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# **Actinium Highlights Successful Administration of Targeted Radiotherapy Iomab-B Across Various BMT Centers with Ease and Without Increasing Radiation Exposure Risks to Treating Nursing Staff in the Pivotal Phase 3 SIERRA Trial at the 48th Annual Oncology Nursing Society (ONS) Congress**

- *24 leading bone marrow transplant (BMT) centers that perform over 30% of transplants in the U.S. participated in the SIERRA trial that enrolled patients with active relapsed or refractory acute myeloid leukemia*
- *Demonstration of rapid ability and ease of adoption for Iomab-B infusions at SIERRA sites*

NEW YORK, April 28, 2023 /PRNewswire/ -- **Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) ("Actinium" or the "Company"), a leader in the development of targeted radiotherapies, today announced that two posters detailing positive clinical experiences of sites in the pivotal Phase 3 SIERRA trial of Iomab-B, including the ease of Iomab-B administration, the rapid proficiency of sites and minimal radiation exposure to personnel are being presented at the 48<sup>th</sup> Annual Oncology Nursing Society (ONS) Congress, which is being held on April 26–30, 2023, in San Antonio, Texas. The SIERRA trial is the first randomized Phase 3 trial intended to take patients with active, relapsed or refractory (r/r) acute myeloid leukemia (AML) to a BMT, which is only feasible due to Iomab-B's targeted radiotherapy approach that enables these patients who are considered unfit and transplant ineligible in current routine clinical practice to access BMT without first achieving a remission.



Actinium's ONS posters demonstrate that Iomab-B can be adopted across a wide variety of BMT centers, evidenced by the 24 sites, which perform over 30% of all allogeneic BMT procedures in the United States, that participated in the SIERRA trial. Through education and utilizing Actinium-developed shielding solutions, site personnel became rapidly adept at

lomab-B administration. Importantly, treating nursing site personnel had minimal average radiation exposure of 0.09 millisievert (mSv), which is similar to the exposure from a roundtrip cross country flight, less than 1/10<sup>th</sup> the general public exposure limit of 1 mSv and significantly below the occupational radiation exposure limit for nursing staff of 50 mSv, clearly demonstrating no increased risk to nursing staff caring for lomab-B patients.

Dr. Avinash Desai, Actinium's Chief Medical Officer, commented, "Throughout the SIERRA trial, Actinium had a great partnership approach with BMT clinical trial sites, which has provided us with valuable insights for the potential commercial adoption and utilization of lomab-B. Through our education efforts and shielding solutions, we have optimized administration of lomab-B across a wide range of BMT centers. BMT centers are large, integrated hospitals that are accustomed to dealing with more complex procedures, such as surgeries or CAR-T cell therapy, and can administer single-infusion lomab-B with relative ease compared to other complex cell therapies. The 24 BMT centers that participated in the SIERRA trial established a strong base that we will now look to build on in anticipation of lomab-B commercial launch, assuming approval. On behalf of Actinium, I would like to thank all the nursing personnel at the SIERRA sites that made this first-of-its-kind trial possible."

Sandesh Seth, Actinium's Chairman and CEO, added, "Our team's commitment to operational excellence at the point of care was integral to our execution of the SIERRA trial and has positioned lomab-B well for future success. Through our SIERRA experience, we have established a playbook for implementing lomab-B at BMT centers that is scalable and efficient. In addition to our educational efforts and shielding solutions, we take great pride in the fact that we did not miss a single patient dose in the SIERRA trial and our end-to-end supply chain delivered a just-in-time personalized therapy to patients treated at the top BMT centers. Our positive experiences in the 24 SIERRA trial sites give us great confidence in our ability to expand to the top 50 BMT centers that perform approximately 75% of the BMT procedures at the time of launch. We are grateful for the opportunity to highlight lomab-B and SIERRA at ONS and look forward to additional opportunities to highlight the positive trial results and site experiences at future medical conferences globally to increase awareness for lomab-B's practice changing potential."

### **ONS Poster Details:**

#### **Successful Interdisciplinary Approach to Treat Patients With R/R AML with lomab-B Prior to HCT: The SIERRA Trial Experience**

- SIERRA site staff became rapidly adept to administering lomab-B and caring for patients via Actinium led educational efforts focused on nursing, radiation safety and nuclear medicine
- All SIERRA sites operated fully independently after treating their initial lomab-B patient
- SIERRA sites were able to establish tailormade individual approaches for their site and quickly established a cadence for subsequent lomab-B patients

#### **Exposure Rates of Staff Caring for SIERRA Trial Patients Receiving lomab-B: Experiences at Five Sites**

- Data was collected from 105 personnel from 5 SIERRA trial sites who were monitored while providing care for lomab-B treated patients
- The average radiation exposure was 0.09 mSv, which is approximately 1/10<sup>th</sup> of the

annual exposure limit for the general public of 1 mSv

- The average SIERRA treating nursing staff exposure of 0.09 mSv is approximately equal to the exposure on a roundtrip flight across the U.S.
- For hospital personnel such as nurses, the occupational dose limit is increased to 50 mSv
- These results indicate that lomab-B radiation exposure to caregivers from lomab-B is minimal

### **About Oncology Nursing Society**

The **Oncology Nursing Society (ONS)** is a professional association that represents 100,000 nurses and is the professional home to more than 35,000 members. ONS is committed to promoting excellence in oncology nursing and the transformation of cancer care. Since 1975, ONS has provided a professional community for oncology nurses, developed evidence-based education programs and treatment information, and advocated for patient care, all in an effort to improve the quality of life and outcomes for patients with cancer and their families. <https://www.ons.org/>.

### **About lomab-B and the Phase 3 SIERRA Trial**

lomab-B is a first-in-class targeted radiotherapy intended to enable a potentially curative bone marrow transplant (BMT) for patients who are considered unfit and ineligible for BMT with current routine treatment either due to the inability to tolerate non-targeted therapies or the inability for these therapies to produce a necessary remission. The SIERRA trial is the first randomized Phase 3 trial intended to take patients with active, relapsed or refractory acute myeloid leukemia (r/r AML) age 55 and above to a BMT without the patient first achieving remission. In February 2023, Actinium reported that lomab-B enabled unprecedented 100% BMT access and engraftment, achieved the primary endpoint of the SIERRA trial, durable Complete Remission of 6-months after initial remission post-BMT, with high statistical significance ( $p < 0.0001$ ), had a favorable safety profile compared to control arm therapies, significantly improved event-free survival and doubled median overall survival. Based on these positive results, Actinium intends to file a Biologics License Application by the end of 2023 to seek approval for lomab-B from the FDA.

### **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 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. Iomab-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-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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