



Actinium Announces Initiation of Phase 2 Clinical Trial of Actimab-A in Patients Newly Diagnosed with Acute Myeloid Leukemia Over Age 60

- *Webinar to be held at 9:00 AM ET to highlight Actimab-A Phase 2 clinical trial and protocol revisions agreed to by the FDA*
- *Protocol revisions agreed to by the FDA include the use of peripheral blast burden as an inclusion criteria, the mandated use of Hydroxyurea in patients with high peripheral blast burden and the elimination of low dose cytarabine*
- *Trial will enroll 53 patients in a multicenter, open-label study designed to evaluate patient complete response rates and overall survival*

NEW YORK, Sept. 27, 2016 (GLOBE NEWSWIRE) -- Actinium Pharmaceuticals, Inc. (NYSE MKT:ATNM) ("Actinium" or "the Company"), a biopharmaceutical Company developing innovative targeted payload immunotherapeutics for the treatment of advanced cancers, announced today that the Company has initiated a Phase 2 clinical trial of Actimab-A in patients newly diagnosed with Acute Myeloid Leukemia (AML) who are over the age of 60. Actimab-A, Actinium's most advanced alpha particle immunotherapy (APIT) program consists of the CD33 targeting monoclonal antibody, HuM195, and the alpha-emitting radioisotope, actinium-225.

"We are excited to have initiated the Phase 2 trial of Actimab-A for elderly patients who are newly diagnosed with AML and ineligible for 7+3 treatment. These older patients face a poor prognosis and have limited viable treatment options" said Sandesh Seth, Actinium's Executive Chairman. "We are encouraged by the safety and efficacy signals we have seen thus far and look forward to the execution of this trial with an eye toward interim and top-line results which are both expected in 2017."

This Phase 2 clinical trial is a multicenter, open-label study that will enroll 53 patients. Patients will receive 2.0 $\mu\text{Ci/kg}$ /fractionated dose of Actimab-A via two injections given at day 1 and day 7. The Phase 2 trial is designed to evaluate complete response rates at up to day 42 after Actimab-A administration, where complete response is defined as complete remission (CR) or complete remission with incomplete platelet recovery (CRp). A formal interim analysis is expected to occur in mid-2017 with topline results expected in the second half of 2017. The Phase 2 trial will include peripheral blast burden as an inclusion criteria and in patients with high peripheral blast (PB) burden, the use of Hydroxyurea will be mandated with the goal of bringing PB burden below a key threshold number that the Company has identified from two previously complete Phase 1 clinical trials totaling 38 patients. In addition,

the use of granulocyte colony-stimulating factors (GCSF) will be mandated. Low dose cytarabine has been eliminated from the protocol and the Phase 2 clinical trial will evaluate Actimab-A as a monotherapy. The secondary endpoint of the Phase 2 trial will be overall survival.

Dr. Joseph Jurcic, Principal Investigator of the Actimab-A Phase 2 trial and Director of Hematologic Malignancies; Professor of Medicine at Columbia University Medical Center said, "Actimab-A has been studied in two clinical trials thus far in patients with AML ranging in age from 18-87 who had a wide array of genetic risk factors that were at various stages of disease progression. Actimab-A has shown a promising safety and efficacy profile thus far that we believe differentiates Actimab-A from other CD33 targeting drug candidate, which is an exciting space in AML. Our PB burden hypothesis indicates that of all factors related to AML including age, stage of disease and genetic factors, peripheral blast burden showed to be the most relevant. With PB burden serving as an inclusion criteria in this Phase 2 trial and the use of Hydroxyurea being mandated in patients with PB burden above a key threshold we look forward to conducting this clinical trial in this older patient population that has a great unmet medical need."

The Company will host a webinar Tuesday, September 27, 2016 at 9:00 AM ET to discuss the Phase 2 clinical trial. Details for the webinar are as follows:

Date: Tuesday, September 27, 2016

Time: 9:00 AM ET

Webinar Link: <https://onecast.thinkpragmatic.com/ses/awQiM-9OD7lysoul6ZD6BQ~~>

Speakers: *Joseph Jurcic, M.D., Director of Hematologic Malignancies; Professor of Medicine at Columbia University Medical Center. Actimab-A Principal Investigator*

Sandesh Seth, Executive Chairman, Actinium Pharmaceuticals

Dragan Cicic, M.D., Chief Medical Officer, Actinium Pharmaceuticals

About Actimab-A

Actimab-A, Actinium's most advanced alpha particle immunotherapy (APIT) program, is in a multicenter, open-label, Phase 2 clinical trial for patients newly diagnosed with Acute Myeloid Leukemia (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 almost 90 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 radioimmunotherapy 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 lomab-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 is conducting a single, pivotal, multicenter Phase 3 clinical study of lomab-B in refractory or 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 in a 53 patient, multicenter, open-label Phase 2 trial for patients newly diagnosed with AML 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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