



# Actinium Pharmaceuticals Provides Update on Pivotal Phase 3 Trial of Iomab-B: Independent Data Monitoring Committee Recommends SIERRA Trial Continue

- Actinium expects enhanced awareness of Iomab-B at ASH annual meeting and expanded site activity to enable completion of trial enrollment by end of 2018, in-line with prior forecast

NEW YORK, Dec. 27, 2017 (GLOBE NEWSWIRE) -- **Actinium Pharmaceuticals, Inc.** (NYSE American:ATNM) ("Actinium" or "the Company") announced today that the Independent Data Monitoring Committee (DMC) for the Pivotal Phase 3 SIERRA Trial (Study of Iomab-B for Elderly Relapsed or Refractory AML) of Iomab-B (<sup>131</sup>I apamistamab) completed its review of the data available from the trial at time of analysis. The DMC recommended that the trial continue to enroll patients as planned. The SIERRA Trial is a 150 patient, controlled, multi-center pivotal study that is comparing Iomab-B followed by a bone marrow transplant (BMT) to physician's choice of salvage chemotherapy in patients with relapsed or refractory acute myeloid leukemia (AML) that are age 55 and above. The primary endpoint of the trial is durable Complete Remission (dCR) at 6 months.

Dr. Mark Berger, Actinium's Chief Medical Officer said, "The DMC's review and recommendations for Iomab-B are in line with our expectations at this stage of the trial and are important given the high unmet need of these patients with current therapies. A bone marrow transplant is the only potential cure for these patients and safer myeloablation could have a major impact on patient outcomes. We believe that Iomab-B will provide safer myeloablation for AML patients seeking a bone marrow transplant, which will expand patient access to transplant, improve rates of transplant engraftment, and improve survival outcomes. We are encouraged that the DMC reviewed initial safety data from the first 20 patients enrolled in the trial at its regularly scheduled late November meeting. We remain confident that we will be able to complete patient enrollment by the end of 2018 due to the significant progress we have made this year setting up the foundations for the trial and also due to certain other factors which are detailed below."

Enrollment activity for the SIERRA trial has continued to build as a function of site activation, familiarity of the site with the patient protocols for using Iomab-B and investigator experience with the drug candidate versus the control. Actinium announced that the fifteenth SIERRA clinical trial site had been activated at the end of October 2017. The SIERRA clinical trial

sites are some of the leading and highest volume BMT centers in the US including the MD Anderson Cancer Center, Memorial Sloan Kettering Cancer Center, the Mayo Clinical, the Fred Hutchinson Cancer Research Center and many others. Together, these active sites account for approximately one third of bone marrow transplant related volume. Actinium previously commented that once a site has treated its initial patient with Iomab-B, recruitment and enrollment accelerates at that site. In addition, to continuing to devote attention to activated sites in order to meet enrollment objectives, Actinium intends to continue to also focus on activating additional clinical trial sites and educating site staff in order to build on the strong foundation for patient enrollment. In 2018, Actinium expects to open the SIERRA trial at 5-7 additional clinical trial sites including sites in Canada where the company received clearance to initiate the trial from Health Canada in 2017.

In addition, Actinium announced that it will amend the protocol of the SIERRA trial to expand the salvage chemotherapy regimens available in the control arm of the study, following the feedback from investigators at trial sites and the advice of its Scientific Advisory Board that was convened during the recent ASH meeting. The Company expects that being responsive to investigator suggestions and amending the protocol removes a hindrance to enrollment at some of the major sites as it provides investigators with the ability to better enroll patients. In addition to the SAB meeting, Iomab-B was featured at a PeerView CME-Certified event on Friday, December 8, 2017 titled "A Master Class on Building Better Therapy for AML: Making the Most of an Increasing Number of Innovative Options" where it was highlighted by Dr. Amir Fathi of Mass General Hospital Cancer Center to several hundred physician attendees. The Company expects to follow-up on the interest generated from this event in order to support the objectives of the SIERRA trial and also to prepare Iomab-B for commercialization.

Actinium also reported that it has successfully supplied dosimetric and therapeutic doses as needed to all patients in the study arm and to all of the patients that have crossed over to the Iomab-B arm from the control arm thus far. Patients that cross over from the control arm are counted as failures for the primary endpoint of durable Complete Remission of at least 6 months. The Company has stated that in 2017 it manufactured additional antibody at commercial scale, and has sufficient quantities to account for the current trial and the planned potential label expansion initiatives in 2018.

