



# Pivotal Phase 3 SIERRA Trial Data Showing 100% Bone Marrow Transplant Engraftment in Patients Treated with Iomab-B presented at the 2021 Virtual SNMMI Conference

- 100% engraftment consistent throughout interim analyses at 25%, 50% and 75% of patient enrollment despite heavy leukemia burden prior to Iomab-B treatment
- Personalized Iomab-B therapy enables targeted delivery of radiation to the bone marrow enabling myeloablation in a well-tolerated manner

NEW YORK, June 15, 2021 /PRNewswire/ -- **Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) ("Actinium" or the "Company") today highlighted data from its pivotal Phase 3 SIERRA trial for Iomab-B in an oral presentation at the 2021 Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting, which is to be held virtually from June 11<sup>th</sup> – 14<sup>th</sup>. Iomab-B is radiotherapy that targets cells expressing CD45, a protein found only on blood cancer cells and immune cells including bone marrow stem cells, with the radioisotope iodine-131 and is intended to be a targeted conditioning agent to enable potentially curative bone marrow transplant (BMT). The SIERRA trial is the only randomized Phase 3 trial to offer potentially curative BMT as an option for patients with active, relapsed or refractory acute myeloid leukemia (r/r AML) age 55 and above, a patient population not considered eligible for BMT with standard non-targeted conditioning regimens.



Dr. Mark Berger, Actinium's Chief Medical Officer, said, "Our enthusiasm for Iomab-B continues to grow at every safety and feasibility update from the pivotal Phase 3 SIERRA trial. With consistently strong engraftment data through 75% of patient enrollment, we believe Iomab-B has the potential to unlock a paradigm shift in the treatment of patients with relapsed and refractory AML. Despite 9 approved drugs for patients with AML since 2017, many of which are targeted agents, AML remains one of the most difficult to treat blood

cancers with the lowest 5-year survival rate. In developing Iomab-B our goal is to improve patient outcomes by enabling potentially curative BMT for a large portion of the AML patient population."

**SNMMI Presentation Title:** Relationship of Marrow Radiation Dose and Timing of Engraftment for Targeted Radioimmunotherapy with Anti-CD45 Iodine (<sup>131</sup>I) Apamistamab [Iomab-B] in Patients with Active Relapsed or Refractory Acute Myeloid Leukemia

**Presenter:** Susan Passalaqua, MD, Banner MD Anderson Cancer Center

**SNMMI Presentation Highlights:**

- 100% BMT and engraftment rate for patients receiving a therapeutic dose of Iomab-B compared to 18% of patients receiving physician's choice of salvage therapy on the control arm
- 79% of all patients enrolled on SIERRA were able to proceed to BMT despite being a patient population not considered eligible for BMT with standard approaches
- Iomab-B delivers high amounts of targeted radiation to the bone marrow with minimal impact on other organs resulting in lower rates and severity of adverse events

Phase 3 SIERRA – 75% Enrollment Results			
Baseline Characteristics	Iomab-B Arm (N=56)	Conventional Care (CC) Arm (N=57)	
Age (yrs, median, range)	63 (55-77)	65 (55-77)	
Cytogenetic and Molecular Risk <sup>1, 2</sup>	Favorable: 4% Intermediate: 35% Adverse: 61%	Favorable: 5% Intermediate: 32% Adverse: 63%	
% Transplanted Intent-to-Treat Group	88% (49/56)	18% (10/57)	64% (30/47)
Results	Underwent Iomab-B based Conditioning and HCT (N=49) <sup>3</sup>	Achieved CR and received standard of care HCT (N=10)	Randomized to Conventional Care and Crossed Over to Iomab-B with HCT (N=30) <sup>4</sup>
Cross-over Rate	n/a	n/a	Received Therapeutic Dose of Iomab-B (N=30) Transplanted (N=30) 64% (30/47)
% Transplanted	100% (49/49)	18% (10/57)	100% (30/30)
% Marrow Blast @ randomization (median, range)	29% (4-95) <sup>5</sup>	20% (5-97)	28% (6-87)
Days to ANC Engraftment	14 (9-22) <sup>6</sup>	17 (13-83) <sup>7</sup>	14 (10-37) <sup>8</sup>
Days to Platelet Engraftment	18 (4-39) <sup>6</sup>	22 (8-35) <sup>7</sup>	19 (1-38) <sup>8</sup>
Days to HCT (Post Randomization)	30 (23-60)	67 (52-104)	62 (36-100) <sup>9</sup>
Myeloablative Dose Delivered to Bone Marrow	14.7 (4.6-32) Gy 646 (354-1027) mCi	n/a	15.5 (6.3-42) Gy 592 (313-1013) mCi
100-day non-Relapse Transplant-Related Mortality	4% (2/45 Evaluable)	20% (2/10 Evaluable)	10.7% (3/28 Evaluable)

