

# Actinium Pharmaceuticals Announces Activation of Sixteenth Clinical Trial Site in the Pivotal Phase 3 SIERRA Trial for lomab-B

- Current clinical trial sites represent over one-third of bone marrow transplant volume in the U.S.
  - Actinium expects continued site additions to support enrollment and trial completion objectives

NEW YORK, Feb. 27, 2018 (GLOBE NEWSWIRE) -- Actinium Pharmaceuticals, Inc. (NYSE American:ATNM) ("Actinium" or "the Company"), announced today that the Company has successfully activated sixteen clinical trial sites in the pivotal Phase 3 SIERRA (Study of Iomab-B in Elderly Relapsed or Refractory Acute Myeloid Leukemia) trial. The SIERRA trial is planned to enroll 150 patients with relapsed or refractory acute myeloid leukemia (AML) who are age 55 and above and will compare Iomab-B and a BMT to physician's choice of salvage chemotherapy. The primary endpoint is durable complete remission (dCR) of at least six months. Iomab-B is intended to provide safer myeloablation of the bone marrow prior to a bone marrow transplant, thus providing a potentially curative treatment option for this patient population and for patients with other leukemias, lymphomas, myelomas and other blood disorders.

With Stony Brook, New York-based Stony Book University, the sixteen clinical trial sites in the Phase 3 SIERRA trial represent over one-third of bone marrow transplant volume in the U.S., which bodes well for reaching the 150-patient enrollment goal. The following medical institutions are clinical trial sites in the lomab-B Phase 3 clinical trials:

Center	Location
MD Anderson Cancer Center	Houston, Texas
Memorial Sloan Kettering Cancer Center	New York, New York
Mayo Clinic	Rochester, Minnesota
Mayo Clinic	Jacksonville, Florida
Washington University School of Medicine	Saint Louis, Missouri
Yale Cancer Center	New Haven, Connecticut
Baylor Charles A. Sammons Cancer Center	Dallas, Texas
The University of Kansas Cancer Center	Westwood, Kansas
Roswell Park Cancer Institute	Buffalo, New York
University Hospitals Cleveland Medical Center	Cleveland, Ohio
The Ohio State University Comprehensive Cancer Center	Columbus, Ohio
Penn State Hershey Cancer Institute	Hershey, Pennsylvania
Loyola University Medical Center	Maywood, Illinois
Banner MD Anderson Cancer Center	Gilbert, Arizona

Dr. Mark Berger, Actinium's Chief Medical Officer said, "We are optimistic that working with these renowned scientific institutions will move lomab-B closer to realization as an accepted treatment to improve the therapy and prospects of bone marrow transplant patients."

Actinium also announced that it expects to provide updates on the Iomab-B SIERRA trial in line with previously stated objectives for 2018 and 2019. The SIERRA trial will have three safety analyses by an independent Data Monitoring Committee when 25%, 50% and 75% patient enrollment has been reached. Also, two ad-hoc efficacy analyses may be requested by Actinium after 70 and/or 110 patients have engrafted and given enough time to achieve the primary endpoint of durable complete remission at six months post-treatment.

Sandesh Seth, Actinium's Chairman and CEO said, "Participation of these leading U.S. transplant centers are in the SIERRA trial reflects strongly on the prospects for our leading drug candidate, lomab-b. We expect to provide several enrollment and Data Monitoring Safety Board related updates during 2018 and topline results next year and believe we are making solid progress toward meeting these goals with the addition of additional sites and participation of these prestigious institutions."

