



Orphan Drug Designation Anticipated to Provide Faster Regulatory Review, Financial Incentives and Market Exclusivity

NEW YORK, NY -- 03/30/16 -- **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 that the U.S. Food and Drug Administration (FDA) has granted

orphan drug

designation for

lomab-B

, a radioimmunotherapeutic that conditions relapsed and refractory Acute Myeloid Leukemia (AML) patients for a Hematopoietic Stem Cell Transplant (HSCT), commonly referred to as a Bone Marrow Transplant (BMT). lomab-B will soon begin a 150 patient, pivotal Phase 3 multicenter trial in relapsed and refractory AML patients over the age of 55.

Sandesh Seth, Executive Chairman of Actinium stated, "We are pleased to have been granted orphan drug status by the FDA for lomab-B, particularly ahead of its pivotal Phase 3 clinical trial. There has not been a new drug approved for relapsed and refractory AML patients over the age of 55 in decades and with lomab-B being the only therapy of its kind, we are pleased to have achieved this important milestone. Orphan drug status for lomab-B follows Actimab-A, which was granted the designation in November 2014. Orphan drug status provides Actinium with several development and financial incentives, including seven years of market exclusivity in the United States, if lomab-B receives marketing approval and exemption from prescription drug user fees."

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 lomab-B

lomab-B is a radioimmunoconjugate consisting of BC8, a novel murine monoclonal antibody, and iodine-131 radioisotope. BC8 has been developed by the 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's 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.

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 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 Statements 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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Actinium Receives Orphan Drug Designation From FDA for lomab-B in Treating Refractory and Relapsed /

Écrit par Actinium Pharmaceuticals

Jeudi, 31 Mars 2016 14:32 - Mis à jour Jeudi, 31 Mars 2016 14:40
