

June 12, 2023



# Actinium Announces Positive Pivotal Phase 3 SIERRA Trial Results in an Oral Presentation at the EHA 2023 Congress

- *SIERRA results demonstrate unprecedented bone marrow transplant access and outcomes with lomab-B*
- *BLA filing for lomab-B expected by year end 2023 based on positive pivotal Phase 3 SIERRA results*

NEW YORK, June 12, 2023 /PRNewswire/ -- Actinium Pharmaceuticals, Inc. (NYSE AMERICAN: ATNM) (Actinium or the Company), a leader in the development of targeted radiotherapies, announced positive SIERRA trial results in an oral presentation at the European Hematology Association 2023 Congress (EHA) in Frankfurt, Germany on June 10. The abstract included data from Actinium's SIERRA controlled phase 3 study comparing the efficacy of lomab-B based conditioning, a first-in-class targeted radiotherapy, versus physician's choice of conventional care in older, relapsed/refractory acute myeloid leukemia (r/r AML) with active disease.



*"We are honored to have been accepted for an oral presentation at EHA," said Sandesh Seth, Chairman and Chief Executive Officer. "This presentation is the third of four orals at prestigious medical conferences globally in 2023, including TCT, EBMT and SNMMI, reflecting the paradigm changing potential of lomab-B in facilitating transplants for patients who are currently not considered for transplant."*

## Details of the EHA presentation:

**Presentation Title:** SIERRA trial results with a targeted radiotherapy, lomab-B, a myeloablative conditioning with reduced intensity tolerability yields high CR, long term survival in HSCT ineligible active r/r AML

**Presenting Author:** Dr. Boglarka Gyurkocza

**Session Type/Title:** Oral / SCT Clinical

**Presentation ID:** S248 (<https://congress-apps.ehaweb.org/eha2023/en-GB/pag/presentation/555675>)

**Date and Time:** June 10, 11:30am – 12:45pm CET

In patients over 55 with active r/r AML, lomab-B was able to safely deliver myeloablative doses of targeted radiation to bone marrow. Lomab-B based conditioning with bone marrow transplant (BMT) resulted in rapid engraftment and high initial complete remission/complete remission with incomplete platelet recovery rates, a favorable toxicity profile and resulted in statistically significant improvement in the pre-specified primary endpoint of durable complete remission (dCR). The majority of patients who achieved dCR are long term survivors, in whom OS and EFS was significant. Lomab-B based conditioning was well-tolerated and provided access to HSCT with curative potential in a vulnerable patient population traditionally not considered eligible for HSCT.

## **About Actinium**

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. Actinium's clinical pipeline is led by targeted radiotherapies 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 bone marrow transplant (BMT), gene therapy or adoptive cell therapy, such as CAR-T, to enable engraftment of these transplanted cells with minimal toxicities. Our lead product candidate, lomab-B (I-131 apamistamab) has been studied in over four hundred patients, including the pivotal Phase 3 Study of lomab-B in Elderly Relapsed or Refractory Acute Myeloid Leukemia (SIERRA) trial for BMT conditioning. The SIERRA trial was positive with lomab-B meeting the primary endpoint of durable Complete Remission of 6-months with high statistical significance ( $p < 0.0001$ ). Lomab-B enabled 100% of patients to access a BMT and produced higher rates of post-BMT CR. Lomab-B produced positive results for the secondary endpoints of the SIERRA trial including reducing the probability of an event by 78% resulting in an Event-Free Survival (EFS) Hazard Ratio of 0.22 ( $p < 0.0001$ ), doubled 1-year overall survival and median overall survival. Lomab-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 with NIH funding. Actimab-A, our second most advanced product candidate has been studied in approximately 150 patients with Acute Myeloid Leukemia or AML, including in combination trials with the chemotherapy regimen CLAG-M and with venetoclax, a targeted therapy. Actimab-A or lintuzumab-Ac225 is an Actinium-225 based antibody radiation conjugate targeting CD33, a validated target in AML. Actinium has entered into a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI) to develop Actimab-A as a single agent or combination with chemotherapy, targeted agents or immunotherapy in Phase 1, 2 or 3 trials. The NCI will fund clinical trial expenses under the CRADA while Actinium will supply Actimab-A. The NCI is currently accepting proposals for non-clinical and clinical studies with Actimab-A. Actinium is a pioneer and leader in the field of Actinium-225 alpha therapies with an industry leading technology platform comprising over 200 patents and patent applications including methods of producing the radioisotope AC-225. Our technology and expertise have enabled collaborative research partnerships with Astellas Pharma, Inc. for solid tumor theranostics, with AVEO Oncology Inc. to create an Actinium-225 HER3 targeting radiotherapy for solid tumors, and with EpicentRx, Inc. to create targeted radiotherapy combinations with their novel, clinical stage small molecule CD47-SIRPα inhibitor. More information is available on Actinium's website: <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.

**Contact:**

Matthew Beck  
Vice President Investor Relations & Communications  
[mbeck@actiniumpharma.com](mailto:mbeck@actiniumpharma.com)  
(917) 415-1750

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