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Actinium Pharmaceuticals Announces Submission of EU Orphan Designation Application for Actimab-A

- *Actimab-A has received Orphan Drug Designation in the U.S.*

- *Orphan Designation in the EU can result in regulatory assistance, reduced fees and 10 years of market exclusivity*

NEW YORK, Dec. 13, 2016 (GLOBE NEWSWIRE) -- Actinium Pharmaceuticals, Inc. (NYSE MKT:ATNM) ("Actinium" or "the Company"), a biopharmaceutical company developing innovative targeted therapies for cancers lacking effective treatment options, announced today that the Company has submitted an application with the European Medicines Agency (EMA) seeking Orphan Designation for Actimab-A for patients newly diagnosed with acute myeloid leukemia (AML) age 60 and above who are ineligible for currently used induction therapies. Actimab-A is currently in a 53-patient, multicenter open label Phase 2 trial where it is being studied as a monotherapy in these patients who have low peripheral blast (PB) burden. In a previously completed Phase 1 trial, Actimab-A showed a 50% composite response rate at the dose level of 2.0 µCi/kg/fraction, which is the dose level being studied in the current Phase 2 trial, in patients with low PB burden.

“Orphan designation brings significant benefits to the drug development process,” said Sandesh Seth, Executive Chairman of Actinium Pharmaceuticals. “We are excited to have submitted this application with the EMA and we are optimistic that Actimab-A will soon have orphan designation in the EU just as it does in the U.S. If this were to occur, both of our clinical product candidates, Iomab-B and Actimab-A, would have orphan designation in the U.S. and EU, which are the largest addressable markets for our product candidates.”

About EU Orphan Designation

The EMA, through its Committee for Orphan Medicinal Products (COMP), examines applications for orphan designation. To qualify for orphan designation, the prevalence of the condition must be less than 5 in 10,000, it must be life threatening or chronically debilitating and there must be no satisfactory method of treating the condition. Sponsors who obtain orphan designation receive numerous incentives including protocol assistance, a reduction or waving of fees and 10 years of market exclusivity should the therapy be approved. The process of filing and receiving the orphan medicines designation can take between eight to fourteen months in most cases. To learn more please visit EMA’s COMP website http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000263.jsp&mid=WC0b01ac0580028e30.

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 calls. 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 almost 90 patients in four clinical trials. Actimab-A has been granted Orphan Drug Designation for newly diagnosed AML age 60 and above.

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. 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. 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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