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Actinium Pharmaceuticals Highlights 86% Response Rate and 71% MRD Negative Rate in Actimab-A CLAG-M Combination Trial in Patients with Relapsed or Refractory AML at ASH 2019 Annual Meeting

- 56% higher response rates with Actimab-A CLAG-M combination is substantially greater than response rates for CLAG-M, CLAG and MEC salvage regimens

- 71% of patients achieved minimal residual disease status in the second dose cohort of Actimab-A and CLAG-M

- First of its kind combination trial demonstrates potentiating effect of targeted Antibody Radiation-Conjugates with other therapeutic modalities and supports rational for Actimab-A plus venetoclax combination trial

NEW YORK, NY – December 09, 2019 –**Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) ("Actinium") today highlighted new data from a Phase 1 trial studying Actimab-A in combination with the salvage chemotherapy regimen CLAG-M that was presented in a poster presentation at the 61st American Society of Hematology (ASH) Annual Meeting. The poster reported results from the ongoing Phase 1 combination trial that is being conducted at the Medical College of Wisconsin (MCW). Patients receiving Actimab-A at a dose of 0.50 uCi/kg in the second dose cohort in addition to CLAG-M had an 86% overall response rate (ORR), which is a 56% higher response rate and is substantially greater than what has been observed with CLAG-M and MEC and more than double that of CLAG in a similar patient population that was treated at MCW. Notably, 71% of patients (5/7) achieved negative minimal residual disease (MRD) status in the second dose cohort. In addition to response rates, the poster reported that three patients on the study proceeded to a bone marrow transplant after receiving Actimab-A and CLAG-M. The addition of Actimab-A to CLAG-M appears to have a clinically acceptable safety profile with no patient deaths reported. A table below compares the ORR of patients receiving Actimab-A and CLAG-M to that of the CLAG-M, MEC and CLAG salvage regimens. The full poster can be accessed HERE.

Regimen	Overall Response Rate
Actimab-A + CLAG-M	86% (6/7)
CLAG-M	55% (41/74)
MEC	44% (25/57)
CLAG	40% (6/15)

Sameem Abedin, M.D., Assistant Professor of Medicine at the Medical College of Wisconsin and Principal Investigator of the study, stated, “CLAG-M has become our preferred salvage regimen for patients with relapsed or refractory AML, as it demonstrated a higher overall response rate than other salvage regimens such as CLAG and MEC. We are pleased by the significantly higher response rate of eighty-six percent that was observed when adding Actimab-A to CLAG-M compared to the fifty-five percent response rate we observed with CLAG-M in prior studies. This efficacy is highly encouraging particularly as the combination appears to have a clinically acceptable safety profile. We look forward to completing this Phase 1 trial and hope to advance to a Phase 2 trial that we believe can serve as a pivotal trial for this promising combination given the high unmet need of patients with relapsed or refractory AML.”

Actimab-A is an Antibody Radiation-Conjugate (ARC) that delivers the potent alpha-emitting radioisotope Actinium-225 (Ac-225) via the antibody lintuzumab to cells that express CD33. CD33 is an antigen that is expressed on the vast majority of cancer cells in patients with acute myeloid leukemia (AML). CLAG-M is a salvage chemotherapy comprised of cytarabine, cladribine, G-CSF (granulocyte-colony stimulating factor) and mitoxantrone. The Phase 1 Actimab-A CLAG-M combination study is enrolling patients age 18 and older who have relapsed or refractory AML and are medically fit. The median age of patients enrolled in the trial to date is 62 and all patients had either intermediate risk or poor risk cytogenetics. Three patients had received three or more prior therapies and three patients had received a prior allogeneic bone marrow transplant. This patient population is similar to the study conducted at MCW that enrolled 146 patients, of which, 74 received CLAG-M, 57 received MEC and 15 received CLAG. MRD status was not reported in that study, however 71% of patients receiving 0.50 uCi/kg of Actimab-A and CLAG-M achieved MRD negative status[1].

“These results further our excitement for the combination of Actimab-A and CLAG-M as well

as other ARC combinations that we have ongoing like that with the Bcl-2 inhibitor venetoclax, commented Dr. Mark Berger, Actinium's Chief Medical Officer. "The emergence of several recently approved agents, including targeted therapies, for patients with AML is exciting but their use can be limited to patients with a specific mutation and the lack of curative outcomes with these therapies points to a need for continued innovation. Our targeted Antibody Radiation-Conjugates can be a solution to the unmet need of many patients as radiation is a validated modality, hematologic cancers are sensitive and susceptible to radiation and patients with hematologic cancers are typically not exposed to external radiation given the diffuse nature of their disease. Because radiation is agnostic to genetic and cytogenetic abnormalities and there is no known resistance mechanism to alpha particles like actinium-225, we see great potential for additional combinations with other chemotherapy regimens like 7+3, targeted agents like FLT3 and IDH inhibitors and immunotherapies. Finally, these results increase our excitement for the Actimab-A venetoclax combination trial, and our Company looks forward to the clinical results next year that we believe can confirm the synergy we observed in our preclinical research."

The overall response rates observed with the Actimab-A CLAG-M combination compare favorably to response rates reported with recently approved therapies in patients with relapsed or refractory AML that are shown in the table below.

Agent or Regimen	**Response Rate**
Actimab-A + CLAG-M	86%
Gilteritinib (FLT3 inhibitor)[2]	68%
Venetoclax + HMA[3]	64%
Enasidenib (IDH2 inhibitor)[4]	40%
Venetoclax[5]	19%
Azacytidine (HMA)[6]	17%

The Actimab-A CLAG-M Phase 1 trial is expected to be completed in mid-2020. Actinium is also conducting a Phase 1 clinical trial studying Actimab-A in combination with the Bcl-2 inhibitor venetoclax in patients with relapsed or refractory AML to evaluate the safety of the combination and determine if the addition of Actimab-A to venetoclax can increase patient responses and outcomes. In preclinical studies, it was observed that Actimab-A can deplete Mcl-1, a protein that has been implicated in mediating resistance to Bcl-2 inhibitors like Venetoclax and provides a potentiating effect.

Sources:

1. MRD data from a subsequent analysis
2. Perl et al. Gilteritinib or Chemotherapy for Relapsed or Refractory FLT3-Mutated AML. N Engl J Med. 2019 Oct 31;381(18):1728-1740.
3. 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.
4. Stein et al. Enasidenib in mutant IDH2 relapsed or refractory acute myeloid leukemia. Blood. 2017 Aug 10;130(6):722-731.
5. 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.
6. 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.

Actinium Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing ARC's or Antibody Radiation-Conjugates, which combine the targeting ability of antibodies with the cell killing ability of radiation. Actinium's lead application for our ARC's is targeted conditioning, which is intended to selectively kill patient's cancer cells and certain immune cells prior to a BMT or Bone Marrow Transplant, CAR-T and other cell therapies. 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, 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 that reached fifty percent enrollment in July 2019. Beyond Iomab-B, we are developing a multi-disease, multi-target pipeline of clinical-stage ARC's targeting the antigens CD45 and CD33 for targeted conditioning. In addition, we are studying our ARC’s in combination with other therapeutic modalities including a Phase 1 trial for the chemotherapy regimen CLAG-M and a Phase 1 trial with the Bcl-2 inhibitor, 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 ARC's 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.

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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