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# Actinium Files Orphan Drug Application for Use of Actimab-A in the Treatment of Newly Diagnosed Acute Myeloid Leukemia in Elderly Patients

*Orphan Drug Designation Could Provide Faster Regulatory Review and Financial Incentives*

NEW YORK-- [Actinium Pharmaceuticals, Inc.](#) (NYSE MKT: ATNM) ("Actinium" or "the Company"), a biopharmaceutical company developing innovative targeted payload immunotherapeutics for the treatment of advanced cancers, today announced it has filed an Application for Orphan Drug Designation with the U.S. Food and Drug Administration (FDA) for Actimab-A, a radiolabeled antibody being developed for newly diagnosed AML in patients over 60, and is currently in a multicenter Phase 1/2 clinical trial. The Company expects to provide interim results for the Actimab-A trial around the same time as the American Society of Hematology (ASH) meeting in December 2014.

Patients over age 60 comprise the majority of those diagnosed with acute myeloid leukemia (AML), but treatment approaches in this population are limited because a majority of these individuals are judged too frail and unable to tolerate standard induction chemotherapy. Orphan drug designation is granted to treatments that are expected to provide significant therapeutic advantage over existing treatments and that target conditions affecting 200,000 or fewer U.S. patients per year. Orphan-designated drugs are eligible for incentives such as a faster approval process and additional market exclusivity.

Kaushik J. Dave, Ph.D., President and CEO of Actinium stated, "Acute myeloid leukemia is the most common acute leukemia affecting adults and accounts for the largest number of annual deaths due to leukemias. With limited treatment options for a majority of AML patients over age 60 who cannot tolerate standard induction chemotherapy, we are confident that Actimab-A may offer a new potential treatment paradigm by utilizing alpha emitters which we believe should provide more efficient leukemia cell killing without the toxicity of intensive chemotherapy. We believe that Actimab-A meets the criteria for orphan drug designation, and represents a significant potential therapeutic advance over currently available treatments options for newly diagnosed elderly AML patients. We remain committed to addressing significant unmet medical needs for AML patients and are moving steadfastly to advance our Phase 1/2 Actimab-A clinical trial and look forward to releasing interim data later this year."

## **About Orphan Drug Status**

The FDA, through its Office of Orphan Products Development (OOPD), grants orphan status to drugs and biologic products that are intended for the safe and effective treatment, diagnosis, or prevention of rare diseases or disorders that affect fewer than 200,000 people

in the U.S. Orphan drug designation provides a drug developer with certain benefits and incentives, including a period of marketing exclusivity if regulatory approval is ultimately received for the designated indication; potential tax credits on U.S. clinical trials; eligibility for orphan drug grants; and waiver of certain administrative fees.

### **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, Johns Hopkins Medicine, University of Pennsylvania Health System, Fred Hutchinson Cancer Research Center, MD Anderson Cancer Center and the Texas Oncology-Baylor Charles A. Sammons Cancer Center. The Company expects interim Phase I/II clinical trial results 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 is 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 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 Acute Myeloid Leukemia (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 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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