

# Actinium Pharmaceuticals Announces Trial to Study Actimab-A in Combination with CLAG-M for Relapsed or Refractory AML Patients

- Actimab-A plus CLAG-M further expands Actinium's CD33 program and addressable patient population of Actimab-A
- Combination aligns with Actinium's focus on improving bone marrow transplant access and outcomes through improved myeloablation
  - Conference call to be held on Tuesday, February 13, 2018 at 4:30 PM ET

NEW YORK, Feb. 06, 2018 (GLOBE NEWSWIRE) -- Actinium Pharmaceuticals, Inc. (NYSE American:ATNM) ("Actinium" or "the Company"), announced today that the Company is initiating a new clinical trial that will study Actimab-A in combination with CLAG-M for patients with relapsed or refractory acute myeloid leukemia (AML). CLAG-M is a salvage chemotherapy regimen that consists of cladribine, cytarabine, and filgrastim with mitoxantrone for patients with relapsed or refractory AML. The combination trial will be a Phase 1, dose-escalation study that will be conducted at the Medical College of Wisconsin by principal investigator Dr. Ehab Atallah.

Dr. Mark Berger, Actinium's Chief Medical Officer said, "Relapsed and refractory AML patients unfortunately have limited treatment options that have little clinical benefit for patients. Actimab-A is ideally suited to be studied in combination with other therapeutic modalities like CLAG-M given its potency and minimal extramedullary toxicities. We are optimistic that this novel combination will demonstrate Actimab-A's key strengths through higher response rates, a greater number of patients successfully receiving a bone marrow transplant and ultimately, survival. Further, it will demonstrate the value of using Actimab-A in combinations as we believe that combination therapies will be the next wave in the treatment of patients with AML just as combinations of regimen's approved in multiple myeloma over the past three or four years have become for patients with that disease."

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, "This latest clinical initiative is especially exciting as it further demonstrates that we are building the industry leading CD33 Program. We the only company with multi-disease, multi-indication clinical trials with our ongoing Actimab-A, Actimab-M and planned Actimab-MDS studies and this latest initiative has the potential of extending the addressable patient population for Actimab-A. This is a viable approach for Actimab-A as we begin to strategize and implement the next phase of Actimab-A's development. In doing so, we expect to maximize the value of our CD33 program and increase its synergies for potential partners and collaborators. Further, this initiative is aligned with Actinium's core strategy of improving access and outcomes to transplants and one we are excited to embark on."

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. 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 like 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.

# **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. Three of our four ARC drug candidates are based on our AWE or Actinium Warhead Enabling Technology Platform that utilizes the isotope Actinium-225 (Ac<sup>225</sup>) that emits alpha particles. We are currently conducting clinical trials for our four product candidates; Iomab-B, Actimab-A Actimab-M and Actimab-MDS, as well as performing research on other potential drug candidates utilizing our proprietary AWE Technology Platform. 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 targeting 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 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 225 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 press release may contain projections or other "forward-looking statements" within the meaning of the "safe-harbor" provisions of the private securities litigation reform act of 1995 regarding future events or the future financial performance of the Company which the These statements are based on Company undertakes no obligation to update. management's current expectations and are subject to risks and uncertainties that may cause actual results to differ materially from the anticipated or estimated future results, including the risks and uncertainties associated with preliminary study results varying from final results, estimates of potential markets for drugs under development, clinical trials, actions by the FDA and other governmental agencies, regulatory clearances, responses to regulatory matters, the market demand for and acceptance of Actinium's products and services, performance of clinical research organizations and other risks detailed from time to time in Actinium's filings with the Securities and Exchange Commission (the "SEC"), including without limitation its most recent annual report on form 10-K, subsequent quarterly reports on Forms 10-Q and Forms 8-K, each as amended and supplemented from time to time.

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Source: Actinium Pharmaceuticals