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Actinium Pharmaceuticals, Inc. Announces 72% MRD Negativity Rate in the Recently Completed Phase 1 Study of Actimab-A in Combination with CLAG-M for Patients with Relapsed or Refractory AML

- High MRD negativity rate compares favorably to 39% MRD negativity rate with CLAG-M alone in prior studies at the Medical College of Wisconsin

- 10 complete remissions reported and an 80% response rate across all dose cohorts in patients receiving less than 4 lines of prior therapy

- 60% response rate in patients receiving prior Venetoclax and HMA therapy including 4 complete remissions

NEW YORK, Dec. 14, 2021 /PRNewswire/ -- **Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) ("Actinium" or the "Company"), a leader in the development of targeted radiotherapies for patients with unmet needs today announced that updated data from the recently complete Actimab-A and CLAG-M Phase 1 combination trial being conducted at the Medical College of Wisconsin (MCW) was presented at the 63rd American Society of Hematology Annual Meeting and Exposition (ASH) that is being held December 11 – 14, 2021 in Atlanta, Georgia and virtually. This Phase 1 trial was a dose escalation study that evaluated Actimab-A, a CD33 targeting antibody radiation conjugate (ARC) armed with the alpha-emitting radioisotope Actinum-225, combined with CLAG-M (Cladribine, Cytarabine, G-CSF and Mitoxantrone), a salvage chemotherapy regimen for patients fit for intensive therapy.

Actimab-A + CLAG-M Phase 1 Results:

- Complete remissions (CR/CRp) in all dose cohorts

- 80% overall response rate (CR/CRp/MLFS) in patients receiving less than 4 lines of prior therapy with a total of 10 complete remissions across all four dose cohorts
- 72% MRD negativity rate determined by flow cytometry compares favorably to 39% MRD negativity rate with CLAG-M alone in MCW's institutional experience[1]
- 60% response rate in patients receiving prior venetoclax therapy including 4 patients that achieved a complete remission
- 75% of patients proceeded to a bone marrow transplant, excluding patients with prior transplant experience
- Median time to best response was 40 days
- No 30-day mortality
- 0.75uCi/kg of Actimab-A identified as recommended Phase 2 dose

Dr. Sameem Abedin, Assistant Professor of Medicine, Medical College of Wisconsin, Division of Hematology and Oncology and Principal Investigator of the study, commented, "We are excited to have completed dose escalation and to report the Phase 1 results of this novel combination of CLAG-M with Actimab-A. AML is known to be highly radio-sensitive, but we cannot treat AML effectively with external radiation sources. Actimab-A solves this issue by directing the potent alpha-emitting radioisotope Actinium-225 at the cellular level inside the body to CD33, which is expressed in virtually all AML patients. Based on our experience with Actimab-A as a single agent, we believed that in combination with CLAG-M it would improve remission rates and the depth of remissions while being safe, given the non-overlapping mechanisms of action. We are very encouraged by the high rates of remissions with MRD negativity, indicating deep responses, and the high number responses seen in patients that had previously failed venetoclax, which is becoming an increasingly larger portion of the AML patient population. Also of note is the high number of patients able to proceed to bone marrow transplant on the study. We look forward to continuing to study this novel combination."

Dr. Avinash Desai, Actinium's Chief Medical Officer, said, "This study will prove invaluable to our future development of Actimab-A. There are several positive findings from this study including high rates of MRD negativity, strong responses in patients failing venetoclax therapy and high rates of transplant, which all represent future development opportunities. With these data and the recommended Phase 2 dose level determined, we look forward to finalizing our future development strategy for Actimab-A and CLAG-M for patients with relapsed or refractory AML. In addition, these results support our broader strategy of leveraging the differentiated mechanism of targeted radiotherapy utilizing Actimab-A as a backbone in combination with other therapeutic modalities to improve patient outcomes."

Sources:

1) Mushtaq et al. Leukemia & Lymphoma 2020

About Actinium Pharmaceuticals, Inc.

Actinium Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing targeted radiotherapies to deliver cancer-killing radiation with cellular level precision to treat patients with high unmet needs not addressed by traditional cancer therapies. Actinium's current clinical pipeline is led by ARCs or Antibody Radiation-Conjugates that are being applied to 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. Actinium's targeted conditioning ARCs 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) has been studied in several hundred patients including in the recently completed, 150-patient, pivotal Phase 3 Study of Iomab-B in Elderly Relapsed or Refractory Acute Myeloid Leukemia (SIERRA) trial for BMT conditioning. Iomab-ACT, low dose I-131 apamistamab is being studied as a targeted conditioning agent in a Phase 1 study with a CD19 CAR T-cell Therapy with Memorial Sloan Kettering Cancer Center. In addition, we are leaders in the field of Actinium-225 alpha therapies. Actimab-A, our clinical stage CD33 targeting ARC alpha therapy has been studied in nearly 150 patients including our ongoing combination trials 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 160 patents, know-how, collective research and expertise in the field are being leveraged to construct and study novel ARCs and ARC combinations such as with CD47 immunotherapies 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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