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# Actinium Engages Goodwin Biotechnology to Supply lomab™-B for Its Phase 3 Clinical Study

*Contract for GMP Manufacturing Represents a Major Step Forward in Actinium's Progress Toward a Key Milestone*

NEW YORK-- Actinium Pharmaceuticals, Inc. (OTCQB:ATNM.OB) ("Actinium" or "the Company"), a biopharmaceutical Company developing innovative targeted payload immunotherapeutics for the treatment of advanced cancers, announced today that the Company entered into a manufacturing supply agreement with Goodwin Biotechnology, Inc. ("Goodwin"). According to the agreement, Goodwin will oversee the current Good Manufacturing Practices (cGMP) production of a monoclonal antibody anticipated to be used in an upcoming phase 3 clinical trial of lomab™-B. lomab™-B will be used in preparing patients for hematopoietic stem cell transplant (HSCT), commonly referred to as bone marrow transplant (BMT).

"This agreement with Goodwin represents a major risk mitigation step in conducting our phase 3 trial of lomab™-B," said Kaushik J. Dave, President and CEO of Actinium. "Goodwin has significant experience in working with companies like ours and the capabilities to provide the scale-up needed for a late-stage clinical trial. Goodwin's competencies in process and product implementation, quality assurance, and GMP manufacturing make it ideally suited as a manufacturing partner for Actinium as we look forward to launching this pivotal phase 3 trial later this year."

"We are very excited to be working with Actinium on lomab™-B, their lead product candidate," said Karl Pinto, CEO of Goodwin. "Actinium's cutting edge proprietary platform is able to target different types of cancers that are without any approved treatment options. We look forward to a long-term partnership with Actinium, not only on lomab™-B, but hopefully also on other products in their pipeline such as Actimab-A."

## **About Goodwin Biotechnology, Inc.**

Goodwin Biotechnology is a world-class CMO that offers a Single Source Solution™ through partnerships with clients for cell line development or exploratory proof of concept projects through process development and cGMP contract manufacturing of monoclonal antibodies, recombinant proteins, vaccines and Antibody Drug Conjugates (ADCs) for early and late stage clinical trials. By working with GBI, our clients can enhance the value of their product candidates with clear development and manufacturing strategies as well as a roadmap to meet the highest quality product requirements from the milligram and gram range to kilogram quantities as the product candidates move along the clinical approval pathway in a cost-effective, timely, and cGMP compliant manner to enhance patients' lives. With over 20 years

of experience as an independent contract manufacturer, GBI has worked as a strategic partner with companies of all sizes from small university spin-offs to major research institutes, government agencies and large, established and multi-national biopharmaceutical companies. Additional information may be found at [www.GoodwinBio.com](http://www.GoodwinBio.com).

## **About Actinium Pharmaceuticals**

Actinium Pharmaceuticals, Inc. ([ATNM.OB](http://ATNM.OB)) 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 conducting 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. For more information, please visit [www.actiniumpharmaceuticals.com](http://www.actiniumpharmaceuticals.com).

## **About lomab™-B**

lomab™-B will be used in preparing patients for hematopoietic stem cell transplant, commonly referred to as bone marrow transplant which is the fastest growing hospital procedure in the U.S. The Company established an agreement with the FDA that the path to a Biologics License Application (BLA) submission will include a single, pivotal Phase 3 clinical study if it is successful. The trial population in this two arm, randomized, controlled, multicenter trial will be refractory and relapsed Acute Myeloid Leukemia (AML) patients over the age of 55. The trial size was set at 150 patients with 75 patients per arm. The study design of the pivotal trial is based on results of an earlier Phase 1/2 trial in which sixty percent of the older patients with refractory and relapsed AML exhibited disease free survival estimated at six months. The primary endpoint in the pivotal Phase 3 trial is durable complete remission, defined as a complete remission lasting at least 6 months. There are currently no treatments approved by the FDA for AML in this patient population and there is no defined standard of care. lomab™-B has completed several physician sponsored clinical trials examining its potential as a conditioning regimen prior to a bone marrow transplant in various blood cancers including the Phase 1/2 study in relapsed and/or refractory AML patients. The results of these studies in over 300 patients have demonstrated the potential of lomab™-B to create a new treatment paradigm for bone marrow transplants by: expanding the pool to ineligible patients who do not have any viable treatment options currently; enabling a shorter and safer preparatory interval for HSCT; reducing post-transplant complications; and showing a clear survival benefit including curative potential.

lomab™-B is a radioimmunoconjugate consisting of BC8, a novel murine monoclonal antibody, and iodine 131 radioisotope. BC8 has been developed by Fred Hutchinson Cancer Research Center to target CD45, a pan-leukocytic antigen widely expressed on white blood cells. This antigen makes BC8 potentially useful in targeting white blood cells in preparation for hematopoietic stem cell transplantation in a number of blood cancer indications, including acute myeloid leukemia (AML), chronic myeloid leukemia (CML), acute lymphoblastic

leukemia (ALL), chronic lymphocytic leukemia (CLL), Hodgkin disease (HD), Non-Hodgkin lymphomas (NHL) and multiple myeloma (MM). When labeled with radioactive isotopes, BC8 carries radioactivity directly to the site of cancerous growth and bone marrow while avoiding effects of radiation on most healthy tissues.

**For more information:**

Visit our web site [www.actiniumpharmaceuticals.com](http://www.actiniumpharmaceuticals.com)

**Forward-Looking Statement for Actinium Pharmaceuticals, Inc.**

This news release contains “forward-looking statements” as that term is 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 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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