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Actinium Announces Receipt of Positive Scientific Advice from the European Medicines Agency for Iomab-B

- EMA guidance provides clear regulatory pathway for EU approval for Iomab-B

- Trial design, primary endpoint and planned statistical analysis from the Iomab-B U.S. pivotal Phase 3 SIERRA trial are acceptable as the basis for a Marketing Authorization Application

- EMA intent from Scientific Advice Program feedback is to increase the probability of positive outcomes and reduce risk of objections during evaluation of a Marketing Authorization Application

NEW YORK, March 21, 2017 (GLOBE NEWSWIRE) -- Actinium Pharmaceuticals, Inc. (NYSE MKT:ATNM) ("Actinium" or "the Company"), a biopharmaceutical Company developing innovative targeted payload immunotherapeutics for the treatment of advanced cancers, announced today that the Company has received positive Scientific Advice from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) related to the EU approval pathway for Iomab-B. In its correspondence to Actinium, the EMA commented that the trial design, primary endpoint and planned statistical analysis of the U.S. pivotal Phase 3 SIERRA (Study of Iomab-B in Relapsed or Refractory AML) trial are acceptable and can serve as the basis for submission of a Marketing Authorization Application. In addition, the EMA commented that it does not anticipate the need for further standalone preclinical toxicology or safety studies. The EMA requested supporting data and information that is already being collected as part of the U.S. pivotal Phase 3 SIERRA trial. The SIERRA trial is a 150 patient, randomized controlled study of Iomab-B that is currently enrolling patients in the U.S. Upon approval, Iomab-B is intended to be an induction and conditioning agent prior to a bone marrow transplant (BMT), often referred to as a hematopoietic stem cell transplant (HSCT) with an initial indication in patients with relapsed or refractory acute myeloid leukemia (AML) who are age 55 and above.

“We thank the EMA for their assistance throughout the Scientific Advice process and for this helpful feedback.“ said Sandesh Seth, Executive Chairman of Actinium. “We are excited that the EMA finds the design, endpoints and statistical analysis of the Iomab-B SIERRA trial acceptable. Their opinion is an extremely favorable outcome as this will potentially reduce the time and cost to gain marketing authorization in the EU, which is a larger addressable market than the U.S. in terms of number of patients and transplant procedures. With orphan designation for Iomab-B in the EU and now with this positive Scientific Advice, a clear regulatory pathway, we are well positioned to maximize the value of Iomab-B by working

strategically to make this potentially curative therapy available to patients in the EU in addition to our efforts in the U.S.”

The EMA provides scientific advice to companies regarding the appropriate studies for the development of a medicine. The goal of scientific advice is to facilitate the development and availability of high-quality, effective and acceptably safe medicines, for the benefits of patients. Scientific Advice helps companies make sure they perform the appropriate tests and studies, so that no major objections regarding the design of tests are likely to be raised during the evaluation of a marketing authorization application. The EMA created this program to increase the probability of positive outcomes and to reduce the risk of objections during the evaluation of a market-authorization application. Following the EMA’s advice increases the probability of a positive outcome.

About Iomab-B

Iomab-B, Actinium’s lead product candidate, is currently being studied in the pivotal Phase 3 SIERRA (Study of Iomab-B in Relapsed or Refractory AML) trial, a 150-patient, randomized controlled clinical trial in patients with relapsed or refractory acute myeloid leukemia (AML) who are age 55 and above. The SIERRA trial is being conducted at preeminent transplant centers in the U.S. with the primary endpoint of durable Complete Remission (dCR) at six months and a secondary endpoint of overall survival at one year. 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 in a potentially safer and more efficacious manner than intensive chemotherapy conditioning that is standard of care in bone marrow transplant conditioning currently. A bone marrow transplant 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 these patients experienced transplant engraftment at day 28. The overall survival rate of the 36 relapsed or refractory AML patients in the proof of concept study was 30% at one year and approximately 20% at two years. Iomab-B was developed at the Fred Hutchinson Cancer Research Center where it has been studied in several Phase 1 and Phase 2 trials 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) and is currently being studied in several ongoing physician trials. 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 biopharmaceutical company developing innovative targeted therapies for patients with cancers lacking effective treatment options. Actinium's proprietary platform utilizes monoclonal antibodies to deliver radioisotopes directly to cells of interest in order to kill those cells safely and effectively. The Company's lead product

candidate Iomab-B is designed to be used, upon approval, in preparing patients for a hematopoietic stem cell transplant, commonly referred to as bone marrow transplant. A bone marrow transplant is often the only potential cure for patients with blood-borne cancers but the current standard preparation for a transplant requires chemotherapy and/or total body irradiation that result in significant toxicities. Actinium believes Iomab-B will enable a faster and less toxic preparation of patients seeking a bone marrow transplant, leading to increased transplant success and survival rates. The Company is currently conducting a single pivotal 150-patient, multicenter Phase 3 clinical study of Iomab-B in patients with relapsed or refractory acute myeloid leukemia (AML) age 55 and older. The Company's second product candidate, Actimab-A, is currently in a multicenter open-label, 53-patient Phase 2 trial for patients newly diagnosed with AML age 60 and over. Actimab-A is being developed to induce remissions in elderly patients with AML who lack effective treatment options and often cannot tolerate the toxicities of standard frontline therapies. In addition, Actinium is developing Actimab-M, which is being studied in patients with relapsed or refractory multiple myeloma in a Phase 1 clinical trial. Actinium is also utilizing its alpha-particle immunotherapy (APIT) technology platform to generate new drug candidates based on antibodies linked to the element Actinium-225 that are directed at various cancers that are blood-borne or form solid tumors. Actinium Pharmaceuticals is based in New York, NY. To learn more about Actinium Pharmaceuticals, please visit www.actiniumpharma.com and to follow @ActiniumPharma on Twitter please visit, www.twitter.com/actiniumpharma.

Forward-Looking Statements for Actinium Pharmaceuticals, Inc.

This news release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995, including statements regarding the proposed offering. These statements are based on management's current expectations and involve risks and uncertainties, which may cause actual results to differ materially from those set forth in the statements. The forward-looking statements may include statements regarding product development, product potential, or financial performance. No forward-looking statement can be guaranteed and actual results may differ materially from those projected. Actinium Pharmaceuticals undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise.

Contact:

Actinium Pharmaceuticals, Inc.

Steve O'Loughlin
Vice President, Finance and Corporate Development
soloughlin@actiniumpharma.com

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