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# Actinium Announces FDA Clearance of IND For Phase 1 trial of Actimab-A in Combination with CLAG-M for Patients with Relapsed or Refractory AML

- Clinical trial to be conducted by the Medical College of Wisconsin as an investigator initiated trial led by Dr. Sameem Abedin in collaboration with Dr. Ehab Atallah
- Combination trial expands addressable patient population for Actinium's CD33 program into relapsed or refractory patients fit for chemotherapy

NEW YORK, March 13, 2018 (GLOBE NEWSWIRE) -- **Actinium Pharmaceuticals, Inc.** (NYSE American:ATNM) ("**Actinium**" or "**the Company**") announced today that the Medical College of Wisconsin received clearance from the U.S. Food and Drug Administration (FDA) for the previously announced Investigational New Drug (IND) application for the Phase 1 trial of Actimab-A in combination with CLAG-M for relapsed or refractory Acute Myeloid Leukemia (AML) patients. This investigator initiated trial will be conducted at the Medical College of Wisconsin and led by principal investigator Dr. Sameem Abedin in collaboration with Dr. Ehab Atallah. This trial will enroll up to 18 patients and will assess safety as well as efficacy, which will be based on response rates, percentage of patients receiving a bone marrow transplant and overall survival. Actimab-A is an antibody radio-conjugate (ARC) that combines the anti-CD33 antibody lintuzumab with the radioisotope actinium-225. CLAG-M is a salvage chemotherapy regimen consisting of cladribine, cytarabine, filgrastim and mitoxantrone that has become the standard of care at many institutions across the U.S. in AML patients with relapse.

Dr. Mark Berger, Actinium's Chief Medical Officer said, "The use of our actinium-225 – anti-CD33 ARC in combination with cytotoxic therapies such as CLAG-M has the potential to improve outcomes for a significant number of patients. We believe our ARC approach, which has shown to be potent while having minimal extramedullary toxicities in over 100 patients to date, has the potential to be synergistic with cytotoxic chemotherapy agents.

CLAG-M has shown compelling results in patients with relapsed or refractory disease and we believe that the combination with our ARC can improve response rates, transplant rates and overall survival for patients. We are excited to begin enrolling patients on this trial and look forward to working with Dr. Abedin, Dr. Atallah and their colleagues at the Medical College of Wisconsin on this important Phase 1 study."

This Phase 1 combination trial is the fourth clinical trial from Actinium's CD33 program. The Company's other CD33 program trials include its Phase 2 trial Actimab-A trial for patients newly diagnosed with AML who are over the age of 60 and unfit for intense chemotherapy and the Phase 1 Actimab-M trial for patients with refractory multiple myeloma. A Phase 2

trial is planned for patients with high-risk myelodysplastic syndrome with a p53 genetic mutation for myeloablation prior to a bone marrow transplant.

Sandesh Seth, Actinium's Chairman and CEO said, "We see the use of our ARC's in combination with chemotherapy as an exciting development opportunity that has the potential to bring benefits to a significant number patients. We believe that this will be the first of many combinations given the potency of our ARC approach together with its minimal extramedullary toxicities and its unique mechanism of action. Together these attributes make our ARC a versatile therapy that we believe can bring benefits to patients as a monotherapy, in combination and for myeloablation prior to a bone marrow transplant."

### **About Actimab-A**

Actimab-A is Actinium's lead drug candidate from its CD33 program and is an antibody radio-conjugate (ARC) that is comprised of the CD33 targeting antibody lintuzumab and actinium-225, an alpha-emitting radioisotope. This ARC is currently being studied in the Phase 2 Actimab-A clinical trial in patients that are newly diagnosed with AML who are over the age of 60 that are ineligible for intense chemotherapy, also known as unfit patients. Actimab-A has been granted Orphan Drug Designation for newly diagnosed AML in patients 60 and above by the U.S. Food and Drug Administration and the European Medicines Agency. The Company is also conducting the Phase 1 Actimab-M trial, an investigator initiated trial for patients with refractory multiple myeloma. Also, Actinium plans to begin the Phase 2 Actimab-MDS trial for patients with high-risk myelodysplastic syndrome (MDS) that have a p53 genetic mutation myeloablation prior to a bone marrow transplant. Actimab-A is a second-generation therapy from the Company's CD33 Program, which was developed at Memorial Sloan Kettering Cancer Center and has now been studied in over 100 patients in four clinical trials.

### **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 ( $Ac^{225}$ ) which emits alpha particles. In addition, our most advanced product candidate, lomab-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. lomab-B has been tested in several of these other cancers with over three hundred patients treated in several Phase 1 and 2 trials with promising results. Upon successful completion of our Phase 3 clinical trial for lomab-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, 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, 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, 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 [www.actiniumpharma.com](http://www.actiniumpharma.com) and our Twitter feed @ActiniumPharma, [www.twitter.com/actiniumpharma](http://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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