



# Actinium Pharmaceuticals Announces Treatment of First Patient in Novel Combination Trial of Actimab-A Plus CLAG-M

- *Trial supports Actinium's strategic expansion of its CD33 program into novel combinations that can lead to increased use of bone marrow transplants and expand the addressable patient population for this program*
- *Phase 1 trial at Medical College of Wisconsin is studying combination of Actinium's Actimab-A with CLAG-M salvage regimen in patients with relapsed/refractory AML*

NEW YORK, June 13, 2018 (GLOBE NEWSWIRE) -- **Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN:ATNM) ("Actinium" or "the Company"), announced today that the Medical College of Wisconsin has treated its first patient in a Phase 1 trial studying Actinium's Actimab-A in combination with CLAG-M for patients with relapsed or refractory (r/r) acute myeloid leukemia (AML). This Phase 1 dose-escalation trial will study a single administration of Actimab-A following treatment of CLAG-M and will evaluate safety and tolerability, response rates, rates of bone marrow transplant (BMT), progression-free survival (PFS), and overall survival (OS).

Dr. Mark Berger, Actinium's Chief Medical Officer said, "We are grateful for all of the hard work that the team at MCW has put in to get to this important milestone. Actimab-A has demonstrated promising activity as a single agent in difficult to treat patient populations that we attribute to its targeting ability, potency and tolerability. We are excited to be leveraging these strengths of Actimab in a combination regimen to bring this potentially important therapy to a greater number of patients in indications that need improved outcomes. We are confident that the addition of Actimab to a salvage chemotherapy regimen has the potential to improve outcomes through improved response rates and by increasing the number of patients that can receive a bone marrow transplant."

Actimab-A is an ARC or Antibody Radio-Conjugate comprised of the anti-CD33 monoclonal antibody lintuzumab labeled with the radioisotope actinium-225. CD33 is a marker expressed on AML cells of virtually all AML patients. Actinium's CD33 ARC has been studied in over 100 patients to date and is the only CD33 targeting agent being studied in a broad range of diseases in which the CD33 antigen is expressed including AML, myelodysplastic syndrome (MDS) and multiple myeloma. CLAG-M is a salvage chemotherapy regimen commonly used to treat patients with AML that consists of cladribine, cytarabine, filgrastim, and mitoxantrone.

Sandesh Seth, Actinium's Chairman and CEO said, "Through the utilization of targeted

radioisotopes we are able to add a new modality of treatment to a salvage cytotoxic chemotherapy regimen with the aim of improving efficacy. Further, we can apply our ARC technology to targeted conditioning to enable a bone marrow transplant that we will explore in this trial as well as our anticipated Actimab-MDS trial. In short time, our team has leveraged our capabilities to create the broadest CD33 program in terms of indications and addressable patient population. We believe our approach for this program which is supported by the strong hypothesis that combinations of targeted internalized radiation using ARC's with chemotherapeutics is underpinned by a strong biologic rationale that can yield the best in class CD33 program".

## **About Our CD33 Program**

We are developing a potentially best in class CD33 program using our ARC comprised of the anti-CD33 monoclonal antibody lintuzumab labeled with the alpha-particle emitter Actinium-225 (Ac<sup>225</sup>-lintuzumab). Our CD33 program was originally developed in conjunction with Memorial Sloan Kettering Cancer Center and has been studied in over 100 patients to date. CD33 is a marker shown to be expressed on cancerous blast cells of virtually all patients with acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS) and approximately 25%- 35% of patients with multiple myeloma. Actinium-225 is highly differentiated radioisotope that emits high amounts of energy through the release of four alpha-particles that can cause double-stranded breaks in DNA with known resistance mechanisms to Actinium-225. Given the limited distance of its energy in the body, it is potentially sparing of non-targeted cells leading to better tolerability and less toxicities.

Our CD33 program includes a Phase 2 clinical trial of for patients advanced over the age of 60 who are newly diagnosed with AML and ineligible for standard induction chemotherapy an indication we have been granted Orphan Drug designation for in the US and EU. We are conducting a Phase 1 trial for patients with refractory multiple myeloma and planning to start a clinical trial for targeted conditioning prior to a bone marrow transplant for patients with high-risk MDS. We are studying Ac<sup>225</sup>-lintuzumab in combination with the chemotherapy regimen CLAG-M. We intend to continue to develop our CD33 program as a targeted therapy and for targeted conditioning of the bone marrow with Ac<sup>225</sup>-lintuzumab as a single agent and with novel combinations.

## **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 called ARC's (Antibody Radio-Conjugates), combine the targeting ability of monoclonal antibodies with the cell killing ability of radioisotopes. We are developing a pipeline of ARC's currently in Phase 3 through Phase 1 clinical trials targeting CD45 and CD33 for patients with a broad range of hematologic malignancies with significant unmet needs as well as our AWE (Actinium Warhead Enabling) technology platform to utilize the highly differentiated radioisotope actinium-225 with a wide range of targets.

Iomab-B, our lead product candidate currently enrolling patients in a pivotal Phase 3 trial, combines the anti-CD45 monoclonal antibody BC8 labeled with iodine-131 is designed to

condition the bone marrow prior to a bone marrow transplant without the need for intense chemotherapy in patients with relapsed or refractory acute myeloid leukemia (AML) age 55 or older. We are also developing a potentially best-in-class CD33 program with our ARC comprised of the anti-CD33 antibody lintuzumab labeled with the alpha-particle emitter actinium-225. Our CD33 program is currently being studied in Phase 2 and Phase 1 clinical trials for patients with AML, myelodysplastic syndrome (MDS) and multiple myeloma. Our AWE technology platform is being utilized in a collaborative research partnership with Astellas Pharma, Inc. and we are advancing research on multiple targets including the anti-CD38 antibody daratumumab.

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 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 Company undertakes no obligation to update. These statements are based on 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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