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## Actinium Engages a Leading CRO to Support Phase 3 Trial of Iomab-B

*Actinium's New Drug Candidate Takes Next Steps Towards Initiating a Pivotal Trial in Older Relapsed and Refractory Acute Myeloid Leukemia Patients*

NEW YORK-- [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 that it has executed an agreement with ACT Oncology, a full-service clinical research organization (CRO) specializing in providing oncology drug development support for biotech, pharmaceutical and non-profit oncology organizations, to utilize their services for a number of clinical development-related projects. This agreement includes the preparations for the Phase 3 clinical trial of Iomab-B, a myeloconditioning drug for bone marrow transplant preparation.

Actinium remains on track to submit all the regulatory documentation for the Phase 3 clinical trial by the end of 2014. ACT Oncology has a full North American coverage and the ability to support global programs.

"We are extremely pleased to have an organization with the skills and experience of ACT Oncology to support the initiation and execution of the Phase 3 trial of Iomab-B. They have been responsible for managing nearly 30 studies in hematological oncology, so their experience in this highly specialized field of medicine will be invaluable to us. Based on our team's previous experience working with ACT Oncology, we have been consistently impressed with their communication and project management systems which will be critical to the successful execution of our pivotal trial," said Kaushik J. Dave, Ph.D., MBA, Actinium's President and CEO.

Dr. Dave added, "We have been working closely with leading US transplant experts and the U.S. Food and Drug Administration (FDA) to develop our Phase 3 trial. Feedback from the FDA on our trial design lead to a very manageable trial size of 150 patients. We are now finalizing our manufacturing scale-up and upgrade and preparation of all regulatory materials with the help of ACT Oncology and anticipate initiating this clinical trial by the end of 2014 or early 2015."

"ACT Oncology is thrilled to have the opportunity to support Actinium's Phase 3 Iomab-B program for the treatment of patients with relapsed/refractory AML", stated Patricia Devitt, Pharm. D., President, ACT Oncology LLC. "This study holds great promise for the AML patient population and we look forward to leveraging ACT Oncology's deep pool of talented clinical research professionals to make our collaboration with Actinium a success."

The Phase 3 trial will be conducted in relapsed and refractory acute myeloid leukemia (AML) patients over the age of 55. The primary endpoint of this Phase 3 trial is durable complete remission (dCR) rate, where durable complete remission is defined as a complete remission

lasting at least 180 days.

### **About lomab™-B**

[lomab™-B](#) will be used in preparing patients for hematopoietic stem cell transplant (“HSCT”), commonly referred to as bone marrow transplant which is 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 will include a single, pivotal Phase 3 clinical study if it is successful. The trial 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 study design of the pivotal trial is based on results of an earlier Phase 1/2 trial in which sixty percent of the older patients with refractory and relapsed AML exhibited disease free survival estimated at six months. The primary endpoint in the pivotal Phase 3 trial is durable complete remission, defined as a complete remission lasting at least 6 months. There are currently no 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 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 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 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 ACT Oncology**

ACT Oncology is a full service, oncology specialist CRO based in Flemington, New Jersey and Madrid, Spain. Founded in 2000 by Patricia Devitt Risse, Pharm.D., the company is comprised of industry experts supported by an infrastructure specifically designed to provide efficient, flexible and cost-effective support to our biotech Sponsors’ oncology development programs. Noted for our expertise in using Study Quality Metrics to drive the effective management of complex protocols, ACT Oncology offers our Sponsors a unique combination of scientific rigor, operational savvy and client service to establish productive, long term relationships.

### **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 is 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 lomab™-B will be used in preparing patients for hematopoietic stem cell transplant, commonly referred to as bone marrow transplant. The Company is preparing a single, pivotal, multicenter Phase 3 clinical study of lomab™-B in refractory and relapsed Acute Myeloid Leukemia (AML) patients over the age of 55 with a primary endpoint of durable complete remission. The Company's second program, 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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