actimab-MDS that will be led by principal investigator Dr. Gail Roboz of Weill-Cornell and the MDS Clinical Research Consortium that is comprised of the Cleveland Clinic, Dana-Farber Cancer Institute, Johns Hopkins, MD Andersen Cancer Center, Moffitt Cancer Center.
- Presented Phase 2 data at ASH from our Actimab-A clinical trial showing a 69% overall response rate in patients with AML who are older and unfit for induction chemotherapy. Actimab-A produced these results as a single agent that is administered via two infusions on day 1 and day 8.
- Launched the AWE Program that is focused on creating ARCs or antibody radio-conjugates or biobetters utilizing actinium-225 in partnership or collaboration with biopharmaceutical companies.

- Presented preliminary preclinical data from our AWE Program at ASH where we showed an up to ten-fold increase in the cell killing ability of daratumumab, a blockbuster CD38 antibody therapy for patients with multiple myeloma that is marketed by Johnson & Johnson.
- An abstract was published in the ASH volume of blood<sup>®</sup> confirming the expression of CD33 in patients with multiple myeloma from a large U.S. patient database, providing further validation for our Actimab-M clinical trial in refractory multiple myeloma patients, which is the first CD33 targeted therapy for this patient population.
- Announced that the independent data monitoring committee reviewed initial data from the first 20 patients in the pivotal Phase 3 SIERRA trial for lomab-B and recommended that the trial continue as planned.

## **2018 Outlook:**

### ***Unlocking Significant Value in Myeloablation for Bone Marrow Transplant***

With the announcement of Actimab-MDS, Actinium is now the only company with a multi-disease, multi-product pipeline focused on improving bone marrow transplant access and outcomes via improved myeloablation. Bone marrow transplant is a potentially curative treatment option for patients with blood cancers and diseases such as leukemias, lymphomas and myelodysplastic syndromes. A majority of bone marrow transplants are performed in fifty leading hospitals in the U.S., which is where Actinium will initially focus and build on its existing presence in leading centers that account for over 35 percent of transplant volume. Actinium is committed to building a franchise serving the bone marrow transplant market and expects to achieve the following milestones in 2018 and beyond for lomab-B as it strives to be the leader in the field:

#### **lomab-B:**

- Complete enrollment of the pivotal Phase 3 SIERRA trial for lomab-B by the end of 2018
- Have successful DMC safety analyses when 25%, 50% and 75% of patients have been enrolled and potential interim analyses when 70 and 110 patients have reached the primary endpoint
- Report topline data results in the second half of 2019
- Prepare for a BLA filing to obtain FDA approval
- Scale up for commercial operations

#### **Actimab-MDS:**

- Have a meeting with the FDA in the first half of 2018 to set a regulatory pathway
- Initiate Phase 2 clinical trial in the second half of 2018

### ***Building an Industry Leading CD33 Program with Multiple Shots on Goal***

The Company is developing a potentially leading CD33 targeting program in the industry with clinical programs in three indications. Actinium is the only commercial sponsor to have a clinical trial in multiple myeloma that is focused on targeting CD33. In addition, Actinium is

the only commercial sponsor to utilize an alpha particle payload in these radiation sensitive cancers. Actinium believes the following programs are best-in-class and/or first-in-class:

- Actimab-A for unfit elderly AML patients in Phase 2
- Actimab-M for refractory multiple myeloma in a proof of concept Phase 1 trial
- Actimab-MDS for BMT conditioning in high-risk MDS patients with a planned Phase 2

Actinium expects numerous milestones from these programs in 2018 including:

Actimab-A:

- Complete enrollment of the Phase 2 trial in the first half of 2018
- Report top line data in the second half of 2018

Actimab-M:

- Complete enrollment of the Phase 1 trial in second half of 2018
- Report top line data by the end of 2018

Actimab-MDS:

- Have a meeting with the FDA in the first half of 2018 to set a regulatory pathway
- Initiate Phase 2 clinical trial in the second half of 2018

### ***Leading Innovation Via the AWE Technology Platform***

Actinium announced its Actinium Warhead Enabling or AWE Technology Platform to capitalize on the utilization of actinium-225 to enhance the cell killing power of targeting agents such as antibodies, peptides, Fab fragments and other modalities. Using the AWE program, Actinium intends to create ARCs or antibody radio-conjugates and biobetters in collaboration or partnership with biopharmaceutical companies. In January, Actinium announced that Dr. Dale Ludwig was appointed Chief Scientific Officer and would be tasked with managing the AWE Technology Platform. In 2018, Actinium expects to achieve the following with its AWE Program:

- Present additional data from its work with labeling daratumumab with actinium-225
- Label additional targeting agents with actinium-225
- Secure a collaboration based on the AWE Technology Platform

The Company reiterates its intent to build upon the promise of both the CD45 and CD33 programs over the next three to five years by gaining approval and commercializing multiple product candidates based on these programs to enhance access to bone marrow transplant with improved outcomes via its improved myeloablation approach and to partner strategically to enhance the value of its programs and technology platforms.

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

Actinium Pharmaceuticals Inc. is a clinical-stage biopharmaceutical company focused on developing and commercializing targeted therapies for potentially superior myeloablation and conditioning of the bone marrow prior to a bone marrow transplant and for the targeting and killing of cancer cells. Our targeted therapies have demonstrated the potential to result in

significantly improved access to bone marrow transplant with better outcomes, namely increased marrow engraftment and survival. Our targeted therapies are ARC's or Antibody Radio-Conjugates that combine the targeting ability of monoclonal antibodies with the cell killing ability of radioisotopes. Three of our four ARC drug candidates are based on our AWE or Actinium Warhead Enabling Technology Platform that utilizes the isotope Actinium-225 (Ac-225) which emits alpha particles. We are currently conducting clinical trials for our four product candidates; lomab-B, Actimab-A Actimab-M and Actimab-MDS, as well as performing research on other potential drug candidates utilizing our proprietary AWE Technology Platform. Our most advanced product candidate, lomab-B, an ARC developed by the Fred Hutchinson Cancer Research Center, 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. lomab-B has been tested in several of these other cancers with over five hundred patients treated in several Phase 1 and 2 trials with promising results. 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 where it has been designated as an Orphan Drug. We are also developing a potentially best in class CD33 program using an ARC comprised of the anti-CD33 monoclonal antibody lintuzumab labeled with the alpha-particle emitter Ac-225. Our most CD33 program candidate, Actimab-A, is currently in a Phase 2 clinical trial for patients advanced over the age of 60 who are newly diagnosed with AML and ineligible for standard induction chemotherapy. Actimab-A also has Orphan Drug designation in the US and EU. Actimab-M, our second CD33 targeting ARC, is being studied in a Phase 1 trial for patients with refractory multiple myeloma. Actinium is also planning a Phase 2 trial for Actimab-MDS, our third CD33 program candidate, as a conditioning regimen prior to a bone marrow transplant for patients with MDS that have a p53 genetic mutation. Our AWE or Actinium Warhead Enabling Technology Platform, originally developed in conjunction with Memorial Sloan Kettering Cancer Center, is focused on leveraging Actinium's know how and intellectual property to create additional ARC drug candidates by labeling Ac-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](https://twitter.com/ActiniumPharma), [www.twitter.com/actiniumpharma](http://www.twitter.com/actiniumpharma).

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