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## Actinium Pharmaceuticals Granted Orphan Designation from the European Medicines Agency for Actimab-A

- Orphan designation provides increased communication and guidance from regulators and 10-year market exclusivity upon marketing authorization
- Actinium's two leading drug candidates, lomab-B and Actimab-A, now have orphan designation in both the U.S. and EU

NEW YORK, May 24, 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 Actimab-A has been granted orphan designation in the European Union (EU) by the European Medicines Agency (EMA). Actimab-A is intended to be used, upon approval, in patients newly diagnosed with Acute Myeloid Leukemia (AML) who are over the age of 60 that are ineligible for standard induction therapy. Actimab-A is currently in a multi-center Phase 2 clinical trial that will enroll 53 patients.

In order to qualify for orphan designation in the EU, a medicine must be intended to treat a disease that is life-threatening or chronically debilitating. Also, no satisfactory treatment of the disease can be authorized, or, if a satisfactory treatment exists, the medicine must be of significant benefit to those affected by the disease. The EMA grants orphan designation to rare diseases that are defined as life-threatening or chronically debilitating conditions that affect no more than 5 in 10,000 people in the EU. With an estimated 30 million people living in the EU this equates to approximately 250,000 people or less for each rare disease.

"Orphan designation for Actimab-A is an important and exciting milestone for Actinium," said Sandesh Seth Actinium's Executive Chairman. "In the EU, hypomethylating agents such as Decitabine and Azacitidine have marketing authorization in the same indication that Actimab-A is intended for. In order to be granted orphan designation not only did Actimab-A have to qualify based on disease prevalence but also had to demonstrate potential clinical benefit to patients versus approved therapies. I'm extremely proud that our team was able to effectively make the case of potential clinical benefit to patients versus approved therapies and for gaining Actimab-A this important designation."

The benefits of orphan designation include up to 10 years of market exclusivity upon market authorization being granted, protocol assistance, which is a specific type of scientific advice for orphan medicines and fee reductions.

### About Actimab-A

Actimab-A, Actinium's most advanced alpha particle immunotherapy (APIT) product candidate, is currently in a 53-patient, multicenter Phase 2 trial for patients newly diagnosed with AML age 60 and above. 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 over 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 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 lomab-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 lomab-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 lomab-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](http://www.actiniumpharma.com) and to follow @ActiniumPharma on Twitter please visit, [www.twitter.com/actiniumpharma](https://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. 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.

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