June 26, 2018

# Actinium Pharmaceuticals Announces Dosing of 38th Patient and 25 Percent Enrollment in Iomab-B Pivotal SIERRA Trial

- *Iomab-B remains the only targeted conditioning treatment in clinical trials with the potential to increase access to and improve outcomes of bone marrow transplant*

NEW YORK, June 26, 2018 (GLOBE NEWSWIRE) -- **Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN:ATNM) ("Actinium" or "the Company"), today announced that it has dosed the 38th patient in the pivotal Phase 3 SIERRA (**S**tudy of **I**omab-B **i**n **E**lderly **R**elapse **R**efractory **A**cute Myeloid Leukemia) study of Iomab-B, reaching twenty-five percent of patient enrollment. As a result, the trial's independent Data Monitoring Committee (DMC) will review the trial data at its next meeting, which has been scheduled for August. The SIERRA trial is a 150 patient, randomized, and controlled multi-center trial that is currently open at 16 leading transplant centers in the US.

The Company highlighted the recent initiatives taken to strengthen the outlook for the trial. Based on the higher than anticipated crossover rate previously announced after the first DMC meeting, the Company deemed it appropriate to increase the number of additional treatment options acceptable for utilization in the control arm. This was done to accommodate requests from the principal investigators at various sites. The amended protocol now allows additional treatment options in the control arm including Mylotarg, Venetoclax, and the FLT3 inhibitors Midostaurin and Sorafenib. Importantly, the Company notes that these treatments may be used based on the preference and discretion of the treating physician in keeping with the design of the study's control arm and are not approved treatments for this patient population. The recent protocol changes have been implemented following review by the FDA and IRB approvals. The Company has also made valuable additions to its clinical organization, including the hiring of Vijay Reddy, M.D., Ph.D., a bone marrow transplant physician with stellar drug development, scientific and clinical experience, as Vice-President of Clinical Development to lead the SIERRA trial. The Company also materially strengthened its clinical operations group with the addition of two directors, two clinical trial associates and a clinical education and support specialist nurse. These initiatives taken since the first DMC update have enabled the recent milestone and are expected to ensure the continued strong progress of the SIERRA trial including both site expansion and enrollment.

Dr. Mark Berger, Actinium's Chief Medical Officer said, "We are excited to have reached this

important milestone for the SIERRA trial. Patients with active relapsed or refractory AML, particularly older patients, have limited treatment options, poor survival prognoses and few successfully receive a bone marrow transplant. We believe Iomab-B has the potential to significantly improve outcomes for these patients and we are optimistic that the SIERRA trial will support approval in an indication with significant unmet needs. We are encouraged that our efforts to expand the choice of regimens in the control arm, the expanded Iomab-B team, and increased communication with trial sites has resulted in the acceleration in enrollment that we expected. With this important milestone behind us, our team is highly motivated to complete enrollment as efficiently as possible and looks forward to the completion of this consequential trial."

Following successful enrollment of twenty-five percent of patients in the SIERRA trial, the Company expects to activate additional clinical trial sites in the United States and Canada with a continued emphasis on leading high-volume BMT centers. In addition, Actinium intends to open clinical trial sites in Europe where Iomab-B has been granted Orphan designation by the European Medicines Agency (EMA) and received Scientific Advice establishing a clear pathway to submit for EU marketing authorization upon successful completion of the SIERRA trial. Based on current forecasts, Actinium expects to complete patient enrollment in 2019. In anticipation of trial completion, Actinium is taking necessary steps to prepare for a Biologics License Application (BLA) submission and is undertaking pre-commercialization activities that are being led by Chief Commercial Officer, Anil Kapur. The SIERRA trial will have multiple data readouts including scheduled DMC safety analyses after twenty-five, fifty and seventy-five percent of patients have been enrolled. In addition, Actinium, at its discretion, may request efficacy analyses by the DMC after 70 and 110 patients have reached the primary endpoint of durable complete remission (dCR) of at least 180 days.

Sandesh Seth, Actinium's Chairman and CEO said, "Actinium is committed to be the leader in the development and commercialization of targeted conditioning agents that improve bone marrow transplant access and outcomes. Through our development of Iomab-B, we have built strong relationships with leading BMT sites and investigators, gained invaluable insights into the BMT field, and have a deep appreciation for the needs of BMT patients. In addition, Actinium has built the exoskeleton of a commercial supply chain that regularly supplies our drug candidates to the major BMT sites. This progress is inspiring to our entire team and is enabling us to create and develop the only multi-target, multi-disease clinical pipeline of targeted conditioning agents for bone marrow transplant. This recent milestone marks what I anticipate will be a series of value creating clinical advancements across our entire pipeline as we build the leading portfolio of targeted conditioning treatments."

**About Iomab-B**

Iomab-B is a targeted conditioning therapy given in conjunction with a bone marrow transplant (BMT) and is comprised of the CD45 targeting monoclonal antibody BC8 labeled with the radioisotope Iodine-131. The high dose chemotherapy used in BMT conditioning has significant toxicities and, as a result, many patients, particularly many older patients, do not receive a BMT. Iomab-B is intended to improve BMT access and outcomes by eliminating the use of intense chemotherapy in BMT conditioning. Actinium obtained the worldwide exclusive license to BC8 from the Fred Hutchinson Cancer Research Center. BC8 has been studied in several hundred patients across multiple Phase 1 and Phase 2 trials for

patients with hematologic malignancies including AML, myelodysplastic syndrome (MDS), acute lymphoblastic leukemia (ALL), Hodgkin's and Non-Hodgkin's lymphoma and multiple myeloma.

**About the SIERRA Trial**

The **S**tudy of **I**omab-B **i**n **E**lderly **R**elapse **R**efractory **A**cute Myeloid Leukemia (SIERRA) trial is studying Iomab-B prior to a bone marrow transplant (BMT) in patients age 55 and above with acute myeloid leukemia (AML) who have active relapsed or refractory disease. It is a 150-patient controlled trial, randomized 1:1 that will compare Iomab-B followed by a BMT to physician's choice of salvage chemotherapy with the primary endpoint being durable complete remission (dCR) rate of at least 180 days and the secondary endpoint being Overall Survival (OS) at one year. Patients in the control arm that receive salvage chemotherapy may cross over to Iomab-B treatment and BMT if they do not attain a CR with the salvage therapy. When they do so, they are counted as failures for the primary endpoint, which is durable complete remission for at least 180 days. The U.S. Food and Drug Administration (FDA) has agreed that the SIERRA trial is a pivotal study.

**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. 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.

Iomab-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-in-class 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 www.actiniumpharma.com and our Twitter feed @ActiniumPharma, www.twitter.com/actiniumpharma.

**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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