

# Actinium Announces Submission of IND For Actimab-A in Combination with CLAG-M for Patients with Relapsed or Refractory AML

- Conference call to be held on Tuesday, February 13<sup>th</sup>, 2018 at 4:30 PM ET to discuss planned Phase 1 clinical trial with Dr. Ehab Atallah
- New trial represents expansion of Actinium's CD33 program and increases addressable patient population in AML

NEW YORK, Feb. 12, 2018 (GLOBE NEWSWIRE) -- Actinium Pharmaceuticals, Inc. (NYSE American:ATNM) ("Actinium" or "the Company") announced today that an Investigational New Drug (IND) application has been submitted with the U.S. Food and Drug Administration (FDA) for Actimab-A in combination with CLAG-M for relapsed or refractory Acute Myeloid Leukemia (AML) patients. The planned Phase 1 trial studying Actimab-A in combination with CLAG-M will be an investigator initiated trial conducted at the Medical College of Wisconsin in a Phase 1, dose escalation study led by principal investigator Dr. Ehab Atallah in collaboration with Dr. Sameem Abedin. CLAG-M, a salvage chemotherapy regimen consisting of cladribine, cytarabine, and filgrastim, with mitoxantrone, is designed to induce remission in AML patients who are refractory to or have relapsed after standard induction therapy.

Dr. Mark Berger, Actinium's Chief Medical Officer said, "CLAG-M has become a widely used regimen for patients that is the standard of care at many institutions across the U.S. based on its ability to produce remissions in patients in relapse. By utilizing Actimab-A with CLAG-M, we expect to leverage Actimab-A's potency and minimal extramedullary toxicities to derive synergies when used in combination with other active AML drugs. This important Phase 1 study will assess safety of the combination and determine an appropriate dose level for future studies. In future studies, we believe that this exciting combination could increase remission rates in relapsed patients. We also expect to use the Actimab-A CLAG-M combination regimen to increase the rate of successful stem cell transplant in relapsed patients, via improved myeloablation with the combination regimen. We look forward to work with Dr. Atallah and his colleagues at the Medical College of Wisconsin."

Actinium will host a conference call on Tuesday, February 13, 2018 at 4:30 PM ET that will be led by Dr. Mark Berger, Actinium's Chief Medical Officer, and Dr. Atallah.

### Webcast Registration:

https://onecast.thinkpragmatic.com/ses/d4PAnC1sn4SzZZdJjklZQA~~

**U.S. Participant Dial-in**: (646) 402-9440

# U.S./Canada Toll Free Dial-in: (855) 698-6739 Conference ID: 2540

Sandesh Seth, Actinium's Chairman and CEO said, "The advantageous properties of our CD33 targeting ARC or Antibody Radio-Conjugate have enabled us to expand our CD33 Program from a single indication to the only multi-disease program in the industry. In addition to the Actimab-A trial in newly diagnosed older AML, we have the only CD33 targeting agent in multiple myeloma via the Actimab-M trial. We are also exploring its use in targeted myeloablation in high-risk MDS with Dr. Roboz and the MDS Clinical Research Consortium via the planned Actimab-MDS trial. We are excited to now be studying the combination with CLAG-M for a large relapsed, refractory AML patient population with high unmet needs. Our intent is to further improve our positioning as the best in class CD33 program with applications as a therapeutic, myeloablative agent, and also the synergistic value of adding internalized radiation as a therapeutic modality to chemotherapy and other treatment approaches. In doing so, we intend to maximize the value of the program to a great number of potential partners and collaborators."

### **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. Actimab-A is currently being studied in Phase 2 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 expects to complete patient enrollment of the Phase 2 trial in the first half of 2018 and report top line data results in the second half of 2018. The Company is also developing Actimab-M and Actimab-MDS, which are also CD33 actinium-225 ARCs. Actimab-M is being studied in a Phase 1 investigator-initiated trial for patients with refractory multiple myeloma. The Phase 1 Actimab-M trial is expected to complete enrollment and report top line data in the second half of 2018. Actimab-MDS is expected to begin a Phase 2 clinical trial in the second half of 2018 following a pre-IND meeting with the FDA in the first half of 2018. Actimab-MDS is intended to bridge patients with high-risk myelodysplastic syndrome (MDS) that have a p53 genetic mutation to a bone marrow transplant via targeted myeloablation. 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 <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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Source: Actinium Pharmaceuticals