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Actinium Highlights Results from Phase 1 Clinical Trial of Actimab-A at 58th American Society of Hematology Annual Meeting

- *Analysis of 2 Actimab-A Phase 1 clinical trials show that 42% of patients with low peripheral blast (PB) burden responded to Actimab-A while no patients with high PB burden responded to Actimab-A*

- *Key threshold level for low PB Burden per PB Burden Hypothesis identified as 200 blasts/µL*

- *Actimab-A has progressed to Phase 2 trial as a monotherapy via two simple fifteen minute injections administered a week apart in patients below PB burden threshold*

SAN DIEGO, Calif., Dec. 05, 2016 (GLOBE NEWSWIRE) -- Actinium Pharmaceuticals, Inc. (NYSE MKT:ATNM) ("Actinium" or "the Company"), a biopharmaceutical company developing innovative targeted therapies for cancers lacking effective treatment options, announced today that results from its Phase 1 trial of Actimab-A were presented at the 58th American Society of Hematology Annual Meeting (ASH) that is currently ongoing in San Diego, CA. Data from the previously conducted Phase 1 study pertaining to safety, efficacy and PB burden were highlighted during the poster session. Actimab-A is currently being studied in a 53-patient Phase 2 clinical trial as a monotherapy for patients newly diagnosed with Acute Myeloid Leukemia (AML) age 60 and above who are ineligible for currently used induction therapies. The Phase 2 trial is studying Actimab-A as a monotherapy administered via two fifteen minute intravenous injections of 2.0 µCi/kg/fraction of Actimab-A given a week apart. PB burden below 200 blasts/µL will serve as an inclusion criteria and patients above this threshold will be administered hydroxyurea to reduce their peripheral blasts counts prior to Actimab-A administration. Results from the Phase 1 trial showed that patients with PB burden below 200 blasts/µL who received a dose of 2.0 µCi/kg/fraction of Actimab-A saw a 50% response rate.

Actinium's PB burden hypothesis states that patients below the key threshold level of 200 blasts/µL have an increased response rate to Actimab-A while patients above the key threshold are unlikely to respond. An analysis of 2 clinical trials with Actimab-A totaling 38 patients, of which 36 were evaluable, showed that 42% (8 of 19) of patients with blasts counts below 200/µL responded to Actimab-A while no patients with blast counts above 200/µL responded to Actimab-A. The Phase 1 trial was a dose escalation study using a 3+3 design. Dose escalation proceeded if dose-limiting toxicities (DLT) were seen in less than

33% of patients. Maximum tolerable dose (MTD) was not reached in the Phase 1 trial.

Dr. Joseph Jurcic, Director of Hematologic Malignancies and Professor of Medicine at Columbia University Medical Center and Principal Investigator of the study said, “Older patients with AML, particularly those that have progressed from MDS, are difficult to treat and have very few treatment options since many have already received lower-intensity therapy with hypomethylating agents. The results from this Phase 1 trial were encouraging in regards to both the safety and efficacy of Actimab-A. We are particularly excited to have identified that patients with peripheral blasts below 200/µL have higher response rates to Actimab-A and that we can reduce blast counts in patients above that level using hydroxyurea. Actimab-A has shown promise in older AML patients, including those previously treated for MDS--a population excluded from trials with most novel agents, including ongoing studies with other CD33-directed therapies. We look forward to continuing to study Actimab-A in the ongoing Phase 2 trial and potentially meeting this critical need.”

Of the 18 patients in the Phase 1 trial, 28% (5 of 18) had objective responses (2 CR, 1CRp and 2 CRi). Amongst patients with objective responses, median response duration was 9.1 months (range, 4.1-16.9 months). At the 3 highest dose levels in the Phase 1 trial (1.0 µCi/kg/fraction - 2.0 µCi/kg/fraction) objective responses were seen in 33% of patients (5 of 15). Mean bone marrow blast reduction amongst evaluable patients was 66% with 57% of patients having bone marrow blast reduction of 50% or greater and 79% of patients (11 of 14) had bone marrow blast reductions after Cycle 1 of therapy. The Phase 1 trial enrolled patients newly diagnosed with AML who are age 60 and above who were administered Actimab-A in combination with low-dose Cytarabine. Median patient age was 77 with 67% of patients having prior myelodysplastic syndrome (MDS) of which, 83% received prior therapy consisting of either hypomethylating agents (HMAs) or a hematopoietic stem cell transplant (HSCT).

A formal interim analysis will occur after 31 patients receive Actimab-A, which the Company expects to occur in mid-2017. The Company anticipates the Phase 2 trial to be complete by the end of 2017.

“Actimab-A, given its benign toxicity profile combined with potent efficacy as evidenced by the results presented today along with its ease of administration via 2 injections, represents an exciting therapy for elderly patients with AML,” said Sandesh Seth, Executive Chairman of Actinium. “Due to our peripheral blast burden hypothesis and optimized Phase 2 protocol we have great excitement for the current Phase 2 clinical trial and future development pathways for Actimab-A.”

About Actimab-A

Actimab-A, Actinium's most advanced alpha particle immunotherapy (APIT) product candidate, is currently in a 53-patient, multicenter Phase 2 trial for patients newly diagnosed with AML age 60 and above. Actimab-A is being developed as a first-line therapy and is a monotherapy that is administered via two 15-minute injections that are given 7 days apart. Actimab-A targets CD33, a protein abundantly expressed on the surface of AML cells via the monoclonal antibody, HuM195, which carries the potent cytotoxic radioisotope actinium-225 to the AML cancer calls. 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. Actimab-A is a second-generation therapy from the Company's HuM195-Alpha program, which was developed at Memorial Sloan Kettering Cancer Center and has now been studied in almost 90 patients in four clinical trials. Actimab-A has been granted Orphan Drug Designation for newly diagnosed AML age 60 and above.

About Actinium Pharmaceuticals, Inc.

Actinium Pharmaceuticals, Inc. is a biopharmaceutical company developing innovative targeted therapies for patients with cancers lacking effective treatment options. Actinium's proprietary platform utilizes monoclonal antibodies to deliver radioisotopes directly to cells of interest in order to kill those cells safely and effectively. The Company's lead product candidate Iomab-B is designed to be used, upon approval, in preparing patients for a hematopoietic stem cell transplant, commonly referred to as bone marrow transplant. A bone marrow transplant is often the only potential cure for patients with blood-borne cancers but the current standard preparation for a transplant requires chemotherapy and/or total body irradiation that result in significant toxicities. Actinium believes Iomab-B will enable a faster and less toxic preparation of patients seeking a bone marrow transplant, leading to increased transplant success and survival rates. The Company is currently conducting a single pivotal 150-patient, multicenter Phase 3 clinical study of Iomab-B in patients with relapsed or refractory acute myeloid leukemia (AML) age 55 and older. The Company's second product candidate, Actimab-A, is currently in a multicenter open-label, 53-patient Phase 2 trial for patients newly diagnosed with AML age 60 and over. Actimab-A is being developed to induce remissions in elderly patients with AML who lack effective treatment options and often cannot tolerate the toxicities of standard frontline therapies. Actinium is also utilizing its alpha-particle immunotherapy (APIT) technology platform to generate new drug candidates based on antibodies linked to the element Actinium-225 that are directed at various cancers that are blood-borne or form solid tumors. Actinium Pharmaceuticals is based in New York, NY. To learn more about Actinium Pharmaceuticals, please visit www.actiniumpharma.com and to follow @ActiniumPharma on Twitter please visit, 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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