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# Actinium Pharmaceuticals Initiates Pursuit of Scientific Advice for lomab-B from the European Medicines Agency

- *Company is seeking guidance on development plan of lomab-B for the EU market*
- *Actinium's small and medium-sized (SME) status and orphan designation results in a 100% reduction in fees for scientific advice*

NEW YORK, Oct. 25, 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 has initiated the European Medicines Agency (EMA) Scientific Advice process for lomab-B. 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.

The Scientific Advice process allows Actinium to dialogue with regulators from the EMA to determine the appropriate development program for lomab-B in Europe. 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. lomab-B, Actinium's lead drug candidate, has been granted orphan designation in the European Union (EU) by the EMA. lomab-B is intended to be used, upon marketing authorization, 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). lomab-B is currently in a 150 patient multicenter, pivotal Phase 3 trial that is being conducted in the United States.

Sandesh Seth, Executive Chairman of Actinium Pharmaceuticals said, "We are very excited about the potential of lomab-B in Europe to address an urgent unmet medical need. We believe lomab-B is a potentially revolutionary therapy for relapsed or refractory AML patients who are over the age of 55 that could benefit from a bone marrow transplant. This remains a patient population that is drastically underserved on a global scale. Today's initiation for scientific advice, together with our SME status and orphan designation for lomab-B in the EU, is invaluable as we explore the regulatory pathway for lomab-B in the EU. We will continue to drive the development of lomab-B in the U.S. and beyond as we endeavor to bring lomab-B to all patients that could potentially benefit from this drug candidate."

## **About lomab-B**

lomab-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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