

February 27, 2023



Actinium Pharmaceuticals Announces Dr. Sergio Giralt to Discuss Positive Results from the Pivotal Phase 3 SIERRA Trial of Iomab-B via KOL Webinar

- *KOL webinar on Tuesday, February 28, 2023, at 8 a.m. EST*

- *Actinium intends to file a BLA for Iomab-B in 2H:2023 following positive SIERRA trial results*

- *Actinium reiterates current cash and cash equivalents of approximately \$100 million are projected to fund operations through 2025*

NEW YORK, Feb. 27, 2023 /PRNewswire/ -- Actinium Pharmaceuticals, Inc. (NYSE AMERICAN: ATNM) (Actinium or the Company), a leader in the development of targeted radiotherapies, today announced that it will host a key opinion leader (KOL) webinar at 8 a.m. EST on Tuesday, February 28, 2023, to discuss the results from the recently completed pivotal Phase 3 SIERRA trial of Iomab-B, which were presented in a late-breaker presentation at the Transplantation & Cellular Therapy (TCT) tandem meetings on February 18, 2023.



Sergio A. Giralt, MD, currently serves as Deputy Division Head, Division of Hematologic Malignancies, the Melvin Berlin Family Chair in Multiple Myeloma and Chief Medical Officer, MSK Direct at Memorial Sloan Kettering Cancer Center and is a Professor of Medicine at Weil Cornell Medical College. Dr. Giralt will discuss the unmet medical needs of older patients with active Relapsed or Refractory Acute Myeloid Leukemia (r/r AML), along with the practice changing potential for Iomab-B in this patient population. The event will highlight the potential for Iomab-B, a first-in-class targeted radiotherapy, to improve access to potentially curative bone marrow transplants for these patients who are not considered viable for this procedure.

A live question and answer session will follow the formal presentations. To register for the event, please click [here](#) or visit the investor relations page of Actinium's website [here](#).

Sandesh Seth, Actinium's Chairman and CEO, said, "We are honored that Dr. Giralt, who is instrumental in advancing the field of bone marrow transplant, will present the SIERRA data and frame how Iomab-B can address the unmet need for the majority of r/r AML patients who are not transplantable today. We are excited to move ahead with the BLA filing of Iomab-B in 2H:2023 following the highly positive, full results from the SIERRA trial which clearly established Iomab-B's ability to provide unprecedented access to a BMT to patients who currently not transplantable and to meaningfully improve outcomes. Additionally, we are enthused by the other consequential milestones we intend to achieve in 2023 including moving Actimab-A into late-stage development following our recent CRADA with the NCI, additional data and important studies with Iomab-ACT, the Early Access Program for Iomab-B and progress with our earlier stage solid tumor programs. Our current balance sheet of approximately \$100 million (unaudited) is expected to fund operations through 2025 and will allow us to continue to create value from these important milestones and provide clarity on how Actinium could radically alter the treatment of r/r AML with Iomab-B and Actimab-A and dramatically improve outcomes".

Sergio Giralt, MD, is a board-certified hematologist-oncologist, and his clinical activity and research focus is on stem cell transplantation for patients with blood disorders. He trained and worked for many years at the University of Texas M.D. Anderson Cancer Center, where he was Deputy Chair of the Department of Stem Cell Transplantation and Cellular Therapies. In May 2010, Dr. Giralt joined the faculty of Memorial Sloan Kettering Cancer Center to lead the Adult Bone Marrow Transplant Service and currently serves as Deputy Division Head, Division of Hematologic Malignancies, the Melvin Berlin Family Chair in Multiple Myeloma and Chief Medical Officer, MSK Direct. He is an Attending Physician, Adult Bone Marrow Transplant Service at MSKCC and Professor of Medicine at Weil Cornell Medical College.

Dr. Giralt's research focus has been on improving treatments for older patients who have acute and chronic leukemia. Along with his colleagues, he pioneered the use of reduced-intensity conditioning regimens for older or more debilitated patients with blood cancers which has changed the standard of care throughout the world. Dr. Giralt's research interests span the continuum of transplant and cellular therapy and include T-cell depletion techniques to reduce the risk of graft-versus-host disease. He is also a proponent of post-transplant maintenance therapies using a variety of targeted therapies, which they are continuing to explore at Memorial Sloan Kettering. Dr. Giralt recently chaired the executive board of the Center for International Blood and Marrow Transplant Research. He is also the past chair of the steering committee of the Blood and Marrow Transplant Clinical Trials Network, a federally funded group that defines the research agenda for stem cell transplantation in the United States.

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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.

Iomab-B met the primary endpoint of durable Complete Remission (dCR) of 6 months after initial remission post-BMT in the pivotal Phase 3 SIERRA trial with high statistical significance ($p<0.0001$). Iomab-B produced a 75% post-BMT CR rate (44/59 patients), which is 12-times greater than the post-BMT rate of 6.3% (4/64 patients) in the control arm. Patients receiving Iomab-B had a 78% lower probability of an event, defined as not achieving a CR/CRp, crossover, not receiving a BMT, relapse or death, with a Hazard Ratio of 0.22 ($p<0.0001$). Iomab-B doubled 1-year overall survival with 26.1% compared to 13.1% in the control arm for patients who did not crossover as well as median overall survival with 6.4 months vs 3.2 months. Overall survival statistics are confounded by the crossover arm. Crossover patients had a 35.8% 1-year overall survival rate. Due to its targeted nature, Iomab-B was well tolerated with four times lower rates of sepsis compared to the control arm (6.1% vs. 28.6%) and lower rates of BMT associated adverse events including febrile neutropenia, mucositis and graft versus host disease (GVHD). Actinium intends to submit a Biologics License Application (BLA) seeking approval for Iomab-B in 2023 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 Iomab-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 agents used alone or in combination as no standard of care exists for this patient population. 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, Iomab-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 Iomab-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 Iomab-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. Iomab-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 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, Iomab-B (I-131 apamistamab) 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. The SIERRA trial was positive with Iomab-B meeting the primary endpoint of durable Complete Remission of 6-months with high statistical significance ($p<0.0001$). Iomab-B enabled 100% of patients to access a BMT and produced higher rates of post-BMT CR. Iomab-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 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 α inhibitor. Approximate cash balance of \$100 million as of February 27, 2023 is unaudited and may be subject to future revision. More information is available on Actinium's website: <https://www.actiniumpharma.com/>.

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