

December 9, 2014



# **Actinium's Scientific Advisory Board Endorses and Supports the Iomab-B Phase 3 Clinical Trial Development Program**

## **Experts in Leukemia and Bone Marrow Transplant Prepare for Upcoming Pivotal Trial of Actinium's Iomab-B With the Potential to Change the Way Relapsed and Refractory Acute Myeloid Leukemia (AML) in Older Patients Is Treated**

SAN FRANCISCO, CA and NEW YORK, NY -- (Marketwired) -- 12/09/14 -- [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 their Scientific Advisory Board (SAB) conducted its year-end meeting to review the progress of Iomab-B, a radiolabeled antibody being developed as a part of bone marrow transplant regimen initially in relapsed and refractory AML patients ages 55 and older. Iomab-B is being readied for a Phase 3 Clinical Trial due to begin in the first half of 2015.

On December 4, 2014, Actinium's SAB meeting was held in San Francisco prior to the American Society of Hematology (ASH) annual meeting. The SAB is Chaired by John Pagel, MD, PhD of the Fred Hutchinson Cancer Research Center and Swedish Cancer Institute, Seattle and has senior members from Memorial Sloan Kettering Cancer Center, MD Anderson Cancer Center and other leading institutions. The SAB's goal is to further the development of Iomab-B as a myeloablative agent for older relapsed and refractory AML patients. If approved, Iomab-B should increase the number of patients eligible for curative bone marrow transplant (BMT, also known as HSCT) and improve clinical outcomes.

The Company updated the SAB on progress made in 2014, including refining and completing the Phase 3 protocol, progress in manufacturing centralization and scale-up, CRO engagement and the completion of other administrative items. Plans for 2015 were also reviewed, including assembly of the IND (Investigational New Drug) Application for submission to FDA early next year, clinical trial sites selection, preparation of ancillary materials and other items related to the upcoming pivotal trial. This study is planned as the final clinical trial prior to potential FDA clearance and approval.

Richard Champlin, MD, Chair of Stem Cell Transplantation and Cellular Therapy at MD Anderson Cancer Center, stated, "We are impressed with progress in Iomab-B development and are looking forward to starting the trial. Iomab-B treatment would be an important new addition to our unfortunately very limited armamentarium for the most difficult-to-treat AML

patients, and could potentially change the way refractory AML in older patients is treated."

As an international leader in the field of hematopoietic stem cell transplantation (HSCT), Dr. Champlin pioneered the use of donor transplants and lower doses of chemotherapy, reducing mortality rates along the way. Under his leadership, the MD Anderson HSCT program grew to become the largest in the world.

Dr. Dragan Cicic, Chief Medical Officer of Actinium, stated, "The Company is committed to the ongoing development of lomab-B with a multi-center Phase 3 pivotal trial due to begin in 2015. With the continued support and input from our world renowned scientific advisors, we are moving quickly to advance lomab-B development. The SAB meeting further supported our belief that, if approved by FDA, lomab-B could significantly change the treatment paradigm for elderly relapsed and refractory AML patients by providing a potentially curative pathway for majority of patients who today have a life expectancy of 5 or fewer 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, most of them in adults. Patients over age 60 comprise the majority of those diagnosed with AML, with a median age of a patient diagnosed with AML being 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 having forms of 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, and only about a third of them receive this treatment because of toxicity of and limited responses to the available therapy. The other two-thirds receive best supportive care, with 2 months survival, according to Oran and Weisdorf (*Haematologica* 2012; 1916-24).

### ***About lomab-B***

lomab-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. lomab-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 lomab-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 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. Additional actinium 225 based drug candidates are in early development for other cancers.

### ***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.

Contact: Actinium Pharmaceuticals, Inc. Evan Smith, CFAVP, Investor Relations and Fi

Source: Actinium Pharmaceuticals