

# Actinium to Provide Update on Pivotal Phase 3 SIERRA Trial Following Positive Data Monitoring Committee Meeting

- Conference call to be held at 9:00 AM ET on Wednesday, August 15, 2018

NEW YORK, Aug. 14, 2018 /PRNewswire/ --Actinium Pharmaceuticals, Inc. (NYSE AMERICAN: ATNM) ("Actinium" or "the Company"), today announced that it will conduct a conference call on Wednesday, August 15, 2018 at 9:00 AM ET to provide an update on the Pivotal Phase 3 SIERRA Trial (Study of Iomab-B in Elderly Relapsed/Refractory AML) of Iomab-B. Actinium recently announced that the SIERRA trial had reached twenty-five percent patient enrollment and that the independent Data Monitoring Committee (DMC) would conduct a formal analysis, which has now occurred. Post this event, members of Actinium's management team are hosting this call to provide an update on the SIERRA trial.



### **Conference Call Details**

Date: Wednesday, August 15, 2018

Time: 9:00 AM ET

Registration Link: https://onecast.thinkpragmatic.com/ses/HKwlrC68IHB UiNbwrpb4w~~

Toll-Free Dial-in: (855) 427-0225

Dial-in: (718) 865-8336 Conference ID: 4831

"Based on the DMC's unanimous recommendation, we are pleased that the ongoing SIERRA trial will continue as planned," said Dr. Mark Berger, Chief Medical Officer of Actinium. "This is an important milestone for lomab-B since it is the first formal safety evaluation of the trial. We note that no lomab-B safety concerns were raised. With new insights from the data available from the trial thus far as well as feedback from the trial sites, we will make certain protocol revisions to further expand salvage regimens in the control arm. We'll also be making it easier for patients on the Conventional Care arm who have disease progression to access lomab-B treatment. In addition, we will be simplifying certain data collection requirements. These improvements coupled with our deeper understanding of referral patterns and other outreach efforts, are anticipated to enable the recently

strengthened SIERRA clinical team to complete the trial as quickly as possible with the goal of bringing lomab-B to a patient population with a significant unmet need."

Sandesh Seth, Actinium's Chairman and CEO added, "Iomab-B is a very compelling drug candidate that has been studied in over 500 patients in multiple hematologic malignancies including AML, myelodysplastic syndrome, lymphoma and multiple myeloma and is intended to facilitate a potentially curative bone marrow transplant. Iomab-B was developed by the Fred Hutchinson Cancer Research Center in collaboration with the National Cancer Institute and has been studied extensively by leading bone marrow transplant physicians. We are incredibly proud of the pedigree of Iomab-B and motivated by its potential to address unmet medical needs as a targeted conditioning agent in multiple hematologic diseases. We believe that Iomab-B via the SIERRA trial can be the linchpin for developing the leading franchise in targeted conditioning with an emphasis on improving bone marrow transplant access and outcomes."

### **About Iomab-B**

lomab-B, Actinium's lead targeted conditioning product candidate, 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. This pivotal Phase 3 study is called the SIERRA Trial (Study of Iomab-B in Elderly Relapsed/Refractory AML). Upon approval, lomab-B is intended to prepare and condition patients for a bone marrow transplant which is often considered the only potential cure for patients with certain bloodborne cancers and blood disorders. Iomab-B targets cells that express CD45, an antigen widely expressed in the hematopoietic system on all leukemic and lymphomic (white blood cells), bone marrow cells and cancer stem cells with the monoclonal antibody, BC8 or apamistamab, 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 that conventional treatments such as chemotherapy and radiation has on most healthy tissues while effectively killing the patient's cancer and marrow cells potentially enabling more bone marrow transplants with better outcomes through targeted conditioning. In a Phase 2 clinical study in 68 patients with advanced AML or high-risk myelodysplastic syndrome (MDS) age 50 and older, who typically would not be transplant candidates, were able to receive a transplant after being conditioned with lomab-B and the study resulted in significantly improved transplant success and survival. Iomab-B was developed at the Fred Hutchinson Cancer Research Center where it has been studied in almost 500 patients in a number of Phase 1 and Phase 2 clinical trials across a variety of blood cancer indications with promising results. The studies included patients with 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 potentially superior targeted conditioning of the bone marrow prior to a bone marrow transplant and for the targeting and killing of cancer cells. The Company's targeted Antibody Radio-Conjugates (ARCs),

combine the targeting ability of monoclonal antibodies with the cell killing ability of radioisotopes. Actinium is developing a pipeline of clinical-stage ARCs targeting CD45 and CD33 for patients with a broad range of hematologic malignancies.

lomab-B, Actinium's lead product candidate, is currently enrolling patients in a pivotal Phase 3 trial. Iomab-B combines the anti-CD45 monoclonal antibody BC8 labeled with iodine-131 and is designed to condition the bone marrow prior to a bone marrow transplant without the need for intense chemotherapy in patients with relapsed or refractory acute myeloid leukemia (AML) of age 55 or older. Actinium's pipeline also includes a potentially best-inclass CD33 program with our ARC comprised of the anti-CD33 antibody lintuzumab labeled with the alpha-particle emitter actinium-225. Its CD33 program is currently being studied in Phase 2 and Phase 1 clinical trials for patients with AML, myelodysplastic syndrome (MDS) and multiple myeloma.

Actinium is also developing its proprietary Actinium Warhead Enabling (AWE) technology platform to utilize the highly differentiated radioisotope actinium-225 with a wide range of targets. AWE is being utilized in a collaborative research partnership with Astellas Pharma, Inc.

More information is available at <a href="https://www.actiniumpharma.com">www.actiniumpharma.com</a> and our Twitter feed <a href="https://www.actiniumpharma.com">@Actiniumpharma.com</a> and our Twitter feed <a href="https://www.actiniumpharma.com">www.twitter.com/actiniumpharma</a>.

## Forward-Looking Statements for Actinium Pharmaceuticals, Inc.

This press release may contain projections or other "forward-looking statements" within the meaning of the "safe-harbor" provisions of the private securities litigation reform act of 1995 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 (the "SEC"), 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.

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