

# Actinium Submits Iomab-B IND Application to the U.S. FDA

## Company Gearing Up for Pivotal, Phase 3 Clinical Trial

NEW YORK, NY -- (Marketwired) -- 11/17/15 -- Actinium Pharmaceuticals, Inc. (NYSE MKT: ATNM) ("Actinium" or "the Company"), is a biopharmaceutical company developing innovative targeted payload immunotherapeutics for the treatment of advanced cancers. Actinium announced today that it has submitted an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) for Iomab-B, a radioimmunotherapeutic that conditions Acute Myeloid Leukemia (AML) patients for a Hematopoietic Stem Cell Transplant (HSCT), commonly referred to as a Bone Marrow Transplant (BMT). Pending the FDA's acceptance of the IND filing, Actinium will initiate a single, pivotal Phase 3 clinical study in refractory and relapsed AML patients over the age 55.

"We are excited to have submitted the Iomab-B IND application to the FDA," said Kaushik J. Dave, Ph.D., MBA, CEO of Actinium. "We focused heavily on Iomab-B in 2015 and overcame our previous manufacturing hurdles, which gave us great confidence when we met with the FDA for our pre-IND meeting. Our filing, well ahead of our year end guidance, is a great milestone for Actinium."

Sandesh Seth, Actinium's Executive Chairman commented, "This much anticipated regulatory filing is an important one that marks the first step in Actinium's transition to a later development stage biopharmaceutical company. As we prepare for the pivotal Phase 3 clinical trial for lomab-B in 2016, we have added key members to our executive, regulatory and clinical operations teams and will continue to add selectively. This strengthening of the company will enable us to meet our goals of efficient execution of not only the lomab-B program but also of the Actimab-A Phase 2 trial planned for early 2016, as well as other preclinical and clinical programs expected for next year."

### About the Iomab-B Pivotal, Clinical Trial

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 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.

#### About Iomab-B

lomab-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. (<a href="www.actiniumpharma.com">www.actiniumpharma.com</a>) 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 lomab-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 lomab-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 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 otherwise.

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