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# Actinium Announces Start of Collaboration to Manufacture lomab™-B for Phase 3 Clinical Trial and Commercialization

## *Important Milestone For lomab™-B Development*

NEW YORK-- 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 that it made further steps towards centralized current good manufacturing practice ("cGMP") manufacturing of its lead drug candidate lomab™-B. The Company engaged IBA Molecular North America, Inc. to scale up under cGMPs, the production of lomab™-B and further develop and validate the quality control testing of the product.

lomab™-B is being developed to enable bone marrow transplants in patients affected by relapsed and refractory acute myeloid leukemia (AML). Manufacturing development is a part of the process leading to the pivotal Phase 3 trial and, if the drug candidate is approved by the FDA, commercialization of the product.

"As we are progressing with clinical development of this important drug candidate, we are working on manufacturing development at the same time," said Dr. Kaushik J. Dave, President and CEO of Actinium Pharmaceuticals. "We want to ensure the highest quality and consistency of our drug candidate and meet regulatory requirements for successful clearance and commercialization."

Bringing lomab™-B manufacturing up to highest regulatory and commercial standards will be a joint responsibility of Actinium and IBA Molecular North America, Inc.

"We are pleased to have been selected by Actinium to further assist with the development of lomab™-B," said Lee Karras, President of IBA Molecular North America. "IBA Molecular has a proven track record of radiopharmaceutical development and manufacturing and we look forward to adding this important product to our manufacturing portfolio."

## **About lomab™-B**

lomab™-B will be used in preparing patients for hematopoietic stem cell transplant, commonly referred to as bone marrow transplant which is 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 will 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 study design of the pivotal trial is based on results of an earlier Phase 1/2 trial in which sixty

percent of the older patients with refractory and relapsed AML exhibited disease free survival estimated at six months. The primary endpoint in the pivotal Phase 3 trial is durable complete remission, defined as a complete remission lasting at least 6 months. There are currently no 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 a bone marrow transplant 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](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 is 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 Iomab™-B will be used in preparing patients for hematopoietic stem cell transplant, commonly referred to as bone marrow transplant. The Company is preparing a single, pivotal, multicenter Phase 3 clinical study of Iomab™-B in refractory and relapsed Acute Myeloid Leukemia (AML) patients over the age of 55 with a primary endpoint of durable complete remission. The Company's second program, 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.

### **About IBA Molecular**

IBA Molecular North America, Inc. is part of IBA Molecular, a global developer, manufacturer and distributor of radiopharmaceutical products and supporting services used in molecular imaging. IBA Molecular has engineered a strong and unique product portfolio and pipeline of diagnostic and therapeutic tracers aimed at advancing the development of the global movement towards personalized medicine and making molecular imaging/therapy a major discipline in healthcare. The company also provides educational, technical and marketing support to medical specialists worldwide to help better respond to patient needs. Founded in 1986, IBA Molecular, with North American headquarters in Dulles, Virginia, is jointly owned by SK Capital Partners and Ion Beam Applications S.A. The company is a leading

manufacturer and distributor of PET agents in North America, and PET and SPECT agents in Europe and Asia, with a network of 49 sites worldwide.

### **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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