Actinium Announces New Clinical Trial to Study Effect of Actimab-A on Minimal Residual Disease in Postremission AML Patients

- Minimal Residual Disease is increasingly recognized as a primary driver of high AML relapse rate highlighting need for improved consolidation therapies
- Webcast to be held on July 10, 2018 at 8:00 AM ET to discuss planned trial featuring Dr. Joseph Jurcic, Director of the Hematologic Malignancies Section at Columbia University Medical Center who is leading this effort

NEW YORK, June 28, 2018 (GLOBE NEWSWIRE) -- Actinium Pharmaceuticals, Inc. (NYSE AMERICAN:ATNM) (“Actinium” or “the Company”), today announced that Dr. Joseph Jurcic, Director of the Hematologic Malignancies Section and Professor of Medicine at Columbia University Medical Center, has initiated Actimab-A MRD, a new clinical trial for patients with AML who are in remission but have detectable minimal residual disease (MRD). The trial will study the safety/tolerability of Actimab-A in the postremission consolidation setting and include dose finding analyses. The trial will also study the impact of Actimab-A on minimal residual disease (MRD) as well as progression-free (PFS) and overall survival (OS) rates. The investigational new drug (IND) application for this trial has been cleared by the FDA.

Together with Dr. Jurcic, Actinium will host a webcast to discuss the planned trial, participation information is as follows:

Date: July 10, 2018
Time: 8:00 AM ET
Registration Link: https://onecast.thinkpragmatic.com/ses/qkRLz4ale4gPNiJMuSsxQg~~
Telephone participation: U.S./Canada Toll Free: (855) 427-0225 or (718) 865-8336
Conference ID: 2540

Dr. Joseph Jurcic said, "Although patients with AML can achieve complete remissions with induction therapy, the rate of relapse remains high resulting in high mortality rates. Strong evidence exists that minimal residual disease is a major driver of disease relapse and clearly demonstrates the need for improved consolidation therapies that can effectively target MRD. Based on the clinical profile of Actimab-A to date, I am excited to study this therapy for use as a consolidation therapy. It will be a significant advancement for AML patients if this trial shows the ability to target MRD and reduce relapse rates."

There are an estimated 21,000 patients diagnosed with AML annually in the United States and over 350,000 cases of AML worldwide. According to the National Cancer Institute, 5-
year survival for AML patients under age 65 is 45% while 5-year survival for patients over 65 is 6% with the median age of diagnosis of AML patients being 68. With curative intent induction chemotherapy, 45% - 65% of patients can achieve complete remission but up to 80% of patients will relapse despite postremission consolidation treatment. Currently, non-transplant-based consolidation therapies consist mainly of chemotherapy such as high-dose Cytarabine. The presence of MRD has been shown to be associated with higher rates of relapse and earlier relapse in multiple studies. Recently, the FDA approved a therapy for patients with a certain type of B-cell leukemia who are in remission but have detectable MRD.

Dr. Mark Berger, Actinium’s Chief Medical Officer said, “Actimab-A has many points of differentiation that I feel make it well suited to address MRD treatment as consolidation therapy. Given that patients receive chemotherapy as induction therapy, I believe it is important to develop a non-chemotherapy based consolidation therapy that has fewer toxicities and side effects than chemotherapy. This is particularly important for older patients, who do not have the same ability to tolerate high dose therapies as young patients, and who are the majority of patients with AML. We believe our ARC or Antibody Radiation Conjugate approach enables precision targeting of residual AML cells and potentially provide a means by which MRD can be eliminated and relapse rates lowered. We look forward to working with Dr. Jurcic to execute this important trial for AML patients.”

