

April 19, 2022



# Actinium Pharmaceuticals, Inc. to Highlight Iomab-B Pivotal Phase 3 SIERRA Trial Data at the Transplantation & Cellular Therapy Tandem Meetings of ASTCT and CIBMTR

- Updated Phase 3 SIERRA data to be presented in an oral presentation by Boglarka Gyurkocza, M.D., SIERRA trial investigator from Memorial Sloan Kettering Cancer Center
- Iomab-B to be featured in a CME symposium event led by KOLs titled "Landmarks Across the Patient Journey in AML, Applying Evidence with Novel Therapeutics Pre- and Post-AlloHCT"
- SIERRA Trial, with the last enrolled patient transplanted 4Q 2021, is the only randomized Phase 3 trial intended to enable patients age 55 and above with active, relapsed or refractory acute myeloid leukemia to receive a potentially curative bone marrow transplant

NEW YORK, April 19, 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 its activity 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.



Updated data from the fully enrolled pivotal Phase 3 SIERRA trial (Study of Iomab-B versus Conventional Care in Elderly, Relapsed or Refractory Acute Myeloid Leukemia) will be highlighted in an oral presentation by Boglarka Gyurkocza, M.D., investigator from Memorial Sloan Kettering Cancer Center, which was the highest enrolling trial site in the SIERRA trial. In addition, Actinium will be conducting medical affairs activity at TCT by engaging with the bone marrow transplant (BMT) community including featuring Iomab-B in a continuing medical education (CME) symposium titled "Landmarks Across the Patient Journey in AML, Applying Evidence with Novel Therapeutics Pre- and Post-AlloHCT" that will be led by Dr. Naval Daver, from The University of Texas MD Anderson Cancer Center and Dr. James

Foran from the Mayo Clinical Cancer Center in Jacksonville, Florida.

Dr. Avinash Desai, Actinium's Chief Medical Officer, stated, "We are excited to attend the TCT Tandem Meetings and once again feature lomab-B and the SIERRA trial at this preeminent bone marrow transplant and cell therapy conference. lomab-B has the potential to lead a paradigm shift in targeted conditioning aimed at increasing access to potentially curative treatments like BMT and improving patient outcomes with its differentiated targeted radiotherapy mechanism. Data from the SIERRA trial has shown a consistent 100% rate of BMT access and engraftment in all patients receiving lomab-B compared to only 17% of patients in the control arm who received multiple therapies including recently approved targeted therapies such as Venetoclax, FLT-3 and IDH inhibitors. In addition, patients receiving lomab-B have had lower rates on non-relapse transplanted related mortality 100-days post-transplant and lower rates of adverse events including statistically significant lower rates of sepsis and lower rates of febrile neutropenia, which we believe is attributed to the targeted nature of lomab-B. With topline data from SIERRA expected in the third quarter of this year, we look forward to SIERRA data being featured in an oral presentation and highlighting it in the numerous interactions we have planned with BMT physicians, scientists and care givers at TCT."

#### **lomab-B TCT Presentation Details:**

**Presentation Title:** High Rates of Transplantation in the Phase III SIERRA Trial Utilizing Anti-CD45 (Iodine) 131-I-Apamistmab (lomab-B) Conditioning with Successful Engraftment and Tolerability in Relapsed/Refractory (R/R) Acute Myeloid Leukemia (AML) Patients after Lack of Response to Conventional Care and Targeted Therapies

**Date and Time:** Saturday, April 23, 2022, 6:30 PM ET

**Location:** Salt Palace Convention Center – Ballroom I

Sandesh Seth, Actinium's Chairman and CEO, added, "TCT is always a highly impactful conference for Actinium as we get to showcase lomab-B to the largest gathering of transplant physicians. This year is particularly exciting as we will highlight the strong data from 100% patient enrollment showing a 5-times greater number of lomab-B patients potentially evaluable for the primary endpoint than control arm in the SIERRA trial at 100-days post BMT. With topline data in sight, this is a great time to be engaging the BMT community. Assuming success with lomab-B, we see an opportunity to be the leading developer of targeted conditioning regimens based on our lomab-B and lomab-ACT radiotherapies that can make BMT, CAR-T and other adoptive cell therapies as well as gene therapies more accessible and bring potential cures closer in reach for patients with high unmet needs."

#### **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 lomab-B**

lomab-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, lomab-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.

lomab-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. lomab-B is being studied in the pivotal Phase 3 SIERRA (Study of lomab-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, lomab-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. lomab-B has been granted Orphan Drug Designation from the U.S. FDA and the European Medicines Agency (EMA). lomab-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 lomab-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 lomab-B, those achieving a remission after salvage therapy or those patients not achieving remission after salvage therapy that crossed over to receive lomab-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-SIRP $\alpha$  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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