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# Actinium Pharmaceuticals Granted Orphan Designation from the European Medicines Agency for Iomab-B

- Orphan designation is expected to provide increased communication and guidance from regulators and 10-year market exclusivity should marketing authorization be obtained
- Orphan designation for Iomab-B follows SME (small or medium-sized enterprise) status, which was granted in August 2016
- Iomab-B now has orphan designation in the US and EU

NEW YORK, Oct. 18, 2016 (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's lead asset, Iomab-B, has been granted orphan designation in the European Union (EU) by the European Medicines Agency (EMA). Iomab-B is intended to be used, upon approval, in preparing patients with relapsed or refractory Acute Myeloid Leukemia (AML) who are over the age of 55 for a bone marrow transplant (BMT), often referred to as a hematopoietic stem cell transplant (HSCT). Iomab-B is currently in a 150 patient multicenter, pivotal Phase 3 trial that is being conducted in the United States.

"We are excited to have been granted orphan designation in the EU for Iomab-B, which comes in addition to the SME status Actinium was granted and orphan designation for Iomab-B in the U.S.," stated Sandesh Seth, Executive Chairman of Actinium Pharmaceuticals. "We believe Iomab-B represents a potentially revolutionary therapy for relapsed or refractory AML patients who are over the age of 55 who could benefit from a bone marrow transplant, which is a drastically underserved patient population. With additional regulatory support for Iomab-B in the EU through orphan designation and SME status we hope to one day bring Iomab-B to the patients of the EU."

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.

## **About Iomab-B**

Iomab-B is a radioimmunoconjugate consisting of BC8, a novel murine monoclonal antibody, and iodine-131 radioisotope. BC8 has been developed by the Fred Hutchinson Cancer Research Center to target CD45, a pan-leukocytic antigen widely expressed on white blood cells. This antigen makes BC8 potentially useful in targeting white blood cells in preparation

for hematopoietic stem cell transplantation 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). When labeled with radioactive isotopes, BC8 carries radioactivity directly to the site of cancerous growth and bone marrow while avoiding effects of radiation on most healthy tissues.

## **About Actinium Pharmaceuticals**

Actinium Pharmaceuticals, Inc. ([www.actiniumpharma.com](http://www.actiniumpharma.com)) is a New York-based biopharmaceutical company developing innovative targeted payload immunotherapeutics for the treatment of advanced cancers. Actinium's targeted radioimmunotherapy products are based on its proprietary delivery platform for the therapeutic utilization of alpha-emitting Actinium-225 and Bismuth-213 and certain beta emitting radiopharmaceuticals in conjunction with monoclonal antibodies. The Company's lead radiopharmaceutical product candidate lomab-B is designed to be used, upon approval, in preparing patients for hematopoietic stem cell transplant, commonly referred to as bone marrow transplant. The Company is conducting a single, pivotal, multicenter Phase 3 clinical study of lomab-B in refractory or relapsed AML patients over the age of 55 with a primary endpoint of durable complete remission. The Company's second product candidate, Actimab-A, is in a 53 patient, multicenter, open-label Phase 2 trial for patients newly diagnosed with AML over the age of 60 in a single-arm multicenter trial.

## **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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