Sandesh Seth, Actinium’s Chairman and CEO said, “We are excited by the continued expansion of our CD33 program and intend to solidify our position as the best-in-class CD33 targeting therapy by demonstrating its potential in multiple diseases and multiple indications. Expansion into the consolidation setting is an important achievement towards this end. Further, the application of our therapy for MRD, strategically aligns us with the forefront of scientific exploration in a clinical setting. We believe the breadth of our CD33 program is unmatched given that we are now studying our ARC not only in multiple AML settings including induction, consolidation and in relapsed/refractory disease but also in multiple myeloma as a therapeutic, and in MDS as targeted conditioning to enable a bone marrow transplant. With this important trial poised to start and clinical data expected from our ongoing trials, we are confident in our ability to realize the intrinsic value of this program and advance these trials to benefit the greatest number of patients.”

About Actimab-A
Actimab-A is an antibody radio-conjugate (ARC) comprised of the anti-CD33 monoclonal antibody lintuzumab labeled with the radioisotope actinium-225. CD33 is a marker expressed on AML cells of virtually all affected patients. Actimab-A has been studied in over 100 patients to date and is the only CD33 targeting agent being studied in a broad range of diseases in which the CD33 antigen is expressed, including AML, myelodysplastic syndrome (MDS) and multiple myeloma.

Actinium-225 is highly differentiated radioisotope that emits high amounts of energy through the release of four alpha-particles that can cause double-stranded breaks in DNA with known resistance mechanisms to Actinium-225. Given the limited distance of its energy in the body, it is potentially sparing of non-targeted cells leading to better tolerability and less toxicities.

Actimab-A has been granted Orphan Drug Designation from both the U.S. Food and Drug Administration and the European Medicines Agency for newly diagnosed AML in patients
age 60 and above.

About Actinium Pharmaceuticals, Inc.

Actinium Pharmaceuticals Inc. is a clinical-stage biopharmaceutical company focused on developing and commercializing targeted therapies for potentially superior myeloablation and conditioning of the bone marrow prior to a bone marrow transplant and for the targeting and killing of cancer cells. The Company’s targeted, Antibody Radio-Conjugates (ARCs), combine the targeting ability of monoclonal antibodies with the cell killing ability of radioisotopes. Actinium is developing a pipeline of clinical-stage ARCs targeting CD45 and CD33 for patients with a broad range of hematologic malignancies.

Iomab-B, Actinium’s lead product candidate, is currently enrolling patients in a pivotal Phase 3 trial. Iomab-B combines the anti-CD45 monoclonal antibody BC8 labeled with iodine-131 and is designed to condition the bone marrow prior to a bone marrow transplant without the need for intense chemotherapy in patients with relapsed or refractory acute myeloid leukemia (AML) age 55 or older. Actinium’s pipeline also includes a potentially best-in-class CD33 program with our ARC comprised of the anti-CD33 antibody lintuzumab labeled with the alpha-particle emitter actinium-225. Its CD33 program is currently being studied in Phase 2 and Phase 1 clinical trials for patients with AML, myelodysplastic syndrome (MDS) and multiple myeloma.

Actinium is also developing its proprietary Actinium Warhead Enabling (AWE) technology platform to utilize the highly differentiated radioisotope actinium-225 with a wide range of targets. AWE is being utilized in a collaborative research partnership with Astellas Pharma, Inc.

More information is available at www.actiniumpharma.com and our Twitter feed @ActiniumPharma, www.twitter.com/actiniumpharma.

Forward-Looking Statements for Actinium Pharmaceuticals, Inc.

This press release may contain projections or other “forward-looking statements” within the meaning of the “safe-harbor” provisions of the private securities litigation reform act of 1995 regarding future events or the future financial performance of the Company which the Company undertakes no obligation to update. These statements are based on management’s current expectations and are subject to risks and uncertainties that may cause actual results to differ materially from the anticipated or estimated future results, including the risks and uncertainties associated with preliminary study results varying from final results, estimates of potential markets for drugs under development, clinical trials, actions by the FDA and other governmental agencies, regulatory clearances, responses to regulatory matters, the market demand for and acceptance of Actinium’s products and services, performance of clinical research organizations and other risks detailed from time to time in Actinium’s filings with the Securities and Exchange Commission (the “SEC”), including without limitation its most recent annual report on form 10-K, subsequent quarterly reports on Forms 10-Q and Forms 8-K, each as amended and supplemented from time to time.

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