June 1, 2016

Actinium Pharmaceuticals Announces Positive Safety and Efficacy Results From Phase 1 Actimab-A Trial in Patients With Newly Diagnosed Acute Myeloid Leukemia and Provides Guidance on Plans for Phase 2 Clinical Trial

NEW YORK, NY -- (Marketwired) -- 06/01/16 --

- Analysis of clinical trials from Actimab-A portion of Actinium's HuM195-Alpha program show low peripheral blast burden results in improved patient responses
- Phase 2 trial to begin enrolling patients in 2H:2016 with revised protocol incorporating latest findings
- Webinar today at 8:00 am EST to discuss results of the Phase 1 trial, key findings regarding peripheral blast burden and the Phase 2 development plan

Actinium Pharmaceuticals, Inc. (NYSE MKT: ATNM) ("Actinium" or the "Company"), a biopharmaceutical Company developing innovative targeted payload immunotherapeutics for the treatment of patients with advanced cancers, today announced positive results from its Phase 1 Actimab-A trial in patients newly diagnosed with acute myeloid leukemia (AML) who are over the age of 60. The median age of patients in the trial was 77 years (range 68-87 years) of which 67% had intermediate-risk cytogenetics and 33% had unfavorable cytogenetics. Importantly, the complete response rate at the dose level which the Company intends to progress into the Phase 2 trial was 50% in patients with low peripheral blast (PB) burden. Most serious adverse events (SAEs) were infections and cytopenias that are considered to be consequences of AML and not drug related.

Dr. Joseph Jurcic, Director of Hematologic Malignancies and Professor of Clinical Medicine at Columbia University Medical Center and Principal Investigator of the study said, "HuM195 conjugated with the alpha particle generator Actinium-225 is a promising technology that has the potency needed to address this difficult leukemia while having the tolerability profile needed in older patients. Results from this Phase 1 trial are particularly compelling when looking at patients with low peripheral blast burden. I look forward to the phase 2 trial in this population of patients."

The Company announced that it will proceed with a Phase 2 trial with Actimab-A at 2 µCi/kg/fractionated dose, the highest dose level from the Phase 1 trial. For the Phase 2 trial, modifications will be made to the protocol including the removal of low dose cytarabine,

which has already been agreed to with the FDA, and the mandatory use of hydroxyurea, which can be used per the current protocol, to reduce PB burden with the goal of accelerating patient enrollment and improving patient outcomes.

The recently completed Phase 1 trial totaled 18 patients having a median age of 77 of which 78% were 75 and older and 28% were 80 and older. Complete responses were observed in 28% of patients at all dose levels and in the three highest dose levels complete response rates equaled 33%. Importantly, the complete response rate at the dose level which the Company intends to progress into the Phase 2 trial was 50% in patients with low PB burden. Of the 18 patients, 67% presented with low PB burden. Also, 67% of patients had secondary AML resulting from myelodysplastic syndrome (MDS). No early mortality was observed within 28 days and 56 day early mortality was observed in 11% of patients. Dose limiting toxicities (DLTs) were observed in 2 patients and both were grade 4 and neither of which were extramedullary. Most serious adverse events (SAEs) were infections and cytopenias that are considered to be consequences of AML and not drug related.

Sandesh Seth, Actinium's Executive Chairman stated, "Given that a majority of AML patients are diagnosed at an older age, it has long been the goal to develop an effective yet tolerable therapy for older patients. We believe that the results from this Phase 1 trial speak to Actimab-A's promising efficacy and tolerability profile. Perhaps most exciting is our discovery that peripheral blast burden plays a significant role in patient responses to Actimab-A. When analyzing the data from two Actimab-A clinical trials we uncovered that patients with low peripheral blast counts experienced a greater anti leukemic effect and achieved significantly higher complete response rates. Armed with this insight, we are very excited to move ahead with the Phase 2 Actimab-A clinical trial."

The Phase 2 portion of the trial will enroll an additional 47 patients bringing the total number of patients in the Phase 1/2 Actimab-A trial to 65. This multi-center, single arm trial will enroll patients newly diagnosed with AML who are over the age of 60. The number of centers for the Phase 2 portion of the trial are expected to be at least double the number of centers in the Phase 1 portion of the trial. In addition, the protocol for the Phase 2 trial has been revised to eliminate low dose cytarabine, which the FDA has already agreed to. The peripheral blast burden key threshold level will serve as an inclusion criteria going forward and the use of hydroxyurea to control peripheral blast burden, which was permitted in the Phase 1 protocol, will be mandated in order to lower PB burden. Patient enrollment is expected to commence in the second half of 2016.

Webinar Information:
Date: June 1, 2016
Time: 8:00 am EST
Webcast Link: http://edge.media-server.com/m/p/2apczh5s
Participant Toll-Free Dial-In Number: (844) 309-0611

Participant International Dial-In Number: (574) 990-9939

About Actimab-A

Actimab-A, Actinium's most advanced alpha particle immunotherapy (APIT) program, is currently in a single arm, multicenter trial Phase 1/2 trial for patients newly diagnosed with AML over the age of 60. Actimab-A is being developed as a first-line therapy and it has

attracted support from some of the leading experts at the most prestigious cancer treatment hospitals due to the potential of its safety and efficacy profile. Actimab-A consists of the monoclonal antibody, HuM195, and the radioisotope, actinium-225. Actinium-225 decays by giving off high-energy alpha particles, which kill cancer cells. When actinium 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. HuM195 is the humanized version of M195 and is a monoclonal antibody that targets CD33, which is abundantly found on myeloid leukemia cells. Both the alpha particle technology and HuM195 were initially developed at Memorial Sloan Kettering Cancer Center. Actimab-A is a second-generation therapy from the Company's HuM195-Alpha program, which has now been studied in over 85 patients in four clinical trials.

About Actinium Pharmaceuticals

Actinium Pharmaceuticals, Inc. (www.actiniumpharma.com) is a New York-based biopharmaceutical company developing innovative targeted payload immunotherapeutics for the treatment of advanced cancers. Actinium's targeted radiotherapy products are based on its proprietary delivery platform for the therapeutic utilization of alpha-emitting actinium-225 and bismuth-213 and certain beta emitting radiopharmaceuticals in conjunction with monoclonal antibodies. The Company's lead radiopharmaceutical product candidate Iomab-B is designed to be used, upon approval, in preparing patients for hematopoietic stem cell transplant, commonly referred to as bone marrow transplant. The Company plans to conduct a single, pivotal, multicenter Phase 3 clinical study of Iomab-B in refractory and relapsed AML patients over the age of 55 with a primary endpoint of durable complete remission. The Company's second product candidate, Actimab-A, is continuing its clinical development in a Phase 1/2 trial for newly diagnosed AML patients over the age of 60 in a single-arm multicenter trial.

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