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# Actinium Initiates cGMP Manufacturing of Iomab-B for Phase 3 Clinical Trial

## Company on Track to Commence Iomab-B Phase 3 Trial in Mid-2015

NEW YORK, NY -- (Marketwired) -- 01/12/15 --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 it has initiated manufacturing of the Phase 3 clinical lot of BC8, a novel murine monoclonal antibody, which is conjugated with iodine-131 radioisotope to form Iomab-B. The cGMP manufacturing process has been successfully completed, including technology transfer, the qualification and validation of methods, and scale-up to commercial scale. Data on the performance of this manufacturing lot will be included in an Investigational New Drug (IND) application for Iomab-B which is anticipated to be filed with the U.S. Food and Drug Administration. Iomab-B, a radiolabeled antibody, is being developed as a part of bone marrow transplant regimen initially in relapsed and refractory acute myeloid leukemia (AML) patients ages 55 and older.

Kaushik J. Dave, Ph.D., President and CEO of Actinium, stated, "We are very pleased to have achieved this critical milestone that supports not only the filing of our IND but also the subsequent commencement of our Phase 3 trial, and ultimately the commercialization of the product. Based on the strong Phase 2 data which demonstrated significant survival and safety benefits when compared to conventional therapy, we remain committed to bringing this potentially lifesaving therapy to market, subject to the successful completion of the Phase 3 trial and FDA approval. We believe Iomab-B addresses a significant unmet need for thousands of elderly AML patients who cannot tolerate current myeloablative conditioning regimens and therefore are unable to receive a potentially curative bone marrow transplant, limiting their life expectancy to only a few months."

### *About AML*

Acute myeloid leukemia (AML) is an aggressive cancer of the blood and bone marrow. It is characterized by an uncontrolled proliferation of immature blast cells in the bone marrow. The American Cancer Society estimates there will be approximately 18,860 new cases of AML and approximately 10,460 deaths from AML in the U.S. in 2014. Patients over age 60 comprise the majority of those diagnosed with AML, with a median age of diagnosis of about 67 years. Treatment approaches in this population are limited because a majority of these individuals are judged too frail and unable to tolerate standard induction chemotherapy or as having disease generally unresponsive to currently available drugs. Elderly, high risk patients ordinarily have a life expectancy of 5 or fewer months if treated with standard chemotherapy, which only about a third of them do because of toxicity. The other two-thirds receive best supportive care, with 2 months survival, according to Oran and Weisdorf (Haematologica 2012; 1916-24).

***About Iomab-B***

Iomab-B will be used in preparing patients for hematopoietic stem cell transplantation (HSCT), the fastest growing hospital procedure in the U.S. The Company established an agreement with the FDA that the path to a Biologics License Application (BLA) submission could include a single, pivotal Phase 3 clinical study if it is successful. The trial population in this two arm, randomized, controlled, multicenter trial will be refractory and relapsed Acute Myeloid Leukemia (AML) patients over the age of 55. The trial size was set at 150 patients with 75 patients per arm. The primary endpoint in the pivotal Phase 3 trial is durable complete remission, defined as a complete remission lasting at least 6 months and the secondary endpoint will be overall survival at one year. There are currently no effective treatments approved by the FDA for AML in this patient population and there is no defined standard of care. Iomab-B has completed several physician sponsored clinical trials examining its potential as a conditioning regimen prior to HSCT in various blood cancers including the Phase 1/2 study in relapsed and/or refractory AML patients. The results of these studies in over 300 patients have demonstrated the potential of Iomab-B to create a new treatment paradigm for bone marrow transplants by: expanding the pool to ineligible patients who do not have any viable treatment options currently; enabling a shorter and safer preparatory interval for HSCT; reducing post-transplant complications; and showing a clear survival benefit including curative potential.

Iomab-B is a radioimmunoconjugate consisting of BC8, a novel murine monoclonal antibody, and iodine-131 radioisotope. BC8 has been developed by 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) 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 such 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 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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