

November 29, 2017



# Actinium Pharmaceuticals Highlights Strong Presence at 59th Annual American Society of Hematology Meeting Evidenced by Clinical Development Progress and Results Showcasing its AWE Technology Platform

- Poster presentation to detail results from ongoing Phase 2 trial for Actimab-A, Actinium's CD33 targeting ARC or Antibody Radio-Conjugate, designed to explore Actimab-A's efficacy in patients newly diagnosed with acute myeloid leukemia that are ineligible for intensive chemotherapy
- In addition, data in multiple myeloma supporting the scientific rationale for the Actimab-M trial and results from the AWE Technology Platform comparing Actinium-225 labeled daratumumab to unlabeled daratumumab, a blockbuster commercial CD38 targeting therapy, will also be presented

NEW YORK, Nov. 29, 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, highlighted its planned activity at the upcoming 59<sup>th</sup> Annual American Society of Hematology (ASH) Meeting & Exposition being held December 9 – 12, 2017 in Atlanta, Georgia. Actinium's Actimab-A Phase 2 trial will be highlighted in a poster presentation that will discuss results to date from the multi-center, open label Phase 2 trial that has been designed to assess overall response rates of patients receiving fractionated doses of Actimab-A. Patients enrolled in this trial are newly diagnosed with acute myeloid leukemia (AML) that are over the age of 60. Preliminary results from the Company's recently announced Actinium Warhead Enabling (AWE) Technology Program will be presented by poster. The results contrast the superior cell-killing power of Actinium-225 labeled daratumumab versus the unlabeled antibody, which is a blockbuster therapy targeting CD38 for patients with multiple myeloma marketed by Johnson & Johnson. In addition, experimental results supporting targeting of the CD33 antigen in multiple myeloma patients that provides the scientific rationale for the Actimab-M trial will also be presented in an abstract.

Details of Actinium's abstract poster presentations are as follows:

**Title:** A Phase 2 Study of Actinium-225 ( $^{225}\text{Ac}$ )-Lintuzumab in Older Patients with Previously

Untreated Acute Myeloid Leukemia (AML) Unfit for Intensive Chemotherapy

**Session:** 616. Acute Myeloid Leukemia: Novel Therapy, excluding Transplantation: Poster II

**Date:** Sunday, December 10, 2017

**Time:** 6:00PM-8:00PM

**Location:** Bldg A, Lvl 1, Hall A2 (Georgia World Congress Center)

**Title:** Actinium Labeled Daratumumab Demonstrates Enhanced Killing of Multiple Myeloma Cells over Naked Daratumumab

**Session:** 652. Myeloma: Pathophysiology and Pre-Clinical Studies, excluding Therapy: Poster III

**Date:** Monday, December 11, 2017

**Time:** 6:00PM-8:00PM

**Location:** Bldg A, Lvl 1, Hall A2 (Georgia World Congress Center)

An online abstract has been accepted highlighting experimental results supporting the rationale for targeting CD33 in patients with multiple myeloma, which will be accessible on December 8, 2017. Details for the online abstract are as follows:

**Title:** CD33 Is Expressed in a Significant Subset of Multiple Myeloma Patients in the US and May Represent a Viable Therapeutic Target

**Session:** 651. Myeloma: Biology and Pathophysiology, excluding therapy

“This year’s American Society of Hematology Meeting & Exposition represents an inflection point for Actinium’s clinical development and research progress,” said Dr. Mark Berger, Actinium’s Chief Medical Officer. “As shown in our abstract, Actimab-A generated strong response rates exceeding 50% in a tremendously difficult to treat AML patient population as a single agent and I look forward to the detailed results being presented at ASH via our poster presentation. In addition to its strong efficacy, we have gained further insights into Actimab-A’s safety profile, namely its minimal extramedullary toxicities. I believe that this strength of Actimab-A will allow us to utilize Actimab-A in additional indications where patients have high unmet needs that can be addressed with strong single agent efficacy, a unique mechanism of action and robust myelosuppressive capabilities with minimal effects outside of the hematopoietic system.”

#### **Key Highlights of Actinium’s Activities Include:**

- Poster presentation highlighting data from Actinium’s Phase 2 trial of Actimab-A, a CD33 targeting agent, in patients newly diagnosed with AML unfit for intensive chemotherapy
- Poster presentation highlighting new data from Actinium’s recently announced AWE Technology Platform
- Abstract supporting the targeting of CD33 in multiple myeloma and the scientific rationale for Actimab-M
- The Clinical Advisory Board will review the progress of the multi-center, Phase 2 trial of Actimab-A, Actinium’s CD33 targeting antibody radio-conjugate for AML
- The Scientific Advisory Board will review the progress of the Phase 3 lomab-B SIERRA trial for patients 55 and older with relapsed and refractory AML
- Meeting with investigators from the 15 participating SIERRA clinical trial sites

Sandesh Seth, Actinium’s Chairman and CEO said, “This year’s ASH annual meeting will be

the most active in the Company's history and will showcase Actinium's strengthened capabilities in clinical development and research and development. I am proud of our team's ability to leverage our AWE technology platform and drive our drug development strategically. As a result, we have demonstrated the potential of utilizing Actinium-225 with established commercial products as a means of developing biobetters, which we will be offering to potential biopharmaceutical partners. We have also identified via our clinical results additional strengths of our CD33 program. We believe that these findings offer additional clinical opportunities where we can leverage our strengths, experience and know-how in the field of bone marrow transplant and targeted alpha particle therapy. We look forward to the ASH annual meeting where our clinical and experimental work on Actimab-A, Actimab-M and the AWE platform will be showcased via the posters and publications, and also in our meetings with the scientific and business community. In addition, we look forward to revealing new clinical opportunities at our December 5<sup>th</sup> Webinar."

