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# Actinium Provides Business Update for 2015 and Achievements for 2014

## Outlook for 2015 Includes Initiating lomab-B Phase 3 Pivotal Trial and Advancing Licensing Discussions in Europe and Asia; Completion of Phase 1 Actimab-A Trial, Progression Into Phase 2 to Support Global Licensing Activity

NEW YORK, NY -- (Marketwired) -- 03/10/15 -- [Actinium Pharmaceuticals, Inc.](#) (NYSE MKT: ATNM) ("Actinium" or "the Company"), a biopharmaceutical company developing innovative targeted payload immunotherapeutics for the treatment of advanced cancers, today provided an overview of the Company's 2014 achievements and a business update for 2015. The stated achievements and highlights below demonstrate the significant progress the Company has made on key initiatives to support the advancement of the ongoing Phase 1/2 program and upcoming Phase 3 clinical development program for Actimab-A and lomab-B, respectively. In addition, the Company continues to expand its visibility with leading bone marrow specialists; enhance its leadership team as most recently evidenced by the addition of Dr. Roland Turck, former President, Global Specialty Medicine, Bayer Healthcare as Senior Board Advisor; and is actively pursuing partnering and licensing opportunities for both products to support further clinical development across multiple indications in cancer and future commercialization.

Corporate and clinical milestones achieved during 2014 include:

### **Key 2014 Achievements**

- Completion of Technology Transfer and Progression of lomab<sup>™</sup>-B Towards Phase 3 Clinical Trial
- Advanced Actimab-A Phase 1/2 Program Supported by Positive Interim Clinical Data; Received Orphan Drug Designation from FDA
- Initiated Support for Third Development Program
- Uplisted to NYSE Markets and Added to the Russell<sup>®</sup> Indexes Both Support Increased Liquidity
- Fortified Company Infrastructure with Key Executive Hires
- Strengthened Balance Sheet

"We wish to thank our existing shareholders for their continued support this year," stated Kaushik J. Dave, Ph.D., President and Chief Executive Officer. "We have made significant progress in a number of areas, including the advancement of our lead development program lomab-B which is anticipated to commence a Phase 3 trial in 2015, as well as reporting promising interim results in the ongoing Phase 1/2 trial for Actimab-A. Based on the favorable safety profile in clinical trials to date, Actimab-A has the potential to be a low

intensity therapy for older AML patients. With respect to lomab-B, the Company is finalizing the manufacturing process to ensure the commercial quality as we enter the Phase 3 trial and, if approved by FDA, support the launch. Given the significant unmet medical need potentially addressed by lomab-B for bone marrow transplant, and Actimab-A initially in newly diagnosed secondary acute myeloid leukemia patients, we remain confident in the potential value-creation the Company can derive from advancing both programs closer to commercialization and through ongoing partnering and licensing activities. The entire team remains focused on executing on value-creating milestones."

### ***Recent Highlights:***

At a Company event held concurrent with the February 2015 BMT Tandem Meetings (the combined annual meetings of Center for International Blood & Marrow Transplant Research (CIBMTR) and the American Society of Blood and Marrow Transplantation (ASBMT)), leading bone marrow specialists, representing major academic cancer centers with high volumes of bone marrow transplant (BMT) patients, demonstrated significant interest in participating in the upcoming lomab-B Phase 3 clinical trial. The validation from these leading BMT physicians is anticipated to support the expansion of participation of leading sites and the pace of subject enrollment upon commencement of the trial.

Dragan Cicic, MD, Chief Medical Officer of Actinium, commented, "Several well attended sessions including one entitled 'What is the Optimal Conditioning Regimen?,' led by Frederick Appelbaum, MD from the Fred Hutchinson Cancer Research Center which cited the strong historical safety and efficacy of lomab-B, continue to increase awareness and support for our upcoming Phase 3 clinical trial from leading bone marrow transplant physicians. The growing positive reception and interest bodes well for our ability to drive participation from leading, high volume bone marrow transplant centers and drive patient recruitment."

The Board has retained Roland Turck, MD, former President, Global Specialty Medicine, Bayer Healthcare, to provide strategic advice. At Bayer, Dr. Turck played a leadership role in the commercialization of the alpha-radiopharmaceutical Xofigo<sup>®</sup> whose successful launch he prepared in close collaboration with Algeta ASA which was subsequently purchased by Bayer for \$2.9 billion. Dr. Turck will provide guidance on the ongoing clinical development, pre-commercialization, and licensing activities for lomab-B and clinical development and licensing activities for Actimab-A.

### ***2015 Outlook:***

- Commence lomab<sup>™</sup>-B Phase 3 Clinical Trial and Seek Orphan Drug Designation
- Announce Completion and Clinical Data from Phase 1 Portion of Actimab-A, a Second Generation Product Candidate for Elderly AML
- Commence the Phase 2 Portion of the Actimab-A trial
- Initiate Preclinical Studies for a Third Program
- Advance Partnering and Licensing Activity for Both Actimab-A and lomab-B
- Expand Clinical, Regulatory and Pre-Commercialization Expertise to Accelerate Clinical Development and Licensing Activities

"In the near-term, we expect to move Actimab-A into the Phase 2 portion of the trial and more importantly, we plan to begin the lomab-B Phase 3 trial," concluded Dr. Dave. "In

addition, we will further strengthen our pipeline with the completion of labeling for the third program using our APIT platform and initiate preclinical studies to support first in man clinical trials. Furthermore, to support our near-term and longer-term objectives, the addition of Dr. Turck is an example of the Company's commitment to add experienced talent to enhance and accelerate the development, commercialization, and licensing potential of these highly differentiated clinical assets. Longer-term, if successful, we expect to bring lomab-B to market across multiple indications and further establish the clinical validity of Actimab-A to maximize the value of our pipeline and support our efforts to build a world-class bone marrow transplant and oncology company."

### ***About Bone Marrow Transplant***

Bone marrow transplants (BMT) are most commonly used to treat leukemia and lymphoma, conditions incurred when a blood or immune cell, respectively, becomes cancerous and proliferates. Together, these diseases account for some 50,000 to 75,000 new cases annually in the United States. BMT involves first clearing a patient's body of his or her own immune cells and then transplanting bone marrow, the source of all blood- and immune-forming cells, from a tissue-matched donor. The new cells, which are free of cancer, repopulate the patient's bone marrow and eventually give rise to a functioning set of blood and immune cells, providing a lifelong cure. BMT offers the chance of a "curative" outcome (2+ year survival), and therefore can play a central role in the treatment of AML. The impact of BMT on AML continues to increase with AML being the most common and fastest growing indication for allogeneic BMT, comprising 25% to 30% of all BMT recipients. There are currently over 100,000 BMT survivors across all indications and this number is expected to increase to 250,000 by 2020 and 500,000 by 2030, with 25% of them over age 60.

### ***About AML***

Acute myeloid leukemia (AML) is an aggressive cancer of the blood and bone marrow. It is characterized by an uncontrolled proliferation of immature blast cells in the bone marrow. The American Cancer Society estimates there will be approximately 18,860 new cases of AML and approximately 10,460 deaths from AML in the U.S. in 2014. Patients over age 60 comprise the majority of those diagnosed with AML, with a median age of a patient diagnosed with AML of about 67 years. Treatment approaches in this population are limited because a majority of these individuals are judged too frail and unable to tolerate standard induction chemotherapy or having forms of disease generally unresponsive to currently available drugs. 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).

### ***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<sup>™</sup>-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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