

September 7, 2023



## **Actinium Pharma Presents Survival Data from Extended Follow-Up from Actimab-A + CLAG-M Trial and Preclinical Data Supporting Program Expansion with FLT3 Inhibitor Combinations at SOHO**

- Extended follow-up in the Actimab-A + CLAG-M trial showed median overall survival in patients proceeding to bone marrow transplant of 24 months in all patients and 30 months in patients who received prior venetoclax treatment
- Actimab-A shown to enhance the anti-leukemic activity of FLT3 inhibition of approved therapies gilteritinib and midostaurin preclinically, supporting the clinical evaluation of Actimab-A combinations with FLT3 inhibitors

NEW YORK, Sept. 7, 2023 /PRNewswire/ -- Actinium Pharmaceuticals, Inc. (NYSE AMERICAN: ATNM) (Actinium or the Company), a leader in the development of targeted radiotherapies, today highlighted updated survival data from its Phase 1b trial evaluating Actimab-A in combination with the salvage chemotherapy CLAG-M in patients with high-risk relapsed or refractory acute myeloid leukemia (r/r AML) and new preclinical data with Actimab-A in combination with FLT3 inhibitors at the Society of Hematologic Oncology (SOHO) 2023 Annual Meeting. In addition, results of the completed and positive Phase 3 SIERRA trial of lomab-B were presented.



### **SOHO Data Highlights:**

#### **Updated Actimab-A + CLAG-M Phase 1b Study Results**

- 30-month median Overall Survival (OS) in patients with prior venetoclax treatment who proceeded to bone marrow transplant (BMT) following Actimab-A + CLAG-M
- 24-month median OS in all patients who proceeded to BMT following Actimab-A + CLAG-M
- 100% measurable residual disease (MRD) negativity in patients with prior

venetoclax treatment and 75% MRD negativity in all patients

- 83% of patients (19/23) had high-risk r/r AML; 57% of patients (13/23) received prior treatment with venetoclax
- Patients who relapse after venetoclax treatment have poor survival outcomes with a limited percentage of patients proceeding to BMT

*Poster Title:* Sequential Salvage Chemotherapy and Lintuzumab-Ac225 in Relapsed/Refractory AML Results in Deep Responses and Prolonged Survival in Adverse Risk Acute Myeloid Leukemia (AML) and in AML Patients that Received Prior Venetoclax Therapy

"These data continue to demonstrate the broad potential and applicability of targeted radiotherapeutics as well as Actinium's leadership position in their development for r/r AML and other blood cancers," said Sandesh Seth, Actinium Chairman and CEO. "As we progress Actimab-A + CLAG-M to a pivotal trial, we are highly encouraged by this new follow-up data showing 100% MRD negativity and median survival of 30 months in patients proceeding to transplant who had prior venetoclax treatment. Given the significant number of patients with AML who receive venetoclax treatment and, unfortunately, have disease relapse, better therapeutic options are needed for this growing patient segment. We are excited by the potential of Actimab-A to meet this high unmet need given its differentiated mechanism of action and clinical profile thus far."

#### **Actimab-A Program Expansion into FLT3 Mutant AML:**

- Actimab-A shown to have single-agent cytotoxic activity against FLT3 mutant AML cell lines
- The addition of Actimab-A enhances the anti-leukemic activity of FLT3 inhibition of approved FLT3 inhibitors gilteritinib (Xospata®, Astellas) and midostaurin (Rydapt®, Novartis) in vitro
- FLT3 mutations are associated with aggressive disease with poor outcomes and occur in approximately 30% of patients, making it one of the most commonly mutated genes in AML
- Combinations of Actimab-A with FLT3 inhibitors can potentially be explored under Actinium's CRADA with the NCI

*Poster Title:* Antileukemic Activity of Lintuzumab-Ac225 in Preclinical Model of FLT3 Mutant AML

Mr. Seth added, "The mutation agnostic mechanism of action, potent cell killing ability and synergistic potential of Actimab-A provides multiple avenues for development as evidenced by this new preclinical data supporting combinations with FLT3 inhibitors. With FLT3 gene mutations being the most common in AML, we are excited to further Actimab-A's backbone potential by continuing to explore this novel combination that could address approximately 30% of the AML patient population."

#### **About Actinium**

Actinium develops targeted radiotherapies to meaningfully improve survival for people who have failed existing oncology therapies. Advanced pipeline candidates lomab-B (pre-BLA), an induction and conditioning agent prior to bone marrow transplant, and Actimab-A

(National Cancer Institute CRADA pivotal development path), a therapeutic, have demonstrated potential to extend survival outcomes for people with relapsed and refractory acute myeloid leukemia. Actinium plans to advance lomab-B for other blood cancers and next generation conditioning candidate lomab-ACT to improve cell and gene therapy outcomes. Actinium's technology platform is the basis for collaborations with Astellas Pharma for solid tumors, AVEO Oncology/LG Chem Life Sciences for HER3 solid tumors and several internal programs in solid tumors. Actinium holds more than 200 patents and patent applications.

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.

### References:

- 1) Maiti et al. Outcomes of relapsed or refractory acute myeloid leukemia after front-line hypomethylating agent and venetoclax regimens. *Hematologica* 2021 Mar 1; 894-898
- 2) Oñate, G., Pratcorona, M., Garrido, A. *et al.* Survival improvement of patients with *FLT3* mutated acute myeloid leukemia: results from a prospective 9 years cohort. *Blood Cancer J.* **13**, 69 (2023). <https://doi.org/10.1038/s41408-023-00839-1>

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