



# Actinium Pharmaceuticals, Inc. Announces 82% of Control Arm Patients Did Not Receive a Bone Marrow Transplant by Conventional Means but 100% of Patients who Received Iomab-B, Including Crossover Patients, in the Phase 3 SIERRA Trial Successfully Engrafted at the Transplantation & Cellular Therapy Tandem Meetings of ASTCT and CIBMTR

- *Data from completed Iomab-B pivotal Phase 3 SIERRA trial demonstrate the potential of Iomab-B in enabling successful BMT in patients who cannot typically be transplanted*
- *5x greater magnitude of Iomab-B versus control arm patients potentially evaluable for the primary endpoint with statistically significant lower rates of sepsis*
- *Trial interim analysis includes data from full enrollment, with last patient transplanted 4Q 2021; topline data results expected 3Q 2022*



NEW YORK, April 25, 2022 /PRNewswire/ -- **Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) (Actinium or the Company) a leader in the development of targeted radiotherapies for patients with unmet needs today highlighted data from full patient enrollment in the pivotal Phase 3 SIERRA trial of Iomab-B was presented in an oral presentation at the upcoming Transplantation & Cellular Therapy (TCT) Tandem Meetings of ASTCT and CIBMTR, the combined annual meetings of the American Society for Transplantation and Cellular Therapy (ASTCT) and the Center for International Blood & Marrow Transplant Research (CIBMTR) being held April 23 – 26, 2022 virtually and in Salt Lake City, Utah.

Highlights of the SIERRA data presentation includes:

**Greater than 5-times increase in Bone Marrow Transplant access for lomab-B versus control arm and universal engraftment in patients receiving lomab-B**

- 100% of patients (66/66) receiving lomab-B were able to proceed to a bone marrow transplant (BMT) and all achieved engraftment compared to only 18% of patients (14/77) on the control arm who received physician's choice of therapy including targeted agents such as Venetoclax (Bcl-2), FLT3 and IDH1/2 inhibitors with 1 patient having a graft failure.
- At full enrollment, 82% of patients (63/77) on the control arm are failures for the primary endpoint of durable Complete Remission (dCR) of 6 months having never achieved a Complete Remission (CR)
- Including patients who crossed over to receive lomab-B after not achieving a CR with control arm therapies, 71% of patients (106/150) were able to access a BMT on the SIERRA trial.

**Lower rates of non-relapse transplant related mortality at day 100 and adverse events in patients receiving lomab-B**

- Non-relapse transplant related mortality (TRM) 100 days post BMT was 9% (6/65) in the lomab-B arm compared to 14% (2/14) in the control arm
- Rates of sepsis were statistically significantly lower in the lomab-B arm ( $p=0.002$ ) with 5% of patients (4/75) experiencing grade 3 or greater sepsis compared to 24% of patients (18/76) in the control arm.
- Rates of febrile neutropenia were 34% lower in patients on the lomab-B arm (25/75) compared to the control arm (34/76)

**Five times greater percentage of patients potentially evaluable for the primary endpoint consistently seen throughout the SIERRA trial**

- At full enrollment, 78% of patients (59/76) on the lomab-B arm are potentially evaluable for the dCR primary endpoint compared to 16% (12/77) after taking into account rates of 100-day TRM
- The approximate five times difference has been consistent at interim analyses at 25%, 50%, 75% and now 100% enrollment

Dr. Avinash Desai, Actinium's Chief Medical Officer, said, "These data from the SIERRA trial were very well received by the transplant community at TCT and there is clear enthusiasm from physicians for the potential of lomab-B. Currently, patients with active, relapsed or refractory AML have limited access to BMT, as seen in the SIERRA control arm, and thus poor survival outcomes of only 2-4 months. Even with the approval of multiple targeted therapies for patients with AML, which were used in about half of the patients in the control arm of SIERRA, they have no meaningful impact in improving BMT access or engraftment. lomab-B is the only targeted radiotherapy being developed for this patient population and it simultaneously delivers high amounts of radiation to the patient's radiosensitive cancer cells and to their bone marrow to achieve induction and conditioning. We are excited to be able to highlight 100% BMT access and engraftment and strong safety data to the transplant community at TCT and now look ahead to delivering strong topline data in the third quarter of this year."

## SIERRA Trial Patient Characteristics:

	Iomab-B Arm (N=76)	Control Arm (N=77)	Cross-Over Patients (N=40)
Median Age	65.0	66.1	64.6
Molecular and Cytogenetic Risk	Favorable: 5.3% Intermediate: 32.9% Adverse: 60.5%	Favorable: 3.9% Intermediate: 33.8% Adverse: 62.3%	Favorable: 5% Intermediate: 35% Adverse: 60%
Median Blast % at Randomization	30%	19.5%	35%

Sandesh Seth, Actinium's Chairman and CEO, stated, "We have always had confidence in Iomab-B given the strong BMT access, engraftment, safety and outcomes data that existed prior to the SIERRA trial. With patient enrollment in the multi-center, randomized SIERRA trial complete, it is incredibly exciting to see the consistency in the data across hundreds of patients who have been treated with Iomab-B. We intend to transform BMT conditioning with Iomab-B, not only for patients with active, relapsed or refractory AML, but across multiple blood cancer indications. Positive topline data from the SIERRA trial will be a major catalyst in allowing us to achieve that goal and even expand beyond BMT to conditioning for cell and gene therapies. We look forward to continuing to advance targeted radiotherapies and work to bring them to patients underserved by current therapies to improve patient outcomes."

