September 20, 2016

Actinium Pharmaceuticals Selects Vector Oncology as its Clinical Research Organization for Actimab-A Phase 2 Trial

CRO Selection Represents Key Milestone in Phase 2 Trial Initiation Process

NEW YORK, Sept. 20, 2016 (GLOBE NEWSWIRE) -- 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 Company has selected Vector Oncology as its Clinical Research Organization (CRO) for its anticipated Actimab-A Phase 2 clinical trial.

“We are delighted to be working with Vector Oncology for our upcoming Phase 2 clinical trial,” stated Dragan Cicic, M.D., Actinium’s Chief Medical Officer. “Vector Oncology displayed an expertise in hematology clinical trials with an emphasis on Phase 2 studies, which gives us great confidence in our selection. We look forward to working with Vector Oncology and to benefiting from their robust clinical capabilities.”

Sean L. Hart, Executive Vice President and Managing Director at Vector Oncology said, “Vector Oncology is excited to be working with Actinium as a member of this important team. Since our first interaction with Actinium, all team members involved have committed to getting this important product in the hands of oncology professionals as soon as possible to advance the research efforts. We very much look forward to an exciting future together.”

The Company recently completed a Phase 1 trial with Actimab-A in 18 patients newly diagnosed with Acute Myeloid Leukemia (AML) who are above the age of 60. The Phase 1 trial was a dose escalation study with fractionated dosing levels of Actimab-A ranging from 0.5 µCi/kg/fractionated dose to 2.0 µCi/kg/fractionated dose. Actinium announced that the dose for the Phase 2 clinical trial will be two doses of Actimab-A at 2.0 µCi/kg/fractionated dose one week apart, the highest dose level from the Phase 1 trial.

The Actimab-A Phase 2 clinical trial is expected to begin in 2016 and will enroll 53 patients bringing the total number of patients in this Phase 1/2 Actimab-A trial to 71. This multi-center, open-label, single-arm Phase 2 trial will enroll patients newly diagnosed with AML who are over the age of 60.The Company will also be incorporating into the Phase 2 trial protocol changes including the removal of low dose cytarabine, the mandated use of granulocyte colony-stimulating factors (GCSF) and the mandated use of Hydroxyurea based on the findings from its peripheral blast (PB) burden hypothesis which was derived from the two Phase 1 clinical trials conducted with Actimab-A in its Hum195-Alpha clinical program.

Based on evidence that suggests that peripheral blasts prevent Actimab-A from reaching the bone marrow at optimal doses, the Company has mandated the use of Hydroxyurea to reduce the PB burden in patients above a certain key threshold. PB burden will serve as an inclusion criteria for the Phase 2 trial but it is not expected to exclude patients due to the ability of Hydroxyurea to reduce peripheral blasts. The end point of the Phase 2 trial will be complete response rate at up to 42 days after Actimab-A administration, where complete response is defined as complete remission (CR) or complete remission with incomplete platelet recovery (CRp). A formal interim analysis is expected to occur in mid-2017.

Sandesh Seth, Actinium's Executive Chairman said, "The selection of Vector Oncology as our CRO marks an important step in the development of Actimab-A. The Phase 2 Actimab-A trial is the second Phase 2 trial from our HuM195-Alpha program, albeit with a second generation, much superior product candidate and tantalizing results from the Phase 1 portion that should bode well for the progress of this trial. With the revised protocol, PB burden hypothesis and strengthened clinical development team we look forward to the Phase 2 trial of Actimab-A and working with Vector Oncology to ensure efficient and timely trial execution."

About Vector Oncology

Vector Oncology is a leader in the design and delivery of care based oncology research and data analytics. Utilizing our comprehensive Oncology Data Warehouse and proprietary Patient Care Monitor (PCM) patient engagement and outcomes platform, our experienced project teams, medical experts and health economics and outcomes scientists design and deliver high-quality projects generating real world evidence and insight. With some of the most experienced medical, scientific, operational, and executive teams in late stage research, Vector Oncology is uniquely positioned to meet the demand to demonstrate product value in terms of economic impact, clinical effectiveness and tolerability, and patient reported outcomes (PRO). For more information, please visit www.vectoroncology.com.

About Actimab-A

Actimab-A, Actinium's most advanced alpha particle immunotherapy (APIT) program, is being prepared for a Phase 2 clinical trial for patients newly diagnosed with AML over the age of 60. Actimab-A is being developed as a first-line therapy and it has attracted support from some of the leading experts at the most prestigious cancer treatment hospitals due to the potential of its safety and efficacy profile. Actimab-A consists of the monoclonal antibody, HuM195, and the radioisotope, actinium-225. Actinium-225 decays by giving off high-energy alpha particles, which kill cancer cells. When actinium decays, it produces a series of daughter atoms, each of which gives off its own alpha particle, increasing the chances that the cancer cell will be destroyed. HuM195 is the humanized version of M195 and is a monoclonal antibody that targets CD33, which is abundantly found on myeloid leukemia cells. Both the alpha particle technology and HuM195 were initially developed at Memorial Sloan Kettering Cancer Center. Actimab-A is a second-generation therapy from the Company's HuM195-Alpha program, which has now been studied in almost 90 patients in four clinical trials.

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 radioimmunotherapy 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 is conducting a single, pivotal, multicenter Phase 3 clinical study of Iomab-B in refractory or 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 patients newly diagnosed with AML 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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Source: Actinium Pharmaceuticals