

June 15, 2021



# **Safety Data Highlighting Low Rates of Adverse Events and Non-Relapse Transplant Related Mortality in Patients Receiving Iomab-B Presented at 2021 SNMMI Virtual Conference**

**Iomab-B enables high amounts of radiation to be delivered to the bone marrow to achieve targeted myeloablation**

**Adverse events are not correlated with the dose of Iomab-B delivered to the marrow or critical organs**

NEW YORK, June 15, 2021 /PRNewswire/ -- **Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) ("Actinium") today highlighted safety data from its ongoing pivotal Phase 3 SIERRA trial of Iomab-B in patients with relapsed or refractory Acute Myeloid Leukemia (r/r AML) were presented at the 2021 Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting which was held virtually June 11<sup>th</sup> – 14<sup>th</sup>. The presentation highlighted Iomab-B's targeting ability and corresponding safety data from 113 patients, representing 75% of patient enrollment on the SIERRA trial.



Iomab-B targets CD45, an antigen expressed on leukemia and lymphoma cancer cells and immune cells including bone marrow stem cells but not on cells outside of the blood forming or hematopoietic system. This allows high amounts of radiation to be delivered to the bone marrow via Iomab-B while sparing critical organs. As a result, statistically significant lower rates of sepsis were reported as well as lower rates of febrile neutropenia, mucositis and non-relapse transplant related mortality in patients receiving Iomab-B and bone marrow transplant (BMT) compared to patients that received salvage therapy and a BMT. In addition, patients who crossed over to receive Iomab-B and went to BMT after receiving salvage therapy but not achieving a complete response also had lower rates of sepsis, febrile neutropenia, mucositis and non-relapse transplant related mortality.

Dr. Mark Berger, Actinium's Chief Medical Officer, commented, "Relapsed and refractory AML in older patients is a particularly challenging disease to treat. Patients are heavily pretreated making their disease resistant to most standard therapies and often have comorbidities that limit treatment options, particularly bone marrow transplant. It is highly encouraging to us that in the SIERRA trial thus far, Iomab-B has enabled all patients receiving a therapeutic dose to proceed to BMT, the only curative treatment option for this patient population. Importantly, Iomab-B has been well tolerated and we are elated with the safety data from 75% of patient enrollment in the SIERRA trial. Given the targeted nature of Iomab-B, we can spare non-targeted organs like GI tract and deliver higher amounts of radiation to the bone marrow, the target organ. We are thrilled to be able to highlight results of the SIERRA trial through 75% of patient enrollment at SNMMI and look forward to future opportunities to present topline data from the full study."

**SNMMI Presentation Title:** Low Incidence Rates of Mucositis, Febrile Neutropenia or Sepsis in the Prospective, Randomized Phase 3 SIERRA Trial for Patients with Relapsed or Refractory Acute Myeloid Leukemia with Target Delivery of Anti-CD45 Iodine (131I) Apamistamab [Iomab-B]

**Presenter:** Neeta Pandit-Paskar, MD, Memorial Sloan Kettering Cancer Center

### **SNMMI Presentation Highlights:**

Adverse Event	Received Iomab-B/HCT (N=49) <sup>1</sup> % (N)	No CR Crossed over to Iomab-B/HCT (N=30) <sup>2</sup> % (N)	Achieved CR and received Std HCT (N=10) % (N)
Sepsis	4 (2)	23 (7)	30 (3)
Febrile Neutropenia Gr 3-4	42 (20)	40 (12)	50 (5)
Mucositis Gr 3-4	10.4 (5)	17 (5)	30 (3)
Day +100 Non-Relapse Mortality <sup>3</sup>	2/45 (4.4)	3/28 (10.7)	2/10 (20)

1 Adverse Event data available for 46 of 47 evaluable patients

2 Adverse Event data available for 27 of 30 evaluable patients

3 Iomab-B arm: 4 patients unevaluable. Conventional Care Arm: 4 patients unevaluable

Patient Group	No. of Patients	Radiation dose delivered to the Marrow. Median	Radiation dose to GI tract. Median
Iomab-B	49	14.6 Gy	2.8 Gy

### **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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