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# Actinium Announces New Data From Ongoing Phase 1/2 Trial of Actimab-A Demonstrating Safety and Robust Clinical Efficacy in High Risk Elderly Acute Myeloid Leukemia Patients

## Strong Anti-Leukemic Effect Demonstrated in Cohort 3; No Dose Limiting Toxicities Observed

NEW YORK, NY -- (Marketwired) -- 03/18/15 -- [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 the completion of the third cohort of the Company's ongoing multi-center Phase 1/2 Study for Actimab-A for the treatment of newly diagnosed Acute Myeloid Leukemia (AML) in elderly patients. Cohort 3, which included 3 additional patients, demonstrated no dose limiting toxicities in patients older than 60 and up to 87 years of age who were not eligible for currently approved therapies. Two out of three Actimab-A treated patients achieved complete remission with different degrees of hematological recovery (CRi). These responses were documented in the settings of high pre-treatment leukemia burdens of up to 88% in the bone marrow. In the previous cohort treated at a lower dose level of Actimab-A, one patient achieved CRi.

"The positive results on both safety and anti-leukemic effect demonstrated in the completed third cohort represents a significant achievement for the Actimab-A program, and supports the advancement to a higher dose with the potential to further enhance the already strong results we have seen to date," stated Dragan Cicic, MD, Chief Medical Officer of Actinium. "We believe the responses observed for Actimab-A, with minimal toxicity being reported, are impressive in this disease setting. These findings build upon those presented and published over the past year which demonstrated a clear survival benefit in secondary AML patients. We remain steadfast in our belief that Actimab-A could play an important role in the treatment regimen for newly diagnosed elderly secondary AML patients who currently have limited treatment options, and have historically achieved overall survival of only 2 to 5 months, depending on treatment modality."

The primary goals of the Phase 1 trial portion of the ongoing Phase 1/2 clinical trial are to establish the safety profile, determine the maximum tolerated dose (MTD) and assess the preliminary clinical activity of Actimab-A in newly diagnosed AML patients over 60. In the first cohort, patients were treated with two doses of Actimab-A at 0.5  $\mu\text{Ci}/\text{kg}$  activity level. In the second cohort, patients received two doses of Actimab-A at 1.0  $\mu\text{Ci}/\text{kg}$  activity level, and in the third cohort, patients received two doses at 1.5  $\mu\text{Ci}/\text{kg}$  activity. As the drug candidate

continues to be well tolerated in these high risk elderly AML patients, the trial will advance to a fourth cohort at two doses of Actimab-A at a  $\mu\text{Ci}/\text{kg}$  activity level of 2.0. Upon reaching the MTD in the Phase 1 portion of the trial, the Phase 2 portion would begin at the established MTD level.

Actinium previously announced positive interim data from the ongoing Phase 1/2 trial of Actimab-A in older patients with newly diagnosed 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 compares favorably to historical norms of 2 to 5 months, depending on the treatment modality. Older AML patients are already higher risk, with secondary AML patients considered to have the more severe and less treatable form of AML, and as a consequence, have shorter expected survival. The clinical abstract was published and is available online in *Blood*, the official Journal of the American Society of Hematology.

### **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 1/2 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 1/2 clinical trial in December 2014. Actimab candidates are in early development for other cancers.

### **About Actinium Pharmaceuticals**

Actinium Pharmaceuticals, Inc. ([www.actiniumpharma.com](http://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 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 plans to conduct 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 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 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 such 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.

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