

December 7, 2020



## **Actinium Highlights lomab-B Safety Data Presented at the 62nd American Society of Hematology Annual Meeting**

- Lower rates of non-relapse transplant related mortality, sepsis, infections, and mucositis reported in patients receiving lomab-B compared to patients on the control arm receiving salvage therapies**
- lomab-B enables high amounts of radiation to be delivered to the bone marrow to achieve targeted myeloablation**

NEW YORK, Dec. 7, 2020 /PRNewswire/ --**Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) ("Actinium" or the "Company") today announced that safety data from its ongoing pivotal Phase 3 SIERRA trial of lomab-B in patients with relapsed or refractory Acute Myeloid Leukemia (R/R AML) were presented at the 2020 American Society of Hematology (ASH) annual meeting. The oral presentation highlighted lomab-B's targeting ability and corresponding safety data from 110 patients from the SIERRA trial for which detailed safety data was available. lomab-B targets CD45, an antigen expressed on leukemia and lymphoma cancer cells and immune cells including bone marrow stem cells but not cells outside of the blood forming or hematopoietic system. This allows high amounts of radiation to be delivered to the bone marrow via lomab-B while sparing healthy 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 lomab-B and bone marrow transplant (BMT) compared to patients that received salvage therapy and a BMT. In addition, patients that crossed over to receive lomab-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, "We are pleased that the engraftment and safety profile of lomab-B remains positive and consistent with prior interim safety results at 75% of patient enrollment in SIERRA and also consistent with the large body of historical data from lomab-B. Collectively, this data gives excitement as we approach the upcoming ad hoc interim analysis for SIERRA that will be completed by year-end and the ultimate potential of lomab-B for patients with R/R AML and other blood cancers

as a targeted conditioning regimen."

Safety data presented in ASH oral presentation are highlighted in the table below:

**ASH Oral Presentation:** *High Doses of Targeted Radiation with Anti-CD45 Iodine (131I) Apamistamab [lomab-B] Do Not Correlate with Incidence of Mucositis, Febrile Neutropenia or Sepsis in the Prospective, Randomized Phase 3 Sierra Trial for Patients with Relapsed or Refractory Acute Myeloid Leukemia*

Adverse Event	Received lomab-B/HCT (N=47) <sup>1</sup> % (N)	No CR Crossed over to lomab-B/HCT (N=30) <sup>2</sup> % (N)	Achieved CR and received Std HCT (N=9) % (N)
Sepsis	4.3 (2)	22.2 (6)	33.3 (3)
Febrile Neutropenia Gr 3-4	34.8 (16)	40.7 (11)	55.6 (5)
Mucositis Gr 3-4	10.9 (5)	18.5 (5)	33.3 (3)

Day +100 Non-Relapse Mortality <sup>3</sup>	2/45 (4.4%)	3/26 (11.5%)	2/9 (22.2%)
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1 Adverse Event data available for 46 of 47 evaluable patients
2 Adverse Event data available for 27 of 30 evaluable patients
3 lomab-B arm: 4 patients unevaluable. Conventional Care Arm: 4 patients unevaluable

Patient Group	No. of Patients	Radiation dose delivered to the Marrow. Median (range)	Radiation dose to GI tract. Median (range)
lomab-B	47	14.9 Gy (4.6-32)	2.8 Gy (1.6-6.7)

Vijay Reddy, Vice President, Clinical Development and Head of BMT, "The targeted nature of lomab-B makes it highly differentiated from current BMT conditioning regimens that are largely comprised of non-targeted cytotoxic chemotherapies. These data from SIERRA showing higher rates of sepsis, neutropenia and mucositis in patients receiving chemotherapy are consistent with the literature and unfortunately what we expected but hope to address with lomab-B. Particularly, chemotherapy's effect on the GI tract and resulting mucositis, which we believe is leading to the higher rates of sepsis seen in the control arm. We are highly encouraged by the lower rates of adverse events and the universal engraftment reported from SIERRA and excited for the potential of targeted conditioning could have an BMT access, patient outcomes and quality of life."

## 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, B cells and 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, Actinium believes lomab-B will avoid the side effects of radiation on most healthy tissues while effectively killing the patient's cancer and marrow cells.

lomab-B is currently 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 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 at one year. 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. More information on this Phase 3 clinical trial can be found at [www.sierratrial.com](http://www.sierratrial.com). I-131 apamistamab will also be studied as a targeted conditioning agent in a Phase 1 study with a CD19 CAR T-cell therapy and in a Phase 1/2 anti-HIV stem cell gene therapy with UC Davis. 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 130 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: [www.actiniumpharma.com](http://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.

**Contacts:**

Investors:

Clayton Robertson

Actinium Pharmaceuticals, Inc.


[crobertson@actiniumpharma.com](mailto:crobertson@actiniumpharma.com)

Hans Vitzthum

LifeSci Advisors, LLC

[Hans@LifeSciAdvisors.com](mailto:Hans@LifeSciAdvisors.com)

(617) 430-7578

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