

February 14, 2023



# Actinium to Present Full Results from Pivotal Phase 3 lomab-B SIERRA Trial on Investor Call Following the Late-Breaker Presentation at the 2023 Transplantation & Cellular Therapy Tandem Meetings on Saturday, February 18, 2023

- Late-breaker presentation at 5:00 PM EST on Saturday, February 18, 2023, to feature lomab-B SIERRA Pivotal Trial results
- Investor call at 6:00 PM EST on Saturday, February 18, 2023, to highlight full results from the Phase 3 SIERRA trial

NEW YORK, Feb. 14, 2023 /PRNewswire/ -- **Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) ("Actinium" or the "Company"), a leader in the development of targeted radiotherapies, today announced its presence at the upcoming Tandem Meetings: Transplantation & Cellular Therapy Meetings of the American Society for Transplantation and Cellular Therapy (ASTCT) and the Center for International Blood & Marrow Transplant Research (CIBMTR) being held February 15 – 19, 2023 at the World Center Marriott in Orlando, Florida. Actinium will host an investor conference call and webcast to present full topline results from its pivotal Phase 3 SIERRA trial of lomab-B at 6:00 PM EST on Saturday, February 18, 2023. The investor conference call will follow the late-breaker presentation of the full Phase 3 SIERRA trial results. In addition, lomab-B will be highlighted in a CME Event titled, "The Convergence of Innovative Therapy and AlloHCT in AML: Applying Current Evidence to Improve Outcomes Across Patient Populations."



## Investor Conference Call and Webcast Details:

Time / Date: 6:00 PM EST on Saturday, February 18, 2023

Presenters: Sandesh Seth, Chairman & CEO, Madhuri Vusirikala M.D., Vice President, Clinical Development – Transplant & Cellular Therapy, Avinash Desai, M.D., Chief Medical Officer, Caroline Yarbrough, Chief Commercial Officer

Dial-in: 1-877-407-0784 (toll-free domestic) or 1-201-689-8560 (international) or by clicking on this [link](#) and requesting a return call

Live webcast: To access the live webcast of the call with slides please visit the Investors section of Actinium's website <https://ir.actiniumpharma.com/presentations-webinars> or [https://viaid.webcasts.com/starthere.jsp?ei=1590226&tp\\_key=580722640c](https://viaid.webcasts.com/starthere.jsp?ei=1590226&tp_key=580722640c)

An archived webcast will be available on the Actinium's website ([click here](#)) after the event.

## **TCT Iomab-B SIERRA Trial Late-Breaker Presentation Details**

Presentation Title: Efficacy and Safety Results of the SIERRA Trial: A Multicenter, Pivotal Phase 3 Study of Iomab-B Prior to Allogeneic Hematopoietic Cell Transplantation Versus Conventional Care in Older Patients with Active, Relapsed or Refractory Acute Myeloid Leukemia

Date: Saturday, February 18, 2022

Time: 5:00 PM EST

Presenter: Dr. Sergio Giralt, Memorial Sloan Kettering Cancer Center

Location: World Center Marriott, Cypress 3

### **CME Event Details:**

Title: The Convergence of Innovative Therapy and AlloHCT in AML: Applying Current Evidence to Improve Outcomes Across Patient Populations

Date: Thursday, February 16, 2023

Time: 12:45 PM EST

Location: World Center Marriott, Cypress 3

## **About Iomab-B and the Pivotal Phase 3 SIERRA Trial**

Iomab-B is a first-in-class targeted radiotherapy intended to improve patient access to potentially curative BMT by simultaneously and rapidly depleting blood cancer, immune and bone marrow stem cells that uniquely express CD45. Multiple studies have demonstrated increased survival in patients receiving BMT, however, an overwhelming majority of patients with blood cancers do not receive BMT as current approaches do not produce a remission, which is needed to advance to BMT, or are too toxic. Studied in over 400 patients, prior studies with Iomab-B have demonstrated nearly universal access to BMT, increased survival and tolerability in multiple clinical trials including the recently completed pivotal Phase 3 SIERRA trial in patients with active (leukemic blasts >5%), relapsed or refractory acute myeloid leukemia (r/r AML) age 55 and above. The SIERRA trial produced positive topline results, meeting its primary endpoint of durable Complete Remission (dCR) of 6 months with statistical significance ( $p < 0.0001$ ). Actinium intends to submit a Biologics License Application (BLA) seeking approval for Iomab-B to address patients age 55+ with r/r AML who cannot access BMT with currently available therapies. Iomab-B has been granted Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) and has patent protection into 2037.

The pivotal Phase 3 SIERRA (Study of Iomab-B in Elderly relapsed or refractory AML) is a

153-patient, randomized, multi-center clinical trial, studying lomab-B compared to the control arm of physician's choice of salvage therapy. Control arm options included chemotherapies like cytarabine and daunorubicin and targeted agents such as a Bcl-2 inhibitor (Venetoclax), FLT3 inhibitors and IDH 1/2 inhibitors. The SIERRA control arm reflects real-world treatment of r/r AML patients with over 20 single agents or combination of agents as no standard of care exists for this patient population. Data from full patient enrollment presented at the Transplantation & Cellular Therapy Tandem Meetings in April 2022 showed that 100% of patients receiving lomab-B accessed BMT and engrafted without delay. lomab-B was also shown to be well tolerated given its targeted nature, consistent with its previous clinical data. The SIERRA trial enrolled patients at 24 leading transplant centers in the United States and Canada that perform over 30% of AML BMTs.

Developed at the Fred Hutchinson Cancer Research Center, a pioneer in the field of BMT, lomab-B is supported by data in six disease indications including leukemias, lymphomas and multiple myeloma, which afflict over 100,000 patients annually. Actinium intends to pursue additional indications for lomab-B beyond AML. Actinium also intends to pursue international regulatory approvals independently and through partnerships. In April 2022, Actinium licensed the European, Middle East and North African commercial rights for lomab-B to Immedica AB, a fully-fledged independent pharmaceutical company headquartered in Sweden. In exchange, Actinium received an upfront payment of \$35 million USD with the potential for an additional \$417 million USD in regulatory and sales milestones and mid-twenty percent royalties. Europe represents a commercial opportunity double the size of the United States by number of patients with AML receiving BMT. lomab-B has been granted Orphan Drug Designation by the European Medicines Agency (EMA) and has received positive Scientific Advice from the Committee for Medicinal Products for Human Use (CHMP) of the EMA indicating that the Phase 3 SIERRA trial design, primary endpoint and planned statistical analysis are acceptable as the basis for a Marketing Authorization Application.

### **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. Actinium's clinical pipeline is led by 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, I-131 apamistamab (lomab-B) 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. Topline data from the SIERRA trial was positive with the study meeting its primary endpoint with a high statistical significance ( $p < 0.0001$ ). 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 ongoing combination trials with the chemotherapy regimen FLAG-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 is a pioneer and leader in the field of Actinium-225 alpha therapies with an industry leading technology platform comprising

over 190 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-SIRP $\alpha$  inhibitor. More information is available on Actinium's 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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