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## **Actinium Pharmaceuticals Announces Positive Preliminary Results from Phase 2 Trial for Actimab-A Highlighted at 59th American Society of Hematology Annual Meeting**

- 69% Overall Response Rate and 98% median reduction in bone marrow blasts reported with Actimab-A given at 2.0  $\mu\text{Ci/kg/fraction}$  as a single agent
- Minimal extramedullary toxicities observed; No evidence of veno-occlusive disease of any grade
- Trial continues at 1.5  $\mu\text{Ci/kg/fraction}$  dose which had a 67% Overall Response Rate in the Phase I portion of the trial

NEW YORK, Dec. 11, 2017 (GLOBE NEWSWIRE) -- **Actinium Pharmaceuticals, Inc.** (NYSE American:ATNM) ("**Actinium**" or "**the Company**") announced positive preliminary data from its ongoing Phase 2 trial of Actimab-A in patients newly diagnosed with Acute Myeloid Leukemia (AML) who are over the age of 60 and not able to tolerate induction chemotherapy. Actinium Pharmaceuticals 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, and for the targeting and killing of cancer cells. Actimab-A is an ARC or Antibody Radio-Conjugate comprised of the anti-CD33 antibody lintuzumab labeled with the alpha-emitting isotope Actinium-225. Actimab-A is the lead candidate from Actinium's CD33 Program, which now includes two additional indications; Actimab-M in Multiple Myeloma and Actimab-MDS as a bridge to transplant in TP53 positive patients with Myelodysplastic Syndrome.

Patients in the Phase 2 trial had an Overall Response Rate (ORR) of 69% when treated with 2.0  $\mu\text{Ci/kg/fraction}$  of Actimab-A administered as a single agent via two infusions administered on day 1 and day 8. In addition, patients that were evaluable had a median reduction in bone marrow blasts of 98%. Actinium had previously reported a 56% response rate in patients that were evaluable at time of the abstract submission when data were available on 9 patients compared to the 13 patients reported in the poster. The Phase 2 trial of Actimab-A is designed to enroll 53 patients, with a formal interim analysis scheduled when 31 patients have been enrolled with the target ORR for the study being thirty-five percent. This hurdle rate has been exceeded with the first thirteen patients treated at 2.0  $\mu\text{Ci/kg/fraction}$  and the number of responses needed at the interim analysis of 31 patients to

progress the trial to the full 53 patients was also cleared in these initial 13 patients. Consequently, the Company has elected to continue the trial at a lower dose in order to develop the best therapeutic profile based on balancing the myelosuppressive effect seen at 2.0 µCi/kg/fraction versus the efficacy seen at both the 2.0 µCi/kg/fraction (50% ORR in Phase 1 and 69% ORR in Phase 2) and the 1.5 µCi/kg/fraction (67% ORR in Phase 1). After making suitable protocol modifications the trial is again robustly enrolling patients who will now receive Actimab-A at 1.5 µCi/kg/fraction. This dose had the highest response rate of any dose cohort in the most recent Phase 1 trial of Actimab-A with patients receiving this dose having a 67% ORR.

Dr. Mark Berger, Actinium's Chief Medical Officer, said, "It is incredibly exciting to see these high response rates and the huge reduction in bone marrow blasts from Actimab-A as a single agent, which I attribute to the targeting ability and potency of our ARC based approach. Having led the development and initial approval of Mylotarg, the only CD33 targeting agent approved in AML, I have since had tremendous interest in this field and today's results confirm my initial inclination that Actimab-A has the potential to be highly differentiated and potentially best-in-class. In addition to these highly encouraging results, we have gained invaluable insights into the profile of Actimab-A that we will leverage to drive value going forward. Given that Actimab-A had a higher response rate of 67% at the 1.5 µCi/kg/fraction compared to a 50% response rate at 2.0 µCi/kg/fraction in our most recent Phase 1 trial, I am excited to be moving ahead with our new dose level, which I believe will be associated with strong efficacy, acceptable myelosuppression and meet the goals for the remainder of the study. Given Actimab-A's highly differentiated mechanism of action, we believe it can be used synergistically with other treatments to increase efficacy but with minimal increase in toxicities."

Compared to other AML agents, very few possibly related extramedullary toxicities were observed with only two (pneumonia and septic shock) being observed in more than one patient, both of which were observed in two patients each. Importantly, no case of veno-occlusive disease, a potentially fatal complication of the liver that can preclude a patient from receiving a stem cell transplant, was observed in any of the patients. Grade 4 myelosuppression was observed in all evaluable patients.

Dr. Berger continued, "These additional data are consistent with previous data indicating that an anti-CD33 antibody labeled with Actinium-225 has minimal extramedullary toxicities and is highly potent. The combination of these factors has allowed us to pursue Actimab-MDS as a bridge to transplant for patients with myelodysplastic syndrome that have a genetic mutation of the TP53 gene. We are excited to leverage the strengths of the Actimab-A trial to expand the patient population that we can treat with this agent."

Sandesh Seth, Actinium's Chairman and CEO, said, "In less than a year we have expanded our CD33 Program from a single asset, Actimab-A, to a full-fledged drug development program with the addition of Actimab-M and Actimab-MDS. This is early evidence of the potential of the newly infused talent and upgraded functionality that is being developed in the Company. We take comfort in the fact that now our team has enrolled more patients in our three trials in the second half of 2017 than the combined total enrollment in the four years prior. In 2018, we expect to have topline results with both Actimab-A and Actimab-M, in line with prior guidance, and also begin the newly announced Actimab-MDS trial. Our CD33 targeting ARC's are showing promise to be utilized for both therapeutic and safer

myeloablative purposes. Exemplifying the unique therapeutic promise of our CD33 targeting ARC's compared to other modalities is the recent involvement of thought leader Dr. Gail Roboz and her consortium who will spearhead the new Actimab-MDS initiative. With these new data in hand, we look forward to continuing to develop our CD33 program as the leading one in the industry in 2018 and beyond."

### **About Actimab-A**

Actimab-A, Actinium's most advanced CD33 Program candidate, is currently in a multi-center, open-label Phase 2 trial for patients newly diagnosed with AML, age 60 and above, that are ineligible for standard induction chemotherapy. Actimab-A is being developed as a first-line therapy and is a monotherapy that is administered via two 30-minute infusions that are given 7 days apart. Actimab-A is an ARC or Antibody Radio-Conjugate that targets CD33, a protein that is expressed in virtually all patients with AML cells via the monoclonal antibody, lintuzumab, which carries the potent cytotoxic radioisotope Actinium-225 to the AML cancer cells. Actinium-225 gives off high-energy alpha particles as it decays, which kill cancer cells and as actinium-225 decays it produces a series of daughter atoms, each of which gives off its own alpha particle, increasing the chances that the cancer cell will be destroyed by crossfire. 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. 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.

### **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 and for the targeting and killing of cancer cells. 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-225), which emits alpha particles. We are currently conducting clinical trials for our four product candidates; lomab-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, 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 four 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 Ac-225.

Our most advanced CD33 program candidate, 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-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 [www.actiniumpharma.com](http://www.actiniumpharma.com) and our Twitter feed @ActiniumPharma, [www.twitter.com/actiniumpharma](https://www.twitter.com/actiniumpharma).

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