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# **Actinium Pharmaceuticals Initiates Pursuit of EU Orphan Designation for lomab-B**

## **Company Engages Leading Regulatory Firm as Consultant to Represent and Advise the Firm in the Process**

NEW YORK, NY -- (Marketwired) -- 03/11/16 --

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 it has engaged a leading European-based regulatory affairs consulting firm to pursue orphan medicines designation by the European Medicines Agency (EMA) for lomab-B. The Company anticipates the following events to occur over the coming months and will provide updates on its EU orphan designation progress as key milestones occur.

In the immediate future, the Company along with its consultant expects to submit preliminary documentation along with the application form, questions and a presentation to the EMA. Following this, the parties are expected to participate in a pre-submission meeting with the EMA prior to entering the final submission to the EMA. These events are expected to occur over a period of a few weeks to months. The consultants anticipate that sometime in second half of this year, the Committee for Orphan Medicinal Products (COMP) will communicate with the Company to address validation issues. Once this interaction is complete, the formal regulatory procedure begins and the COMP will provide a summary report and potentially a list of items that would need to be addressed. The Company will then submit its responses to the COMP's list of items to be addressed and after satisfying this request the COMP will issue an opinion on the orphan designation.

Kaushik J. Dave, Ph.D., Actinium's Chief Executive Officer, CEO stated, "We are excited to begin the process of pursuing orphan designation in the EU for lomab-B. lomab-B is intended to address the niche patient population of relapsed and refractory Acute Myeloid Leukemia (AML) patients over the age of 55 and we are confident that it meets the criteria for orphan designation. We look forward to working with our regulatory consultants and the EMA over the next several months as we endeavor to obtain EU orphan designation for lomab-B."

### ***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.

### ***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 radiotherapy 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 Iomab-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 plans to conduct a single, pivotal, multicenter Phase 3 clinical study of Iomab-B in refractory and 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 newly diagnosed AML patients over the age of 60 in a single-arm multicenter trial.

### ***Forward-Looking Statement 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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