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# Actinium Pharmaceuticals Announces Activation of Fifteenth Clinical Trial Site in the Phase 3 SIERRA Trial for Iomab-B

- Current clinical trial sites represent approximately one third of bone marrow transplant volume in the U.S.
- Actinium to provide update on SIERRA clinical trial by year-end

NEW YORK, Oct. 25, 2017 (GLOBE NEWSWIRE) -- **Actinium Pharmaceuticals, Inc.** (NYSE MKT:ATNM) ("**Actinium**" or "**the Company**"), a clinical-stage biopharmaceutical company focused on developing and commercializing targeted therapies for safer myeloablation and conditioning of the bone marrow prior to a bone marrow transplant (BMT) and for the targeting and killing of cancer cells announced today that the Company has successfully activated fifteen 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 end point is durable complete remission (dCR) of at least 6 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. The following medical institutions are clinical trial sites in the Iomab-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
Fred Hutchinson Cancer Research Center	Seattle, Washington

Dr. Mark Berger, Actinium's Chief Medical Officer said, "I am delighted to be working with these world-renowned investigators and institutions in this important SIERRA trial for lomab-B. Their interest and enthusiasm for lomab-B further motivates my team as we work on this trial to bring lomab-B to patients who could benefit from safer myeloablation prior to a bone marrow transplant. In many blood cancers and disorders a bone marrow transplant is the only potentially curative treatment option for patients and it is our goal to improve outcomes for these patients with lomab-B by getting them to their transplant faster and with less complications than currently available myeloablative regimens allow. We are looking forward to adding additional clinical trial sites located in the U.S. and Canada to make this trial available to a greater range of patients and to expedite completion of the trial."

Actinium also announced that it will provide an update on the lomab-B SIERRA trial by year end. 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 & CEO said, "Until this trial, lomab-B had only been studied in a single center and Actinium is proud to have facilitated use of this important therapeutic option in most of the leading transplant centers in the U.S. via the SIERRA trial. These fifteen centers perform approximately a third of all AML related bone marrow transplants. Our ability to introduce lomab-B in these centers bodes well for enrollment in the trial and also the commercial opportunity for lomab-B as the top fifty centers account for approximately eighty percent of bone marrow transplants. There is no visible competition for lomab-B from any drug or drug candidate that can provide safer myeloablation and enable improved outcomes of bone marrow transplant. Actinium intends to build on the clinical experience, infrastructure and supply chain capabilities that we have established thus far to complete the trial in accordance with prior guidance and, assuming a successful outcome, establish lomab-B as the standard of care in providing safer myeloablation first in in AML and then in the other hematologic indications in which it has shown positive results."

## **About lomab-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 blood-borne cancers and blood disorders. lomab-B targets cells that express CD45, a pan-leukocytic 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 lomab-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. lomab-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). lomab-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 safer myeloablation and conditioning of the bone marrow prior to a bone marrow transplant (BMT) and for the targeting and killing of cancer cells. The Company is currently conducting clinical trials for its three product candidates, lomab-B, Actimab-A and Actimab-M, as well as performing research on other potential drug candidates utilizing its proprietary alpha-particle technology platform. Actinium's most advanced product candidate, lomab-B, is comprised of an anti-CD45 monoclonal antibody labeled with iodine-131 (I-131). lomab-B is currently in a pivotal Phase 3 trial 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 option for patients with AML and other blood cancers including leukemias, lymphomas and multiple myeloma as well as certain blood disorders. Upon successful completion of its Phase 3 clinical trial for lomab-B, Actinium intends to submit for marketing approval in the U.S. and European Union. Actinium's most advanced alpha-particle based therapy, Actimab-A, is an anti-CD33 monoclonal antibody conjugated with the alpha-particle actinium-225 (Ac-225). Actimab-A is currently in a Phase 2 clinical trial for patients over the age of 60 who are newly diagnosed with AML and ineligible for standard induction chemotherapy. Actimab-M, is being studied in a Phase 1 trial for patients with refractory multiple myeloma and is the same anti-CD33 monoclonal antibody conjugated to Ac-225 but a different dose and dosing regimen. Actinium expects its alpha-particle technology platform to generate additional drug candidates that it will progress in clinical trials and or out-license. More information available at [www.actiniumpharma.com](http://www.actiniumpharma.com) and Twitter feed @ActiniumPharma, [www.twitter.com/actiniumpharma](https://www.twitter.com/actiniumpharma).

### **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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