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# Actinium Targets Fourth Quarter IND Filing for lomab-B Subsequent to Pre-IND Meeting With FDA

## IND Filing to Enable Initiation of Single, Pivotal Phase 3 Trial

NEW YORK, NY -- (Marketwired) -- 10/06/15 -- 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 subsequent to its pre-IND (Investigative New Drug) meeting with the U.S. Food and Drug Administration (FDA) for its lomab-B drug candidate, the Company is finalizing the IND filing for submission to the FDA to support the start of the Phase 3 clinical study.

"We are quite pleased with the outcome of our pre-IND meeting which provided valuable feedback regarding our forthcoming IND submission for lomab-B. We are close to finalizing our application package and remain on track to file the IND in the fourth quarter of this year, in-line with our guidance. We are optimistic that the FDA will award the filing an IND designation which will allow us to move into the critical Phase 3 stage for lomab-B," noted Kaushik J. Dave, Chief Executive Officer of Actinium Pharmaceuticals. "We are also continuing to establish the infrastructure necessary to enable speedy Phase 3 development of lomab-B."

Actinium expects to complete and file the IND submission in the fourth quarter of this year in-line with guidance provided. Based on the feedback received during the recent pre-IND meeting, and the completion of significant amounts of work related to manufacturing, the Company anticipates a straightforward path to IND designation. Once such designation is achieved, the Company can move lomab-B into the Phase 3 trial.

### **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 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.

lomab-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. is a New York, NY based biopharmaceutical company that develops innovative alpha particle immunotherapeutics based on its proprietary platform for the therapeutic utilization of alpha particle emitting actinium-225 and bismuth-213 radiopharmaceuticals in association with monoclonal antibodies.

### ***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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