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Actinium Files Orphan Drug Application for Use of lomab-B in Treating Refractory and Relapsed Acute Myeloid Leukemia in Elderly Patients

Orphan Drug Designation Could Provide Faster Regulatory Review and Financial Incentives

NEW YORK, NY -- (Marketwired) -- 11/23/15 --

Actinium Pharmaceuticals, Inc. (NYSE MKT: ATNM) ("Actinium" or "the Company"), is a biopharmaceutical company developing innovative targeted payload immunotherapeutics for the treatment of advanced cancers. Actinium announced today that it has filed an Application for Orphan Drug Designation with the U.S. Food and Drug Administration (FDA) for lomab-B, a radioimmunotherapeutic that conditions refractory and relapsed Acute Myeloid Leukemia (AML) patients for a Hematopoietic Stem Cell Transplant (HSCT), commonly referred to as a Bone Marrow Transplant (BMT). The Company has recently submitted an Investigational New Drug (IND) application for lomab-B with the FDA and is preparing for a pivotal, Phase 3 trial.

Kaushik J. Dave, Ph.D., MBA, CEO of Actinium stated, "We are pleased to have filed an Application for Orphan Drug Designation for lomab-B. We are confident that lomab-B meets the criteria for Orphan Drug Designation and are eager to begin the Phase 3, pivotal trial for lomab-B. Acute Myeloid Leukemia is the most common acute leukemia affecting adults and accounts for the largest number of annual deaths due to leukemia. Refractory and relapsed AML patients, particularly elderly patients, have very few, if any, treatment options other than a Bone Marrow Transplant. Unfortunately, many of these patients cannot tolerate the intensive chemotherapy given prior to BMT. We believe that lomab-B will allow a greater number of AML patients to receive a BMT and could be a paradigm shift in the way AML patients are treated."

Actinium's Actimab-A, which is intended to treat newly diagnosed AML patients over the age of 60, received Orphan Drug Designation on December 1, 2014. Results from the Phase 1 portion of Actimab-A's Phase 1/2 trial will be presented at the 57th American Society of Hematology (ASH) Annual Meeting being held in Orlando, Florida on December 4 - 8, 2015. Actimab-A data, including patients from the fourth and final cohort, will be presented in a poster session on December 7, 2015 at 6 pm EST.

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 Iomab-B

Iomab-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 Iomab-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 Iomab-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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