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# Actinium Announces Iomab-B IND Has Been Cleared By FDA; Pivotal, Phase 3 Trial to Proceed

## Much Anticipated Milestone Sets Stage for Transformation of Company in 2016

NEW YORK, NY -- (Marketwired) -- 12/17/15 -- 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. The Company announced today that the FDA has cleared the Company's IND filing for Iomab-B, and that it will proceed with the pivotal, Phase 3 clinical trial. Actinium anticipates the Phase 3, controlled, randomized, pivotal trial to begin enrolling in the first half of 2016 and assuming that the trial meets its end points, it will form the basis for a Biologics Licensing Application (BLA). Actinium also indicated that it will update investors with further details on the company's pipeline including new programs and product candidates from its APIT (alpha particle immunotherapy) platform at its R&D Day in Q1:2016.

"After a challenging twelve month period, we are pleased to have the Iomab-B IND cleared and to be in a position to proceed with the pivotal, Phase 3 trial. In anticipation of this much awaited milestone, we have strategically expanded our core team in recent months and strengthened the balance sheet to prepare for not only the upcoming Phase 3 trial for Iomab-B but also the expected Phase 2 trial for Actimab-A, our novel CD33 targeting construct. The IND clearance represents the elimination of a major risk factor that had been hampering Actinium's progress and our entire team is energized by the achievement of this milestone. This event is a major catalyst that signals Actinium's transformation in 2016 from an early clinical stage company to a later stage company with two product candidates that have the potential to be major medical advances. We look forward to updating investors and potential partners about all of our programs at our R&D Day in Q1:2016," said Sandesh Seth, M.S., MBA, Executive Chairman of Actinium Pharmaceuticals, Inc.

"The clearance of the IND for Iomab-B is a major milestone for Actinium Pharmaceuticals," said Kaushik Dave, Ph.D., MBA, Chief Executive Officer of Actinium Pharmaceuticals, Inc. "Our team has worked extremely hard this year to prepare our IND filing with significant focus being placed on our Chemistry, Manufacturing and Controls efforts. With the IND now cleared, we are eager to ramp up our clinical development activities related to the pivotal, Phase 3 Iomab-B trial."

Actinium's Chief Medical Officer, Dragan Cicic, M.D., MBA, said, "Acute Myeloid Leukemia is a disease that has not seen an approved therapy in decades. Elderly patients in particular

have very few treatment options, especially when they are relapsed and refractory. We are excited to begin our Phase 3 trial for Iomab-B as we believe it represents a paradigm shift in the ability to condition, with better outcomes, elderly relapsed and refractory AML patients for a bone marrow transplant, which is the only potential curative treatment for this difficult to treat patient population. In addition, Iomab-B, longer-term, can potentially become the standard of care for many types of bone marrow transplants given the promising body of clinical evidence that has been amassed to date and being added to via the eight other ongoing physician sponsored clinical trials."

The Company established an agreement with the FDA that the path to a Biologics License Application 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***

Iomab-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 Actimab-A***

Actimab-A, Actinium's most advanced alpha particle immunotherapy program, is currently in a single arm, multicenter trial Phase 1/2 trial for newly diagnosed AML patients over the age of 60. Actimab-A is being developed as a first-line therapy and it has attracted support from some of the leading experts at the most prestigious cancer treatment hospitals due to the potential of its safety and efficacy profile.

Actimab-A consists of the monoclonal antibody, lintuzumab, and the radioisotope, actinium-225. Actinium-225 decays by giving off high-energy alpha particles, which kill cancer cells. When actinium decays, it produces a series of daughter atoms, each of which gives off its

own alpha particle, increasing the chances that the cancer cell will be destroyed. Lintuzumab is the humanized version of M195 and is a monoclonal antibody that targets CD33, which is abundantly found on myeloid leukemia cells. Both the alpha particle technology and lintuzumab were initially developed at Memorial Sloan Kettering Cancer Center.

### ***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.

### ***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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