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Actinium Pharmaceuticals Announces First Patient Treated in Third and Final Dose Cohort of Actimab-A CLAG-M Combination Phase 1 Trial in Acute Myeloid Leukemia

- 86% complete remission rate with 71% of patients achieving negative minimal residual disease status with a sub-therapeutic dose of Actimab-A with CLAG-M in second dose cohort of early stage safety trial

- Preliminary remission rates achieved with Actimab-A combined with CLAG-M compare favorably to targeted agents recently approved for patients with relapsed or refractory AML

NEW YORK, March 5, 2020 /PRNewswire/ --**Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) ("Actinium") today announced that the first patient has begun treatment in the third and final cohort of the Actimab-A CLAG-M combination trial. This Phase 1 trial is an investigator-initiated trial being conducted at the Medical College of Wisconsin in patients with relapsed or refractory acute myeloid leukemia (AML). Patients in the third cohort will receive a cycle of CLAG-M (cladribine, cytarabine, G-CSF, and mitoxantrone) followed by 0.75 uCi/kg of Actimab-A on day 6, 7 or 8. Actimab-A is an antibody radiation conjugate (ARC) that targets the CD33 receptor on blood cancer cells and delivers potent cytotoxic radiation via the radioisotope Actinium-225. This trial will enroll up to 18 patients and will evaluate the safety of this combination including determining the maximum-tolerated dose as well as response rates, progression-free survival and overall survival. Actinium expects the third cohort to be completed mid-2020.

Patients in the trial to date have been high-risk with intermediate and poor risk cytogenetics with most patients having received three or more prior therapies including bone marrow transplant in some patients. Patients in the first cohort received 0.25 uCi/kg of Actimab-A and the second cohort received 0.50 uCi/kg of Actimab-A. In a prior Phase 1/2 trial of

Actimab-A single agent in newly diagnosed AML with 58 patients the 0.5 uCi/kg dose was sub-therapeutic (with response rates of 17%, 22% and 69% at doses of 1.0, 1.5 and 2.0 uCi/kg respectively). In this trial, the second cohort with CLAG-M plus the sub-therapeutic 0.5 uCi/kg dose showed that 86% (6/7) of patients achieved complete remission (CR/CRi) after receiving the 0.50 uCi/kg dose. 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. Assuming a successful outcome of the Phase 1 trial, Actinium intends to advance this combination to a Phase 2 randomized trial to demonstrate significance.

"These rates of high complete remission and MRD negative status are not easily achieved in AML let alone in patients with high-risk relapsed or refractory disease. However, AML, and other hematologic cancers, are highly radiation sensitive. Targeting the CD33 receptor on AML cells with potent alpha radiation via an Actinium-225 ARC hits these cells with a cytotoxic agent they have not been exposed to before and have no resistance mechanism against. The result is significant DNA damage that can have a profound anti-tumor effect via targeted delivery that overcomes the limitations of current radiation delivery methods," stated Dr. Mark Berger, Actinium's Chief Medical Officer. "It is exciting to see data supporting our hypothesis that improved outcomes can be achieved with an ARC therapy in combination with chemotherapy. We feel these results support the additive benefits, mechanistic synergy and potentiating abilities of ARC combinations. We have great excitement for the third and final cohort and hope to improve on the already encouraging results we have seen thus far."

Remission rates achieved with Actimab-A in combination with CLAG-M in this Phase 1 trial compare favorably to targeted agents recently approved for patients with relapsed or refractory AML.

Agent or Regimen	Overall Response Rates
Actimab-A + CLAG-M	86%
Gilteritinib (FLT3 inhibitor)[1]	68%
Venetoclax + HMA[2]	64%
Enasidenib (IDH2 inhibitor)[3]	40%
Venetoclax[4]	19%
Azacytidine (HMA)[5]	17%

Actinium intends to explore a larger, randomized Phase 2 and potentially pivotal trial to confirm these preliminary results and provide support for approval of Actimab-A.

Sources:

1. Perl et al. Gilteritinib or Chemotherapy for Relapsed or Refractory FLT3-Mutated AML. N Engl J Med. 2019 Oct 31;381(18):1728-1740.

2. Aldoss et al. Efficacy of the combination of venetoclax and hypomethylating agents in relapsed/refractory acute myeloid leukemia. Haematologica. 2018 Sep;103(9):e404-e407.

3. Stein et al. Enasidenib in mutant IDH2 relapsed or refractory acute myeloid leukemia. Blood. 2017 Aug 10;130(6):722-731.

4. Konopleva et al. Efficacy and Biological Correlates of Response in a Phase II Study of Venetoclax Monotherapy in Patients with Acute Myelogenous Leukemia. Cancer Discov. 2016 Oct;6(10):1106-1117.

5. Itzykson et al. Azacitidine for the treatment of relapsed and refractory AML in older patients. Leuk Res. 2015 Feb;39(2):124-30.

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.

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