## About the Tandem Meetings

The Tandem Meetings I Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR are the combined annual meetings of the American Society for Transplantation and Cellular Therapy (ASTCT) and the Center for International Blood & Marrow Transplant Research (CIBMTR). Administrators, clinicians, data manager / clinical research professionals, fellows-in-training, investigators, laboratory technicians, MD/PhDs, nurses, nurse practitioners, pharmacists, physician assistants, and other allied health professional attendees benefit from a full scientific program that addresses the most timely issues in hematopoietic cell transplantation and cellular therapy.

## About Iomab-B

Iomab-B (I-131 apamistamab), via the monoclonal antibody apamistamab, targets CD45, an antigen widely expressed on leukemia and lymphoma cancer cells, immune cells and bone marrow stem cells. Apamistamab is linked to the radioisotope iodine-131 (I-131) and once attached to its target cells emits energy that travels about 100 cell lengths, destroying a patient's cancer cells and ablating their bone marrow. By carrying iodine-131 directly to the bone marrow in a targeted manner, Iomab-B may avoid the side effects of non-targeted chemotherapy and external radiation on most healthy tissues while effectively killing the patient's cancer (induction) and marrow cells (myeloablation) including those in bone marrow niches due to the "crossfire" effect enabled by the I-131 radioisotope.

Iomab-B was licensed from the Fred Hutchinson Cancer Research Center where it was studied in nearly 300 patients, in multiple clinical trials in 6 blood cancer indications. Iomab-B is being studied in the pivotal Phase 3 SIERRA (Study of Iomab-B in Relapsed or Refractory AML) trial, a 150-patient, randomized controlled clinical trial in patients with active, relapsed or refractory Acute Myeloid Leukemia (AML) who are age 55 and above. If granted approval,

Iomab-B is intended to prepare and condition patients for a bone marrow transplant, also referred to as a hematopoietic stem cell transplant, in a potentially more efficacious manner and with a more beneficial safety profile than the non-targeted intensive chemotherapy conditioning that is the current standard of care in bone marrow transplant conditioning. A bone marrow transplant is often considered the only potential cure for patients with certain blood-borne cancers and blood disorders. Iomab-B has been granted Orphan Drug Designation from the U.S. FDA and the European Medicines Agency (EMA). Iomab-B also has patent terms extending to at least 2036/2037 in the US and EU. In addition, Actinium 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 the SIERRA Phase 3 Trial**

The SIERRA trial is a 150-patient, randomized clinical trial, studying Iomab-B compared to physician's choice of salvage therapy in patients with active, relapsed or refractory acute myeloid leukemia (r/r AML) age 55 and above. The SIERRA trial completed enrollment in the third quarter of 2021 with the last patient receiving a BMT in the fourth quarter of 2021. Topline data from the SIERRA trial is expected in the third quarter of 2022. In SIERRA, patients receiving Iomab-B, those achieving a remission after salvage therapy or those patients not achieving remission after salvage therapy that crossed over to receive Iomab-B were offered a BMT, which is the only treatment option with curative potential for patients with active r/r AML. The SIERRA trial is the only randomized Phase 3 trial to offer BMT to this patient population. The control arm of SIERRA included over 20 single agents or combination treatment options based on physician's choice, including salvage chemotherapy and recently approved targeted agents including Bcl-2 inhibitor (Venetoclax), FLT3 inhibitors and IDH 1/2 inhibitors as there is no standard of care for this patient population. The SIERRA trial enrolled patients at 24 leading transplant centers in the United States and Canada.

### **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 not addressed by traditional cancer therapies. Actinium's current clinical pipeline is led by ARCs or Antibody Radiation-Conjugates 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 BMT or Bone Marrow Transplant, Gene Therapy or Adoptive Cell Therapy (ACT) such as CAR-T to enable engraftment of these transplanted cells with minimal toxicities. Actinium's targeted conditioning ARCs seek to improve patient outcomes and access to these potentially curative treatments by eliminating or reducing the non-targeted chemotherapy that is used for conditioning in standard practice currently. Our lead product candidate, I-131 apamistamab (Iomab-B) has been studied in over four hundred patients including the pivotal Phase 3 Study of Iomab-B in Elderly Relapsed or Refractory Acute Myeloid Leukemia (SIERRA) trial for BMT conditioning that complete patient enrollment in the third quarter of 2021. Topline data from the SIERRA trial is expected in the third quarter of 2022. In April 2022, we announced we licensed the EUMENA commercial rights for Iomab-B to Immedica AB in exchange for \$35 million

upfront, with a \$452 million total deal value and mid-twenty percent royalties. 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. In addition, we are leaders in the field of Actinium-225 alpha therapies. Actimab-A, our clinical stage CD33 targeting ARC alpha therapy has been studied in nearly 150 patients including our ongoing combination trials with the salvage chemotherapy CLAG-M and the Bcl-2 targeted therapy venetoclax. Underpinning our clinical programs is our proprietary AWE (Antibody Warhead Enabling) technology platform. This is where our intellectual property portfolio of over 170 patents and patent applications, know-how, collective research and expertise in the field are leveraged to design and study novel targeted radiotherapies and combinations to strategically bolster our pipeline. Our AWE technology platform is currently being utilized in collaborative research partnerships with Astellas Pharma, Inc. for solid tumor theranostics, with AVEO Oncology 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-SIRPa inhibitor. 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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