



Actinium Pharmaceuticals Announces Publication of Actimab-A + CLAG-M Trial Results in Patients with Relapsed or Refractory Acute Myeloid Leukemia in the Peer-Reviewed Journal *Leukemia*

- Median Overall Survival of 18.4 months with Actimab-A + CLAG-M in patients with relapsed or refractory AML who received 1 or 2 lines of prior therapy
- Mutation agnostic potential of Actimab-A demonstrated by high rates of Complete Remissions and Measurable Residual Disease Negativity in patients with high-risk features including TP53 mutations and prior Venetoclax treatment
- Actimab-A + CLAG-M combination yielded deep and clinically meaningful responses with expected and manageable safety profile supporting planned pivotal Phase 2/3 trial

NEW YORK, March 17, 2025 /PRNewswire/ -- **Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) (Actinium or the Company), a pioneer in the development of targeted radiotherapies, today announced that results from the clinical trial evaluating Actimab-A in combination with the chemotherapy CLAG-M in patients with relapsed/refractory acute myeloid leukemia (r/r AML) have been published in the peer-reviewed journal *Leukemia*. The publication highlights data including long-term survival outcomes from two-year follow-up and better outcomes in high-risk patients. Actimab-A is a novel targeted radiotherapeutic that uses the Actinium-225 (Ac-225) isotope payload directed against CD33, a marker expressed ubiquitously on AML blasts. The trial was conducted at the Medical College of Wisconsin (MCW) which has extensive experience treating relapsed refractory AML patients with CLAG-M.



Actimab-A + CLAG-M Trial Data Highlights from Publication:

- 18.4 month median Overall Survival (OS) in patients who received 1 or 2 lines of prior therapy
- 52% of patients in the Actimab-A +CLAG-M trial had TP53 mutations, 56% had prior

- allogeneic stem cell transplant and 56% of patients had prior Venetoclax therapy
- Actimab-A + CLAG-M outcomes compare favorably to the results from historical data with CLAG-M alone in the pre-Venetoclax era from MCW's study (median OS of 13.3 months). Typically, patients who have failed Venetoclax treatment demonstrate median survival between 2.4 – 4.6 months as reported in the literature and the patients with a TP53 mutation even have more dismal survival outcomes. Hence this data supports the use of Actimab-A plus CLAG-M for these patients.
- Actimab-A + CLAG-M produced high rates of measurable residual disease negativity (MRD-) including 75% across all patients, 83.3% in patients with a TP53 mutation and 100% in patients with prior Venetoclax therapy
- 71% of eligible patients received a bone marrow transplant (BMT) and median OS in these patients was 24.05 months

Dr. Sameem Abedin, Associate Professor of Medicine at the Medical College of Wisconsin and Principal Investigator of the Actimab-A + CLAG-M study said, "We are delighted that the Actimab-A + CLAG-M results have been published in the peer-reviewed journal *Leukemia*. Despite advancements in treatment, patients with r/r AML, particularly those with high-risk features including TP53 mutations and prior Venetoclax therapy like those in our study, continue to have dismal outcomes and limited treatment options. We are excited that the combination of Actimab-A and CLAG-M produced high response rates with deep remissions including high rates of MRD negativity, improving access to potentially curable BMT resulting in enhanced survival outcomes. Importantly, we observed that responses were retained in high-risk patients. We believe these results support the utility of targeted radiotherapy for the treatment of AML and its mutation agnostic mechanism of action. We look forward to the initiation of the Phase 2/3 trial of Actimab-A + CLAG-M and further advancing this potentially important therapeutic modality in this patient population with a high unmet need."

Actinium has aligned with the FDA on a pivotal Phase 2/3 operationally seamless trial that will study Actimab-A + CLAG-M in r/r AML patients. The trial will optimize the dose of Actimab-A in combination with CLAG-M, that will be studied in the Phase 3 portion of the trial, which will be a randomized trial comparing overall survival and other outcomes of patients with r/r AML receiving Actimab-A + CLAG-M to CLAG-M alone. The trial is expected to be initiated in 2025.

Sandesh Seth, Actinium's Chairman and CEO, said, "There is significant momentum for Actimab-A with the publication of these positive results in *Leukemia* and the recent initiation of the frontline AML triplet combination with Venetoclax and the hypomethylating agent ASTX-727 under our NCI CRADA. Actinium is committed to addressing the needs of the over 100,000 patients with AML and MDS in the U.S. and Europe with Actimab-A to realize its multi-billion-dollar market opportunity. Over the course of 2025, we expect to generate additional clinical data further supporting Actimab-A's mutation agnostic, backbone therapy potential for radiation sensitive myeloid malignancies."

About Actinium Pharmaceuticals, Inc.

Actinium is a pioneer in the development of targeted radiotherapies intended to meaningfully improve patient outcomes. Actinium is advancing its lead product candidate Actimab-A, a CD33 targeting therapeutic, as potential backbone therapy in acute myeloid leukemia (AML) and other myeloid malignancies leveraging the mutation agnostic alpha-emitter radioisotope payload Actinium-225 (Ac-225). Actimab-A has demonstrated potential activity in relapsed

and refractory acute myeloid leukemia (r/r AML) patients in combination with the chemotherapy CLAG-M including high rates of Complete Remissions (CR) including measurable residual disease (MRD) negativity with improved survival outcomes and is being advanced to a pivotal Phase 2/3 trial. In addition, Actinium is engaged with the National Cancer Institute (NCI) under the Cooperative Research and Development Agreement (CRADA) for development of Actimab-A in AML and other myeloid malignancies. The first clinical trial under the CRADA will evaluate the triplet combination comprised of Actimab-A, Venetoclax (Abbvie/Roche) an oral Bcl-2 inhibitor and ASTX-727 (Taiho Oncology, an Otsuka holdings company) a novel oral hypomethylating agent (HMA) in frontline acute myeloid leukemia (AML) patients. Iomab-ACT, Actinium's next generation conditioning candidate, is being developed with the goal of improving patient access and outcomes for potentially curative cell and gene therapies. Iomab-B is an induction and conditioning agent prior to bone marrow transplant in patients with r/r AML, which Actinium is seeking a potential strategic partner for in the U.S. In addition, the company's R&D efforts are primarily focused on advancing several preclinical programs for solid tumor indications. Actinium holds 230 patents and patent applications including several patents related to the manufacture of the isotope Ac-225 in a cyclotron.

For more information, please visit: <https://www.actiniumpharma.com/>

Forward-Looking Statements

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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