1) Iomab-B arm: data unavailable (4) and patient was excluded (1)  
 2) Per NCCN guidelines version 3. 2020  
 3) No therapy dose (7) due to: declining KPS (4), Infusion reaction (1), unfavorable biodistribution (1), post-randomization eligibility (1). Two (2) did not receive DI and five (5) received DI without proceeding to TI.  
 4) Thirteen (13) patients ineligible for crossover due to: hospice care/progression (4), declined/ineligible for HCT (5), died pre-crossover (4). Additionally, four (4) patients were eligible for crossover and did not receive Iomab-B due to declining KPS.  
 5) One (1) patient with 4% blasts in the marrow had circulating AML blasts  
 6) ANC engraftment data not available (4), platelet engraftment data not available (7)  
 7) ANC and platelet engraftment data not available (1)  
 8) ANC engraftment data not available (1), platelet engraftment data not available (2)  
 9) One (1) patient at 161 days had delayed transplant due to infection & respiratory failure, received Iomab & transplant when stable, not included in range

## About Iomab-B

Iomab-B (I-131 apamistamab) is an Antibody Radiation Conjugate (ARC) that is intended to condition or prepare patients for a potentially curative bone marrow transplant (BMT) in a targeted manner with the goal of reducing adverse events and increasing patient access to BMT. Via the monoclonal antibody apamistamab, Iomab-B targets CD45, an antigen widely expressed on leukemia and lymphoma cancer cells, immune cells and stem cells.

Apamistamab is linked to the radioisotope iodine-131 (I-131) and once its attached to its target cells, it 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, Actinium believes Iomab-B can avoid the side effects of radiation on most healthy tissues while effectively killing the patient's cancer and marrow cells.

Iomab-B is currently 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 relapsed or refractory Acute Myeloid Leukemia (AML) who are age 55 and above. The SIERRA trial is being conducted at preeminent transplant centers in the U.S. with the primary endpoint of durable Complete Remission (dCR) at six months and a secondary endpoint of overall survival. Upon 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 safer and more efficacious manner 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. Additional information on the Company's Phase 3 clinical trial in R/R can be found at [www.sierratrial.com](http://www.sierratrial.com).

## About Actinium Pharmaceuticals, Inc. (NYSE: ATNM)

Actinium Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing ARCs or Antibody Radiation-Conjugates, which combine the targeting ability of antibodies with the cell killing ability of radiation. Actinium's lead application for our ARCs is 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. With our ARC approach, we 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) is being studied in the ongoing pivotal Phase 3 Study of Iomab-B in Elderly Relapsed or Refractory Acute Myeloid Leukemia (SIERRA) trial for BMT conditioning. The SIERRA trial is over seventy-five percent enrolled and positive single-agent, feasibility and safety data has been highlighted at ASH, TCT, ASCO and SOHO annual meetings. Iomab-ACT (low dose I-131 apamistamab) is also be studied as a targeted conditioning agent in a Phase 1 study with a CD19 CAR T-cell Therapy with Memorial Sloan Kettering Cancer Center and is intended to be studied for conditioning prior to gene therapy. In addition, we are developing a multi-disease, multi-target pipeline of clinical-stage ARCs targeting the antigens CD45 and CD33 for targeted conditioning and as a therapeutic either in combination with other therapeutic modalities or as a single agent for patients with a broad range of hematologic malignancies including acute myeloid leukemia,

myelodysplastic syndrome and multiple myeloma. Ongoing combination trials include our CD33 alpha ARC, Actimab-A, in combination 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 140 patents, know-how, collective research and expertise in the field are being leveraged to construct and study novel ARCs and ARC combinations to bolster our pipeline for strategic purposes. Our AWE technology platform is currently being utilized in a collaborative research partnership with Astellas Pharma, Inc. 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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