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Actinium Pharmaceuticals Initiates Pivotal Phase 3 SIERRA Trial

NEW YORK, NY -- (Marketwired) -- 06/29/16 --

- *Iomab-B Uniquely Positioned as the Only Investigational Therapy Intended to be an Induction and Conditioning Agent Prior to a Bone Marrow Transplant in its Target Patient Population*
- *SIERRA Phase 3 Trial to Study Iomab-B as an Induction and Conditioning Agent Prior to a Bone Marrow Transplant in Patients with Relapsed or Refractory Acute Myeloid Lukemia (AML) over the Age of 55*
- *Iomab-B Proof of Concept Study Demonstrated Significant Survival Benefit at Two Years Versus Current Therapy and has been Studied in Almost 300 Patients to Date in Multiple Phase 1 and Phase 2 Studies in Numerous Blood Cancers*

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 pivotal Phase 3 clinical trial for Iomab-B has been initiated. Iomab-B, the Company's lead asset, upon approval, is intended to be an induction and conditioning agent used to prepare patients with relapsed or refractory AML who are over the age of 55 for a hematopoietic stem cell transplant (HSCT), commonly referred to as bone marrow transplant (BMT). Iomab-B is a radioimmunotherapy comprised of the monoclonal antibody BC8 coupled with the radioisotope Iodine-131 that is designed to deliver targeted payloads to cells that express CD45, a pan-leukemic antigen expressed on white blood cells and stem cells.

Sandesh Seth, Actinium's Executive Chairman stated, "The initiation of this pivotal Phase 3 SIERRA trial is a significant milestone for Actinium and one we are excited to announce. There are currently no approved therapies for elderly patients with relapsed or refractory AML and more often than not these patients cannot receive a bone marrow transplant due to the intense nature of the preparative regimens required. Iomab-B represents a potentially new treatment paradigm in bone marrow transplantation of elderly relapsed or refractory AML patients as it is both an induction and conditioning agent that provides a safer and potentially curative outcome from a bone marrow transplant."

The pivotal Phase 3 SIERRA trial is a multi-center, randomized, controlled study that will enroll 150 patients and it is designed to evaluate if Iomab-B followed by a bone marrow transplant can increase durable Complete Remission (dCR) rates at 6 months compared to physician's choice of chemotherapy followed by a bone marrow transplant or other treatment modaltiies with curative intent. There are currently no effective treatments approved by the FDA for AML in this patient population and there is no defined standard of care. The SIERRA trial will include independent Data Monitoring Committee (DMC) reports, which will occur at 25, 50, 75 and 100 percent patient enrollment with the potential for two additional ad-hoc

DMC reports. Approximately 150 medical centers provide AML bone marrow transplants, with the top 30 centers performing over 50 percent of the AML BMT procedures. Actinium expects many of the highest volume BMT centers to participate in the SIERRA trial given that the results of previous studies in almost 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.

Felix Garzon, M.D., Ph.D., Actinium's Senior Vice President and Head of Clinical Development said, "All of us at Actinium are committed to the SIERRA trial and this underserved relapsed or refractory eldery AML patient population. The survival statistics for this patient population, particularly those that cannot receive a bone marrow transplant, are quite dismal. The clinical development team is fully engaged and committed to ensuring efficient execution of this important trial for a potentially life-saving therapy that can offer patients who are currently consigned to hospice a chance of a cure."

More information about Iomab-B and the SIERRA trial can be found by visiting www.actiniumpharma.com.

About the SIERRA trial

The SIERRA (***S***tudy of ***I***omab-B in ***E***lderly ***R***elapsed or ***R***efractoy ***A***ML) trial is a multi-center, randomized, controlled pivotal Phase 3 study of Iomab-B in patients with relapsed or refractory Acute Myeloid Leukemia (AML) who are over the age of 55. The Company established an agreement with the FDA that the path to a Biologics License Application (BLA) submission could include the SIERRA trial, if it is successful. 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 almost 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.

About Iomab-B

Iomab-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. Iomab-B is being studied in the pivotal Phase 3 SIERRA trial and is designed to be used, upon approval, in preparing relapsed or refractory patient 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) 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 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 is conducting a single, pivotal, multicenter Phase 3 clinical study of Iomab-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 otherw

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