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Actinium Pharmaceuticals Announces Successful Completion of Planned Phase 1 Actimab-A CLAG-M Combination Trial in Patients with Relapsed/Refractory AML at Medical College of Wisconsin

- Trial results including data from third dose cohort to be presented by year end;

- Second dose cohort demonstrated 86% complete remission rate with 71% of patients achieving negative minimal residual disease status, as previously reported

NEW YORK, Sept. 14, 2020 /PRNewswire/ --**Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) (the "Company" or "Actinium") today provided an update on the Actimab-A CLAG-M combination Phase 1 trial being conducted at the Medical College of Wisconsin ("MCW") in patients with Relapsed or Refractory ("R/R") Acute Myeloid Leukemia (AML) age 18 and above who are fit for intensive therapy. All patients in the third dosing cohort, which was scheduled as the final cohort of the planned Phase 1 dose escalation trial, completed treatment with a 0.75 uCi/kg dose of Actimab-A followed by CLAG-M and have cleared their initial safety evaluation. Results from the planned portion of the Phase 1 trial including complete safety and efficacy data are expected to be presented by year end. Previously, it was reported that the second dose cohort demonstrated an 86% complete remission rate with 71% of patients achieving negative minimal residual disease status. Investigators at MCW have indicated that based on safety results thus far, they intend to expand the Phase 1 portion of the trial assuming FDA clearance.

Dr. Mark Berger, Actinium's Chief Medical Officer, said, "We are excited that the planned portion of the Actimab-A CLAG-M trial has been completed and look forward to presenting results of the trial by year-end. The high rates of remission and MRD negativity with good tolerability seen in this trial thus far demonstrate the potential of our Antibody Radiation Conjugate (ARC) approach and the power of delivering radiation to a highly relevant target such as CD33, particularly in combination with other synergistic modalities. In the second

dose cohort in this study, 0.50 uCi/kg of Actimab-A was administered, which was previously shown to be a subtherapeutic dose as a single agent. Despite receiving a subtherapeutic dose of Actimab-A, the second cohort in this study demonstrated an 86% complete remission rate, an improvement of nearly 60% over CLAG-M alone—implying mechanistic synergy. We look forward to the results of the full trial including the third cohort and a matured data set. If the trial continues to yield such strong results, we believe that the Actimab-A plus CLAG-M combination regimen will warrant further development as relapsed or refractory patients continue to have high unmet needs despite current treatments."

Antibody Radiation Conjugate (ARC) Actimab-A targets the CD33 antigen that is expressed on virtually all AML cells with the antibody lintuzumab which delivers potent alpha radiation via its Actinium-225 radioisotope payload. Blood cancers like AML are highly sensitive to radiation but cannot treated with the current standard of external beam delivery because the disease is too widespread throughout the body. The combination of targeted radiation with Actimab-A potentially allows for greater cancer cell death than a standalone chemotherapy regimen such as CLAG-M (cladribine, cytarabine, and filgrastim, with mitoxantrone), which is used frequently in the treatment of fit patients with relapsed or refractory AML.

Sandesh Seth, Actinium's Chairman and Chief Executive Officer, said, "We believe that Actimab-A can be utilized in multiple AML treatment settings in combination with other drugs or drug regimens where there is the potential for synergy between their different mechanisms of action. We are initially focusing in R/R AML as there is still a significant unmet need. The Actimab-A CLAG-M combination trial is focused on the fit population while the Actimab-A Venetoclax combination trial addresses the unfit population of R/R AML. These two combination regimens are being studied for their utility as therapeutics with curative intent or as a bridge to transplant. Our expanding focus on R/R AML fits strategically with our pivotal stage Iomab-B program. Our Iomab-B SIERRA trial is in the later stages of a Phase 3 pivotal trial as a conditioning regimen that enables older patients with R/R AML to get a potentially curative bone marrow transplant for which they otherwise are not eligible. We look forward to updates from all three trials by year-end."

Patients in the Phase 1 combination trial, for which data has been presented, have been high-risk with intermediate or poor risk cytogenetics with most patients having received three or more prior therapies including bone marrow transplant in some cases. Patients in the first cohort received 0.25 uCi/kg of Actimab-A and in the second cohort received 0.50 uCi/kg of Actimab-A. In a prior Phase 1/2 trial consisting of 58 patients, Actimab-A as a single agent in newly diagnosed AML a 0.5 uCi/kg dose was shown to be sub-therapeutic, while higher dose levels of 1.0, 1.5 and 2.0 uCi/kg demonstrated response rates of 17%, 22% and 69%, respectively. As previously reported, the second cohort with CLAG-M plus the 0.50 uCi/kg dose showed that 86% (6/7) of patients achieved complete remission (CR/CRi) after receiving the 0.50 uCi/kg dose of Actimab-A. This is a nearly 60% increase over the remission rate reported in a trial of seventy-four patients with relapsed or refractory AML who received CLAG-M alone. Further, 71% (5/7) of patients achieved negative minimal residual disease (MRD) status following treatment with the combination. MRD negative status means the patient had no detectable disease after treatment. Results from the completed Phase 1 trial including the third dose cohort will be available by the end of the year.

About Actinium Pharmaceuticals, Inc. (NYSE: ATNM)

Actinium Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing

ARCs or Antibody Radiation-Conjugates, which combine the targeting ability of antibodies with the cell killing ability of radiation. Actinium's lead application for our ARCs is targeted conditioning, which is intended to selectively deplete a patient's disease or cancer cells and certain immune cells prior to a BMT or Bone Marrow Transplant, Gene Therapy or Adoptive Cell Therapy (ACT) such as CAR-T to enable engraftment of these transplanted cells with minimal toxicities. With our ARC approach, we seek to improve patient outcomes and access to these potentially curative treatments by eliminating or reducing the non-targeted chemotherapy that is used for conditioning in standard practice currently. Our lead product candidate, I-131 apamistamab (Iomab-B) is being studied in the ongoing pivotal Phase 3 Study of Iomab-B in Elderly Relapsed or Refractory Acute Myeloid Leukemia (SIERRA) trial for BMT conditioning. The SIERRA trial is over fifty percent enrolled and positive single-agent, feasibility and safety data has been highlighted at ASH, TCT, ASCO and SOHO annual meetings. I-131 apamistamab will also be studied as a targeted conditioning agent in a Phase 1/2 anti-HIV stem cell gene therapy with UC Davis and is expected to be studied with a CAR-T therapy in 2020. In addition, we are developing a multi-disease, multi-target pipeline of clinical-stage ARCs targeting the antigens CD45 and CD33 for targeted conditioning and as a therapeutic either in combination with other therapeutic modalities or as a single agent for patients with a broad range of hematologic malignancies including acute myeloid leukemia, myelodysplastic syndrome and multiple myeloma. Ongoing combination trials include our CD33 alpha ARC, Actimab-A, in combination with the salvage chemotherapy CLAG-M and the Bcl-2 targeted therapy venetoclax. Underpinning our clinical programs is our proprietary AWE (Antibody Warhead Enabling) technology platform. This is where our intellectual property portfolio of over 100 patents, know-how, collective research and expertise in the field are being leveraged to construct and study novel ARCs and ARC combinations to bolster our pipeline for strategic purposes. Our AWE technology platform is currently being utilized in a collaborative research partnership with Astellas Pharma, Inc. Website: https://www.actiniumpharma.com/

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.

Contacts:

Investors:

Clayton Robertson
Actinium Pharmaceuticals, Inc.
crobertson@actiniumpharma.com

Hans Vitzthum
LifeSci Advisors, LLC
Hans@LifeSciAdvisors.com
(617) 535-7743

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