

March 2, 2016



# **Actinium Pharmaceuticals Selects Medpace Inc. as Clinical Research Organization for Pivotal Phase 3 Iomab-B Trial**

## **CRO Selection Marks Significant Milestone Toward Start of Iomab-B Pivotal Trial**

NEW YORK, NY -- (Marketwired) -- 03/02/16 --

Actinium Pharmaceuticals, Inc. (NYSE MKT: ATNM) ("Actinium"), a biopharmaceutical company developing innovative targeted payload immunotherapeutics for the treatment of advanced cancers announced today that it has selected Medpace as its Clinical Research Organization (CRO) for its pivotal Phase 3 Iomab-B clinical trial. Medpace is a full service CRO that provides Phase 1 - 4 core development services for drug, biologic and device programs.

Dr. Felix Garzon, M.D., Ph.D., Senior Vice President, Head of Clinical Development for Actinium Pharmaceuticals said, "We worked extremely diligently to identify the right specialist CRO partner for the pivotal Phase 3 Iomab-B clinical trial and we are delighted to announce that we have selected Medpace. Medpace is full service CRO with a global reach, demonstrated track record of successfully managing clinical trials and medical and clinical expertise in the field of bone marrow transplantation. With this major milestone now complete and with Medpace as our partner, we are excited to move into the next chapter of Iomab-B's clinical development of bringing clinical sites online and enrolling patients."

"Medpace is pleased to be Actinium's CRO of choice for this pivotal study," said Franklin O. Smith, III, M.D., FAAP, FACP Vice President, Medical Affairs, Hematology and Oncology at Medpace. "Medpace teams have deep experience in conducting complex studies in advanced cancer therapies. We look forward to bringing our extensive knowledge and experience in hematopoietic cell transplantation to Actinium's Pivotal Phase 3 Iomab-B Trial."

The Company established an agreement with the FDA that the path to a Biologics License Application submission for Iomab-B 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 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.

Sandesh Seth, Executive Chairman of Actinium Pharmaceuticals said, "Since receiving clearance of our IND for Iomab-B in December, we have focused on the execution of our clinical milestones. The selection of Medpace as our CRO is a significant milestone as it greatly expands our clinical and operational capacities for the Phase 3 Iomab -B pivotal trial. Iomab-B is the only therapy of its kind and addresses a patient population with significant unmet needs, we remain steadfastly focused on the execution of this trial with the goal of delivering this much needed therapy to patients in need of a bone marrow transplant and we welcome the addition of Medpace as our partner."

### ***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 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.

### ***About Medpace Inc.***

Medpace Inc. is a global full-service clinical research organization (CRO) providing Phase I-IV core development services for drug, biologic, and device programs. Medpace has strong experience supporting development programs across a number of therapeutic areas including oncology, cardiovascular, metabolic/diabetes, infectious disease, neuroscience, regenerative medicine, gastrointestinal diseases, pediatrics, and orphan disease. With extensive medical expertise, and renowned regulatory affairs department, Medpace employs 2,400 employees and has clinical trial experience in over 50 countries and 6 regions - North America, Europe, Asia Pacific, Latin America, Africa, and the Middle East. From feasibility, research site compatibility, safety, and logistics, Medpace brings efficiencies and operational excellence to both drug and device development programs. In addition, Medpace offers integrated imaging, central and bioanalytical lab capabilities, and clinical pharmacology through wholly-owned business units to provide cohesive, streamlined, and standardized trial management. For more information visit the Medpace website at: [www.medpace.com](http://www.medpace.com)

***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.

Actinium Contact:

Steve O'Loughlin

Senior Director, Finance and Corporate Development

Actinium Pharmaceuticals, Inc.

[soloughlin@actiniumpharma.com](mailto:soloughlin@actiniumpharma.com)

Medpace Contact:

Mary Kuramoto

Associate Director

Marketing Medpace Inc.

[m.kuramoto@medpace.com](mailto:m.kuramoto@medpace.com)

Source: Actinium Pharmaceuticals