### **About Iomab-B**

lomab-B is Actinium's lead product candidate that is currently being studied in a 150-patient, multicenter pivotal Phase 3 clinical trial in patients with relapsed or refractory acute myeloid leukemia who are age 55 and above. Upon approval, lomab-B is intended to prepare and condition patients for a bone marrow transplant, also referred to as a hematopoietic stem cell transplant, which is often considered the only potential cure for patients with certain bloodborne cancers and blood disorders. Iomab-B targets cells that express CD45, a panleukocytic antigen widely expressed on white blood cells with the monoclonal antibody, BC8, labeled with the radioisotope, iodine-131. By carrying iodine-131 directly to the bone marrow in a targeted manner, Actinium believes Iomab-B will avoid the side effects of radiation on most healthy tissues while effectively killing the patient's cancer and marrow cells. In a Phase 2 clinical study in 68 patients with advanced AML or high-risk myelodysplastic syndrome (MDS) age 50 and older, lomab-B produced complete remissions in 100% of patients and patients experienced transplant engraftment at day 28. Iomab-B was developed at the Fred Hutchinson Cancer Research Center where it has been studied in almost 300 patients 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). Iomab-B has been granted Orphan Drug Designation for relapsed or refractory AML in patients 55 and above by the U.S. Food and Drug Administration and the European Medicines Agency.

## **About Actinium Pharmaceuticals, Inc.**

Actinium Pharmaceuticals Inc. is a clinical-stage biopharmaceutical company focused on developing and commercializing targeted therapies for potentially superior myeloablation and conditioning of the bone marrow prior to a bone marrow transplant and for the targeting and killing of cancer cells. Our targeted therapies have demonstrated the potential to result in

significantly improved access to bone marrow transplant with better outcomes, namely increased marrow engraftment and survival. Our targeted therapies are ARC's or Antibody Radio-Conjugates that combine the targeting ability of monoclonal antibodies with the cell killing ability of radioisotopes. We have four clinical trials based on our AWE or Actinium Warhead Enabling Technology Platform that utilizes the isotope Actinium-225 (Ac <sup>225</sup>) which emits alpha particles. In addition, our most advanced product candidate, Iomab-B, an ARC developed by the Fred Hutchinson Cancer Research Center, is comprised of an anti-CD45 monoclonal antibody labeled with iodine-131. We are currently conducting a pivotal Phase 3 trial of lomab-B for myeloablation and conditioning of the bone marrow prior to a bone marrow transplant for patients with relapsed or refractory acute myeloid leukemia (AML) age 55 and older. A bone marrow transplant is a potentially curative treatment for patients with AML and other blood cancers including leukemias, lymphomas and multiple myeloma as well as certain blood disorders. Iomab-B has been tested in several of these other cancers with over five hundred patients treated in several Phase 1 and 2 trials with promising results. Upon successful completion of our Phase 3 clinical trial for Iomab-B we intend to submit this candidate for marketing approval in the U.S. and European Union where it has been designated as an Orphan Drug. We are also developing a potentially best in class CD33 program using an ARC comprised of the anti-CD33 monoclonal antibody lintuzumab labeled with the alpha-particle emitter actinium-225. Our most advanced CD33 program candidate, Actimab-A, is currently in a Phase 2 clinical trial for patients advanced over the age of 60 who are newly diagnosed with AML and ineligible for standard induction chemotherapy. Actimab-A also has Orphan Drug designation in the US and EU. Actimab-M, our second CD33 program ARC, is being studied in a Phase 1 trial for patients with refractory multiple myeloma. Actinium is also planning a Phase 2 trial for Actimab-MDS, our third CD33 program candidate, as a conditioning regimen prior to a bone marrow transplant for patients with MDS that have a p53 genetic mutation. Our Phase 1 trial studying Actimab-A with CLAG-M is our fourth CD33 program clinical trial for patients with relapsed or refractory AML. Our AWE or Actinium Warhead Enabling Technology Platform, originally developed in conjunction with Memorial Sloan Kettering Cancer Center, is focused on leveraging Actinium's know how and intellectual property to create additional ARC drug candidates by labeling Ac<sup>225</sup> to targeting moieties that we will either progress in clinical trials ourselves or out-license.

More information is available at <u>www.actiniumpharma.com</u> and our Twitter feed @ActiniumPharma, <u>www.twitter.com/actiniumpharma</u>.

# Forward-Looking Statements 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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