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Actinium Pharmaceuticals Announces Plans For Iomab™-B Phase 3 Pivotal Trial Following Meeting With FDA

Actinium Expects Single Trial Required for Regulatory Approval

NEW YORK, Nov. 18, 2013 /PRNewswire/ -- Actinium Pharmaceuticals, Inc. (OTCQB: ATNM.OB) ("Actinium" or "the Company"), a biopharmaceutical Company developing innovative, targeted payload immunotherapeutics for the treatment of advanced cancers, provided a corporate update on its two most advanced clinical programs. Kaushik J. Dave Ph.D., MBA, President and Chief Executive Officer, hosted a call on November 11, 2013 to discuss recent progress and outline development plans for the Company's clinical stage products: Iomab™-B and Actimab™-A.

Based on the successful Iomab-B End of Phase 2 (EOP-2) meeting and subsequent discussions with the FDA, the Company established an agreement on the path to a Biologics License Application (BLA) submission which will include only a single pivotal Phase 3 clinical study. The FDA agreed that the study design of the pivotal trial may be adequate to support the license indication as a single study, providing that results are sufficiently robust that it would be unethical to repeat the study. The study design of the pivotal trial is based on results of an earlier Phase 1/2 trial in which the older patients with advanced leukemia and myelodysplastic syndrome achieved a 100% complete remission rate at 6 months. The primary endpoint in the trial is durable complete remission, defined as a complete remission lasting 6 months.

Iomab-B will be used in preparing patients for hematopoietic stem cell transplant, commonly referred to as bone marrow transplant (HSCT). The trial population in this two arm, randomized, controlled, multicenter trial will be refractory Acute Myeloid Leukemia (AML) patients over the age of 55. The trial size was set at 150 patients with 75 patients per arm. There are currently no treatments approved by the FDA for AML in this patient population and no defined standard of care.

"We are very pleased with the EOP-2 meeting outcome," said Kaushik J. Dave, Ph.D., MBA, President and Chief Executive Officer. "This puts us on our way to start a registration trial, eagerly anticipated not only by the Company but also by leukemia experts, next year. We are delighted with the enthusiasm that Iomab™-B generated among leading leukemia physicians and their interest in participating in our trial which further validates the large and unmet opportunity for a safe and effective drug in this space. We anticipate based on this enthusiasm that the study enrollment will be swifter than originally expected."

Iomab™-B has completed several physician sponsored clinical trials examining its potential as a conditioning regimen prior to a bone marrow transplant in various blood cancers

including the Phase 1/2 study in relapsed and/or refractory AML patients. The results of these studies 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
- Showing a clear survival benefit including curative potential.

Actimab-A, Actinium's second program 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. The Company expects to make significant progress in the Phase 2 portion of the trial and announce interim results in 2014. Actimab-A is being developed as a first line therapy and 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.

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 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 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 is a drug candidate construct made using Actinium Pharmaceuticals' proprietary patented technology for arming monoclonal antibodies with alpha emitters actinium 225 and bismuth 213. Antibodies are used as high precision delivery systems that bring powerful alpha emitters into or immediately next to targeted cancer cells. Actimab-A consists of the Lintuzumab monoclonal antibody and 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. The technology was first developed by Dr. David Scheinberg at Memorial Sloan Kettering Cancer Center.

Lintuzumab is a monoclonal antibody that targets CD33, found on myeloid leukemia cells. It is the humanized version of M195, the antibody initially developed by Dr. David Scheinberg of Memorial Sloan Kettering Cancer Center.

About Actinium Pharmaceuticals

Actinium Pharmaceuticals, Inc. (OTCQB: ATNM.OB), is a New York based

biopharmaceutical company developing innovative targeted payload immunotherapeutics for the treatment of advanced cancers. Actinium's targeted radiotherapy is based on its proprietary delivery platform for the therapeutic utilization of alpha emitting actinium-225 and bismuth-213 radiopharmaceuticals in conjunction with monoclonal antibodies. The Company also develops other radiopharmaceuticals for select applications.

For more information:

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Forward-Looking Statement for Actinium Pharmaceuticals, Inc.

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