### **About Actimab-A**

Actimab-A, Actinium's most advanced alpha-particle therapy product candidate, is currently in a 53-patient, multicenter Phase 2 trial for patients newly diagnosed with AML age 60 and above that are ineligible for standard induction chemotherapy. Actimab-A is being developed as a first-line therapy and is a monotherapy that is administered via two 15-minute injections that are given 7 days apart. Actimab-A targets CD33, a protein abundantly expressed on the surface of AML cells via the monoclonal antibody, HuM195, which carries the potent cytotoxic radioisotope actinium-225 to the AML cancer cells. Actinium-225 gives off high-energy alpha particles as it decays, which kill cancer cells and as actinium-225 decays it produces a series of daughter atoms, each of which gives off its own alpha particle, increasing the chances that the cancer cell will be destroyed. Actimab-A is a second-generation therapy from the Company's HuM195-Alpha program, which was developed at Memorial Sloan Kettering Cancer Center and has now been studied in almost 90 patients in four clinical trials. Actimab-A has been granted Orphan Drug Designation for newly diagnosed AML in patients 60 and above by the U.S. Food and Drug Administration.

### **About Actimab-M**

Actimab-M is being investigated in patients with refractory multiple myeloma. Multiple myeloma is a currently incurable cancer of plasma cells, which are white blood cells that produce antibodies. Actimab-M is currently being studied in a Phase 1 dose escalation study in up to 12 patients that is designed to establish safety, maximum tolerable dose and proof of concept. Actimab-M consists of actinium-225, an alpha-emitting radioisotope coupled to the anti-CD33 monoclonal antibody, HuM-195. CD33 has been shown to be expressed on myeloma plasmocytes in 25% to 35% of multiple myeloma patients and has also shown to be correlated with poorer outcomes.

### **About Our AWE Technology Platform**

The Actinium Warhead Enabling (AWE) Technology Platform enables a highly potent and selective form of targeted therapy that combines the powerful alpha-emitting radioisotope actinium-225 with targeting agents, which are designed to seek out cancer cells in the body that express particular markers. Actinium-225 emits significant alpha radiation making it a potent treatment modality against targeted cancer cells while limiting damage to healthy tissues as its radiation travels extremely short distances in the body. When labeled to

targeting agents, actinium-225 can be delivered directly to cancer cells where the high linear energy transfer resulting from the emission of alpha particles results in irreparable DNA double stranded breaks and ultimately cancer cell death. Despite this superior cell killing power, actinium-225 when delivered in a targeted manner is sparing of the surrounding environment in the body due to the short path length of its alpha-particle radiation and can result in a superior safety profile. Actinium Pharmaceuticals owns or has licensed the rights to several issued and pending patents that pertain to its AWE Technology Platform including technology to manufacture actinium-225 in a cyclotron. In addition, the Company obtains actinium-225 from various sources such as the U.S. Department of Energy at Oak Ridge National Laboratories and has developed considerable know-how, expertise and validated processes related to production of radioimmunoconjugates, management of the supply chain and dealing with various regulatory bodies. The AWE Technology Platform can be utilized to potentially improve the cell-killing power of targeting agents such as antibodies, peptides, Fab fragments, nanobodies etc. via labeling with actinium-225. In addition to increased efficacy, these actinium-225 enhanced targeting agents can offer optimized dosing or administration and in the case of approved targeting agents provide an opportunity to extend intellectual property protection by the creation of “Biobetters” or improved versions of the approved agent. The Company’s Actinium Warhead Enabling (AWE) Program can be accessed by biopharmaceutical companies that are interested in creating Biobetters through the utilization of the AWE Platform Technology. To learn more about the AWE Technology Platform or the AWE Program please contact Keisha Thomas, Ph.D., Corporate Development at [kthomas@actiniumpharma.com](mailto:kthomas@actiniumpharma.com).

### **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 three product candidates, lomab-B, Actimab-A and Actimab-M, 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 option 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. Our most advanced alpha particle based therapy, Actimab-A, is an anti-CD33 monoclonal antibody conjugated with the alpha-particle actinium-225 (Ac-225). 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 third product candidate, is the same anti-CD33 monoclonal antibody conjugated to Ac-225 administered at a different dose and dosing regimen. Actimab-M, is being studied in a Phase 1 trial for patients with refractory multiple myeloma. We expect our AWE Technology Platform will generate additional drug candidates that we will progress in clinical trials ourselves and or out-license.

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

@ActiniumPharma, [www.twitter.com/actiniumpharma](http://www.twitter.com/actiniumpharma).

**Contact:**

**Actinium Pharmaceuticals, Inc.**

Steve O'Loughlin

Principal Financial Officer

[soloughlin@actiniumpharma.com](mailto:soloughlin@actiniumpharma.com)

Investor Relations

Marek Ciszewski, J.D.

949.574.3860

[ATNM@liolios.com](mailto:ATNM@liolios.com)



Source: Actinium Pharmaceuticals