

June 11, 2024



Actinium Announces Results of Actimab-A + CLAG-M Combination Trial Highlighted in Oral Presentation at the 2024 Society of Nuclear Medicine & Molecular Imaging Annual Meeting

- Novel targeted radiotherapy-based combination being studied as potential backbone therapy potential relapsed or refractory acute myeloid leukemia
- Actimab-A + CLAG-M produced high rates of response, measurable residual disease negativity, bone marrow transplant access and improved survival outcomes in high-risk patients including TP53+ and venetoclax treated patients
- SNMMI oral presentation highlighted dosimetry results and safety data supporting this novel radiotherapy combination

NEW YORK, June 11, 2024 /PRNewswire/ -- **Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) (Actinium or the Company), a leader in the development of Antibody Radiation Conjugates (ARCs) and other targeted radiotherapies, today highlighted data from the completed Phase 1b combination trial of Actimab-A + CLAG-M in patients with relapsed or refractory acute myeloid leukemia (r/r AML) at the 2024 Society of Nuclear Medicine & Molecular Imaging (SNMMI) Annual Meeting held June 8 – 11, 2024, in Toronto, Canada. Actimab-A is an ARC comprised of a CD33 targeting monoclonal antibody conjugated with the alpha-particle emitter Actinium-225 isotope payload. Actimab-A has been studied as a single agent and in combination with chemotherapies and targeted therapies in Phase 1 and Phase 2 trials.



Sandesh Seth, Actinium's Chairman and CEO, said, "These results demonstrate the immense potential of targeted radiotherapy via ARCs from both an efficacy and safety perspective. Through the use of dosimetry, we can estimate radiation doses to the target organ and non-targeted healthy organs and as observed in this trial, we saw no safety signals for the kidneys, liver or other major organs. Together with the potent efficacy, particularly in these high-risk relapse and refractory patients, we are highly excited by the building clinical profile Actimab-A. We look forward to continuing to advance our Actimab-A

program as a broad-based combination approach with targeted and non-targeted therapies in collaboration with the NCI for the benefit of AML patients who are eligible for targeted radiotherapy."

The Phase 1b Actimab-A + CLAG-M combination trial enrolled patients with high-risk r/r AML with the following features:

- Median age of 62 with patients up to 73 years old
- 91% of patients had intermediate (n=3, 13%) or adverse cytogenetics (n=18, 78%)
- Over 50% of patients had a TP53 mutation
- Median of 2 lines of prior therapy (range:1-5) including:
 - Prior bone marrow transplant: 57%
 - Prior venetoclax treatment: 57%

Despite the high-risk profile of the patients on the study, the combination of Actimab-A + CLAG-M produced high rates of response and measurable residual disease negativity and improved survival outcomes across all patient subsets:

Patients	Overall Response Rate	MRD- Rate	1-year Overall Survival
All (n=23)	65 %	75 %	48 %
High-Risk (n=19)	58 %	75 %	42 %
ELN Adverse Risk (n=17)	53 %	67 %	35 %
TP53+ (n=12)	58 %	80 %	42 %
Ven Failures (n=13)	54 %	100 %	46 %

64% of eligible patients proceeded to bone marrow transplant with these patients having a median overall survival of 24 months.

Dosimetry and Safety:

- A validated pharmacokinetic model was used to estimate the biodistribution of Actimab-A based on the distribution of CD33+ AML blast cells based on data derived from patients in the Phase 1b study
- Across all dose levels including 0.75 µCi/kg, which was determined to be the optimal dose, and 1.0 µCi/kg (the highest dose in the Phase 1b study) radiation doses for key organs were well below known tolerance levels with external beam radiation therapy (EBRT)
- No safety signals for major organs such as liver, heart, kidneys, lungs and intestines were observed and a safety profile consistent with that expected in heavily pre-treated r/r AML patients given salvage therapy
- A single 30-minute administration of Actimab-A results in rapid radiation delivery and clearance with peak concentration reached around 0.6 hours and undetectable in the blood by 48 hours after administration
- The dose of 0.75 µCi/kg was identified as optimal for this combination therapy and will be further evaluated in the next stage of clinical development

About the SNMMI Annual Meeting

The SNMMI Annual Meeting is recognized as the premier educational, scientific, research, and networking event in nuclear medicine and molecular imaging. The four-day event, taking place each June, provides physicians, technologists, pharmacists, laboratory professionals, and scientists with an in-depth view of the latest research and development in the field as well as providing insights into practical applications for the clinic.

About Actinium Pharmaceuticals, Inc.

Actinium develops targeted radiotherapies to meaningfully improve survival for people who have failed existing oncology therapies. Advanced pipeline candidates lomab-B (pre-BLA & MAA (EU)), an induction and conditioning agent prior to bone marrow transplant, and Actimab-A (National Cancer Institute CRADA pivotal development path), a therapeutic agent, 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 holds more than 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.

Investors:

investorrelations@actiniumpharma.com

📄 View original content to download multimedia <https://www.prnewswire.com/news-releases/actinium-announces-results-of-actimab-a--clag-m-combination-trial-highlighted-in-oral-presentation-at-the-2024-society-of-nuclear-medicine--molecular-imaging-annual-meeting-302168916.html>

SOURCE Actinium Pharmaceuticals, Inc.