

August 9, 2016



# Actinium Pharmaceuticals Granted SME Status by the European Medicines Agency; Reiterates Focus on EU Market

NEW YORK, NY -- (Marketwired) -- 08/09/16 --

- *Small and Medium-Sized Enterprise (SME) Status Provides Administrative, Regulatory and Financial Support with Fee Reductions up to 90%*
- *Actinium Continues to Pursue Orphan Designation in the EU*

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 been granted Small and Medium-Sized Enterprise (SME) status by the European Medicines Agency (EMA).

Dr. Roland Turck, Advisor to the Board of Directors of Actinium Pharmaceuticals said, "SME status is an integral step in the Company's approach to the EU market and will serve the company well going forward. Based on our initial assessment of the EU market we believe there is a compelling commercial opportunity for lomab-B and I look forward to continuing to work with Actinium in the pursuit of Orphan designation in the EU as well as progressing Actinium's exciting radioimmunotherapy candidates."

SME status was established by the EMA to promote innovation and development of new medicines. Companies granted SME status receive administrative and regulatory support including scientific advice, scientific services, pre-authorization inspection and post-authorization procedures. In addition, financial support is provided with fee reductions up to 100% in certain instances. Based on Actinium's SME status the Company expects to receive fee reductions up to 90%.

"We are excited and grateful to have been granted this important SME status by the EMA," said Sandesh Seth, Executive Chairman of Actinium Pharmaceuticals. "The assistance and financial support we will receive as a result of this status will be beneficial as we drive towards bringing our lomab-B and Actimab-A drug candidates to patients located in the EU."

## **About lomab-B**

lomab-B is a radioimmunotherapy 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. lomab-B is being studied in the pivotal Phase 3 SIERRA trial and is designed to be used, upon approval, in preparing relapsed or refractory AML patients over the age of 55 patients for hematopoietic stem cell transplant, commonly referred to as bone marrow transplant.

### ***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 continuing its clinical development in a Phase 1/2 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.

Investor Relations Contact:

Steve O'Loughlin  
Vice President, Finance and Corporate Development  
Actinium Pharmaceuticals, Inc.  
[soloughlin@actiniumpharma.com](mailto:soloughlin@actiniumpharma.com)

Source: Actinium Pharmaceuticals