Sandesh Seth, Actinium's Chairman and CEO said, "Iomab-B is a drug candidate that is not only first in class with no visible competition in clinical development but it also has the potential to establish a new treatment paradigm for bone marrow conditioning. The SIERRA trial is the first multi-center, company sponsored trial for Iomab-B and it is supported by data generated at the Fred Hutchinson Cancer Research Center in several hundred patients in multiple hematologic indications, including the patient population of the SIERRA trial. Actinium has achieved significant progress this year not only by opening the trial at some of the highest volume transplant centers but conducting educational efforts to raise the profile of this important therapeutic and potentially life saving therapeutic option. The progress made in enrollment and the validation of our assumptions regarding the trial safety and efficacy makes this initial DMC report incredibly exciting for us. We look forward to continuing to progress Iomab-B concurrent with our ever-growing focus, as exemplified by the latest initiative of Actimab-MDS, on developing treatments for superior myeloablation in multiple indications, which we believe to be a significant value creation opportunity. We are incredibly proud that our supply chain team has successfully delivered doses to all patients

in the SIERRA trial including crossover patients while simultaneously supplying drug to all patients in the Actimab-A trial and Actimab-M trials and that our clinical team has opened up nearly 30 trial sites across our clinical trials. We note also that the strengthened clinical development team has enrolled more patients since June of 2017 than had been enrolled in the past five years. This combination of the ability to successfully enroll patients and establish a reliable supply chain into a network of leading hospitals that represent over a third of bone marrow transplant procedure volume is proving to be an invaluable clinical asset that we hope to leverage into a value enhancing asset as we look ahead to our next phase of growth.”

The SIERRA trial is expected to complete patient enrollment by the end of 2018 which is in line with prior guidance from the Company. The trial will have safety analyses by an independent Data Monitoring Committee when 25%, 50% and 75% patient enrollment has been reached. Also, two ad-hoc efficacy analyses may be requested by Actinium after 70 and/or 110 patients have engrafted and given enough time to achieve the primary endpoint of durable complete remission at six months post treatment.

### **About Iomab-B**

Iomab-B (<sup>131</sup>I apamistamab) is Actinium’s lead product candidate that is currently being studied in a 150-patient, multicenter pivotal Phase 3 clinical trial in patients with relapsed or refractory acute myeloid leukemia who are age 55 and above. Upon approval, Iomab-B is intended to prepare and condition patients for a bone marrow transplant, also referred to as a hematopoietic stem cell transplant, which is often considered the only potential cure for patients with certain blood-borne cancers and blood disorders. Iomab-B targets cells that express CD45, a pan-leukocytic antigen widely expressed on white blood cells with the monoclonal antibody, BC8, labeled with the radioisotope, iodine-131. By carrying iodine-131 directly to the bone marrow in a targeted manner, Actinium believes Iomab-B will avoid the side effects of radiation on most healthy tissues while effectively killing the patient’s cancer and marrow cells. In a Phase 2 clinical study in 68 patients with advanced AML or high-risk myelodysplastic syndrome (MDS) age 50 and older, Iomab-B produced complete remissions in 100% of patients and patients experienced transplant engraftment at day 28. Iomab-B was developed at the Fred Hutchinson Cancer Research Center where it has been studied in almost 300 patients in a number of blood cancer indications, including acute myeloid leukemia (AML), chronic myeloid leukemia (CML), acute lymphoblastic leukemia (ALL), chronic lymphocytic leukemia (CLL), Hodgkin’s disease (HD), Non-Hodgkin lymphomas (NHL) and multiple myeloma (MM). Iomab-B has been granted Orphan Drug Designation for relapsed or refractory AML in patients 55 and above by the U.S. Food and Drug Administration and the European Medicines Agency.

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

Actinium Pharmaceuticals Inc. 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. 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; Iomab-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, Iomab-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 Iomab-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. Iomab-B has been tested in several of these other cancers with over four hundred patients treated in several Phase 1 and 2 trials with promising results. Upon successful completion of our Phase 3 clinical trial for Iomab-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 advanced CD33 program candidate, 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-A is 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, [www.twitter.com/actiniumpharma](http://www.twitter.com/actiniumpharma).

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