

February 11, 2021



# **Actinium Showcases Targeted Conditioning Program with 2 Oral Presentations Highlighting lomab-B and Pivotal Phase 3 SIERRA Trial at 2021 Transplantation & Cellular Therapy Annual Meeting**

- TCT conference visibility bolsters strong momentum as SIERRA nears full enrollment following recent positive interim analysis**
- Strong results from 75% of patient enrollment highlighted in CME events, oral presentations and investigator interactions at TCT**

NEW YORK, Feb. 11, 2021 /PRNewswire/ --**Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) ("Actinium" or the "Company") today highlighted its presence at the 2021 Transplantation & Cellular Therapy (TCT) Annual Meeting, which is being held virtually from February 8<sup>th</sup> – 12<sup>th</sup>. The TCT meeting organizes thousands of transplant professionals from over five hundred transplant centers worldwide and is a seminal event for Actinium given its focus on targeted conditioning for bone marrow transplant (BMT), CAR-T and other adoptive cell therapies and gene therapy. At TCT, Actinium's pivotal Phase 3 trial SIERRA trial for lomab-B was featured in 2 oral presentations, as well as CME event focused on AML and BMT and in investigator interactions led by Actinium's clinical development and medical affairs teams.



Dr. Mark Berger, Actinium's Chief Medical Officer, said, "TCT is the ideal venue to showcase Actinium's lomab-B and lomab-ACT targeted conditioning programs given the concentrated audience of thought leaders in these fields that TCT brings together. The timing of TCT is also ideal as it follows shortly after ASH resulting in a data rich period for Actinium that drives investigator interest. This is particularly the case this year as we have built strong momentum in SIERRA following positive data from 75% enrollment featured in 2 oral presentations at ASH and now in 2 oral presentations at this year's TCT, which has driven high levels of investigator and referring physician interactions. We have coupled this with

bolstered outreach efforts, which will continue beyond TCT, that have resulted in new site activation despite the advanced stage of SIERRA and robust enrollment rates that give us great confidence in completing SIERRA enrollment rapidly."

**Summary data presented in TCT oral presentations include:**

- 100% BMT and engraftment rate for patients receiving a therapeutic dose of lomab-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
- lomab-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

**TCT Oral Presentation:** Targeted Radioimmunotherapy with Anti-CD45 Iodine (131I) Apamistamab [lomab-B] in Older Patients with Active, Relapsed or Refractory (R/R) Acute Myeloid Leukemia Results in Successful and Timely Engraftment Not Related to the Radiation Dose Delivered

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)
<b>Results</b>	<b>Underwent Iomab-B based Conditioning and HCT (N=49)<sup>3</sup></b>	<b>Achieved CR and received standard of care HCT (N=10)</b>	<b>Randomized to Conventional Care and Crossed Over to Iomab-B with HCT (N=30)<sup>4</sup></b>
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) Gv	n/a	15.5 (6.3-42) Gv 592 (313-1013) mCi
	646 (354-1027) mCi		
100-day non-Relapse Transplant-Related Mortality	4% (2/45 Evaluable)	20% (2/10 Evaluable)	10.7% (3/28 Evaluable)

- 1) lomab-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 lomab-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 lomab & transplant when stable, not included in range

<https://tct.confex.com/tct/2021/meetingapp.cgi/Paper/16878>

**TCT Oral Presentation:** Myeloablative Targeted Conditioning with Anti-CD45 Iodine (131I) Apamistamab [lomab-B] Spares the GI Tract and Has Low Incidence of Severe Mucositis, Febrile Neutropenia and Sepsis in the Prospective, Randomized Phase 3 Sierra Trial for Patients with Relapsed or Refractory Acute Myeloid Leukemia (AML)

Adverse Event	Iomab-B Arm (N=56)	Conventional Care Arm (N=57)	
	Received Iomab-B/HCT (N=49) <sup>1</sup>	Achieved CR and received Std HCT (N=10)	No CR Crossed over to Iomab-B/HCT (N=30)
Sepsis % (N)	4.2 (2)*	30.0 (3)	23.3 (7)
Febrile Neutropenia Gr 3-4 % (N)	41.7 (20)	50.0 (5)	40.0 (12)
Mucositis Gr 3-4 % (N)	10.4 (5)	30.0 (3)	16.7 (5)

Day +100 Non-Relapse Mortality <sup>3</sup>	2/45 (4.4%)	2/10 (20.0%)	3/28 (10.7%)
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- 1 Adverse Event data available for 48 of 49 evaluable patients  
Iomab-B arm: 4 patients unevaluable. Conventional Care Arm: 2 patients unevaluable. \*p=
- 3 <0.05

Patient Group	No. of Patients	Radiation dose delivered to the Marrow. Median (range)	Radiation dose to GI tract. Median (range)
Iomab-B	49	14.6 Gy (4.6-32)	2.8 Gy (1.6-6.7)

<https://tct.confex.com/tct/2021/meetingapp.cgi/Paper/16876>

"We are proud of the leadership position we have developed in targeted conditioning for BMT and CAR-T and the progress we have made across our pipeline in these areas", said Sandesh Seth, Actinium's Chairman and CEO. In the second half of 2020 we reached 75% enrollment in SIERRA, announced an NIH funded collaboration with Memorial Sloan Kettering focused on conditioning for CAR-T utilizing lomab-ACT and SIERRA data was featured in 2 oral presentations at ASH. These milestones are emblematic of our team's capabilities and the differentiated nature of our targeted radiotherapy that is addressing unmet patient needs not effectively treated with current approaches. We anticipate 2021 to be a significant year for Actinium with milestones expected across our pipeline and technology platform. I'm excited to build upon our growing momentum from ASH, our recently announced research collaboration with Astellas leveraging our AWE technology platform and TCT to meet our core objectives of completing SIERRA enrollment, advancing

lomab-ACT in the clinical for CAR-T and gene therapy conditioning, presenting proof of concept data from our Actimab-A combination trials with CLAG-M and venetoclax and continuing to utilize AWE to develop novel targeted radiotherapies."

## **About lomab-B**

lomab-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, lomab-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 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. Upon 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 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 radioisotopes. 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 Bone Marrow Transplant (BMT), Gene Therapy or Adoptive Cell Therapy 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 (lomab-B) is being studied in the ongoing pivotal Phase 3 Study of lomab-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 is also being studied as a targeted conditioning agent in a Phase 1 study with a CD19 CAR T-cell therapy in collaboration with Memorial Sloan Kettering Cancer Center for which we have been awarded NIH grant funding. 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 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.

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