

November 6, 2014



Actinium Pharmaceuticals Actimab-A Phase I/II Trial Interim Data Demonstrate Extension of Overall Survival to 9.1 Months in Elderly Secondary Acute Myeloid Leukemia

NEW YORK, NY -- (Marketwired) -- 11/06/14 --

- *Significant Reductions in Bone Marrow Blasts Demonstrated*
- *No Early Mortality Observed*
- *ASH Abstract Highlights Actimab-A's Significant Survival Benefit in Patients with Secondary Acute Myeloid Leukemia*

Actinium Pharmaceuticals, Inc. ("Actinium" or the "Company") (NYSE MKT: ATNM), a biopharmaceutical company developing innovative targeted payload immunotherapeutics for the treatment of advanced cancers, today announced positive interim data from the ongoing Phase I/II trial of Actimab-A in older patients with newly diagnosed Acute Myeloid Leukemia ("AML"). Most notably, median overall survival ("OS") of the seven secondary AML patients (with prior myelodysplastic syndrome, or MDS) in the study was 9.1 months, which is a prolongation of life compared to historical norms of typically 2 to 5 months.¹ Older AML patients are already higher risk, with secondary AML patients considered to have the more severe and less treatable form of AML, and the shortest expected survival. The clinical abstract will be published and available online in *Blood*, the official Journal of the American Society of Hematology.

"Alpha emitting isotopes may result in more efficient leukemia cell killing without the toxicity of intensive chemotherapy," said Joseph Jurcic, M.D., Professor of Medicine and Director of the Hematologic Malignancies Section of the Hematology/Oncology Division at Columbia University Medical Center, and lead study investigator. "In this study, Actimab-A was safely and effectively combined with low-dose chemotherapy in older AML patients. Even at this early stage in development, the tolerability of the regimen and promising survival data in this poor-risk population are highly encouraging and support our center's commitment to this program. Because many of these patients cannot tolerate intensive chemotherapy, potentially less toxic treatments such as this are desperately needed."

"We believe the data presented provide further evidence that Actimab-A has substantial clinical activity, including a survival benefit, in the hardest to treat AML patients," said Dragan Cicic MD, Chief Medical Officer of Actinium. "The potential efficacy in killing other treatment resistant leukemia cells combined with the limited side effects identified in the study to date could offer a new hope to patients whose age, comorbidities and nature of

disease currently leaves them with very limited treatment options. We continue to work with a world-class team of clinical investigators to advance this program and technology."

The interim analysis from this company-sponsored trial is consistent with results from the prior three trials in Actinium's HuM195-Alpha Program. The abstract, *Phase I Trial of Targeted Alpha-Particle Therapy Using Actinium-225 (²²⁵Ac)-Lintuzumab (Anti-CD33) in Combination with Low-Dose Cytarabine (LDAC) for Older Patients with Untreated Acute Myeloid Leukemia (AML)*, will be published and available online in *Blood*, the official Journal of the American Society of Hematology.

In this interim analysis, a total of 9 patients were evaluated thus far with a median age of 76 (range 73-81). All had intermediate or poor risk cytogenetics, and 7 of 9 patients had secondary AML as a result of prior MDS. These 7 secondary AML patients had a median OS of 9.1 months from study entry (range 2.3-24 months). Of these, 2 patients lived longer than 12 months and the longest surviving patient lived greater than 24 months. Overall, for all 9 patients median OS was 5.4 months (range 2.2-24 months).

Two dosing levels have been evaluated to date (0.5 or 1.0 μ Ci/kg/fraction), and the study is ongoing at higher doses until the maximum tolerated dose ("MTD") is reached. Despite not having yet reached MTD, the Company has observed significant bone marrow blast reductions, another important marker of efficacy. Of the 7 evaluable patients in the overall study, 5 patients (71%) had bone marrow blast reductions with a mean of 61% reduction.

The sites participating in this multi-center trial are Memorial Sloan Kettering Cancer Center, MD Anderson Cancer Center, Johns Hopkins Medicine, Columbia University Medical Center, University of Pennsylvania Health System, Fred Hutchinson Cancer Research Center, and the Texas Oncology-Baylor Charles A. Sammons Cancer Center. The Company expects to announce further information related to Actimab-A development subsequent to its Clinical Advisory Board meeting, during the ASH 2014 time frame (December 6-9, 2014).

Elderly, high risk patients ordinarily have a life expectancy of 5 or fewer months if treated with standard chemotherapy, though only about a third of them do receive treatment because of toxicity. The other two-thirds receive best supportive care, with 2 months survival, according to Oran and Weisdorf (*Haematologica* 2012; 1916-24). The majority (5 of 7) of the secondary AML patients receiving Actimab-A had been previously treated with hypomethylating agents, a criterion which would have excluded such patients from some other clinical trials. Previous treatment with hypomethylating agents, and subsequent failure, further demonstrates the disease severity of patients in the Actimab-A trial.

The safety profile of Actimab-A was satisfactory and acceptable for this patient population in this interim analysis. The only drug-related serious adverse events seen were related to myelosuppression, which is expected in the treatment of leukemia.

The antibody portion of Actimab-A, HuM195 (also known as lintuzumab) when labeled with alpha particles has been evaluated in three prior studies, including two studies of Bismab-A, which was an earlier, first generation construct, and an investigator sponsored trial with Actimab-A. Today's interim results mark the first look at what the Company believes are clinically meaningful data in the ongoing, Company sponsored Phase I/II trial of Actimab-A.

Secondary AML is a common form of AML in the U.S., and is defined as AML that develops

following exposure to cytotoxic agents or as a subsequent event in another hematologic disorder, usually MDS. According to the American Cancer Society there is an annual incidence of 12,000 new cases of MDS in the U.S. Between 30% and 50% of these new cases go on to develop AML, or approximately 3,600-6,000 secondary AML patients in the U.S.

About Actimab-A

Actimab-A is a radiolabeled antibody being developed for newly diagnosed AML in patients over 60, and is currently in a multicenter Phase I/II clinical trial. Based on Actinium's alpha-particle immunotherapy (APIT) platform, Actimab-A consists of the CD33 antibody lintuzumab linked to the actinium-225 payload. Actimab-A has attracted support from leading experts at the prestigious and high-volume cancer treatment hospitals due to the potential of its safety and efficacy profile, as well as its potential potency, specificity and ease of use. Clinical trials are being conducted at world-class cancer institutions such as Memorial Sloan Kettering Cancer Center, MD Anderson Cancer Center, Johns Hopkins Medicine, Columbia University Medical Center, University of Pennsylvania Health System, Fred Hutchinson Cancer Research Center, and the Texas Oncology-Baylor Charles A. Sammons Cancer Center. The Company expects additional updates to its Phase I/II clinical trial in December 2014. Actimab candidates are in early development for other cancers.

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 lomab-B will be used, upon approval, in preparing patients for hematopoietic stem cell transplant, commonly referred to as bone marrow transplant. The Company is preparing a single, pivotal, multicenter Phase 3 clinical study of lomab-B in refractory and relapsed AML patients over the age of 55 with a primary endpoint of durable complete remission. The Company's second program, 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 Statement 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 undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

¹ Oran B, and Weisdorf DJ. Survival for older patients with acute myeloid leukemia: a population-based study. *Haematologica* 2012; 97(12):1916-1924.

doi:10.3324/haematol.2012.066100.

¹ N Okuyama et al, *Prognosis of acute myeloid leukemia transformed from myelodysplastic syndromes: A multicenter retrospective study*, *Leukemia Research* 37 (2013) 862- 867

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Source: Actinium Pharmaceuticals