

November 4, 2020



## **Actinium Announces Two Oral Presentations Featuring Data and Findings from the Phase 3 SIERRA Trial of lomab-B at the 62nd American Society of Hematology Annual Meeting**

**-- Universal rates of BMT and engraftment continue in Phase 3 SIERRA pivotal trial in relapsed/refractory AML for all patients receiving therapeutic dose of lomab-B**

**-- Second oral presentation to showcase lower rates of sepsis, infections, and mucositis for lomab-B patients compared to control arm**

NEW YORK, Nov. 4, 2020 /PRNewswire/ --**Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) ("Actinium") today announced that two abstracts on the Company's Antibody Radiation Conjugate (ARC) lomab-B were accepted for oral presentations at the 2020 American Society of Hematology (ASH) annual meeting that is being held virtually December 5-8, 2020.



"This is an exciting fourth quarter for the company and we are honored to have multiple oral presentations at this year's ASH conference. Our 3 oral presentations and one poster presentation demonstrate the clinical progress we have seen not only with lomab-B, but our other programs including Actimab-A in combination with novel and approved therapeutic agents," stated Sandesh Seth, Actinium's Chairman and CEO. "We look forward to presenting the lomab-B data in further detail during the two oral presentations on the lomab-B SIERRA study at ASH in December. The company remains on track to report safety and feasibility data from 75% of the patients to be enrolled in SIERRA, as well as to complete the ad hoc interim analysis in the fourth quarter."

Mark Berger, Actinium's Chief Medical officer, said, "We are encouraged that we continue to see positive ongoing results from our Phase 3 pivotal SIERRA trial in relapsed or refractory Acute Myeloid Leukemia (R/R AML) patients. In the lomab-B Phase 3 trial we continue to see 100% engraftment in patients receiving a therapeutic dose of lomab-B in the treatment

arm whereas 83% of control arm patients failed salvage therapy, which includes the recently approved targeting agents such as venetoclax. This high failure rate demonstrates the significant need that exists in R/R AML and represents the paradigm shift we are looking to initiate with lomab-B. The strong safety and feasibility data we have seen thus far gives us confidence that these older patients with active AML may benefit by undergoing a potentially curative bone marrow transplant which they could not receive otherwise."

## Details & Highlights for Oral Presentations

*Note: The two abstracts include SIERRA Phase 3 trial data available to the company from its CRO prior to August 10, 2020, the ASH submission cutoff date. Per ASH rules, updated data sets are permitted to be included in the live presentations.*

Oral Presentation Title: Personalized Targeted Radioimmunotherapy with Anti-CD45 Iodine (<sup>131</sup>I) Apamistamab [lomab-B] in Patients with Active Relapsed or Refractory Acute Myeloid Leukemia Results in Successful Donor Hematopoietic Cells Engraftment with the Timing of Engraftment Not Related to the Radiation Dose Delivered

Publication Number: 193

Session Name: 721. Clinical Allogeneic Transplantation: Conditioning Regimens, Engraftment, and Acute Transplant Toxicities

Session Date: Saturday, December 5, 2020

Presentation Time: 1:00 PM PT / 4:00 PM ET

- 53 patients (median age 64) were randomized to lomab-B. 87% (46/53) received allogeneic transplant. 100% (46/46) lomab-B transplanted patients engrafted, despite a pre-therapy median of 26% marrow blasts.
- After randomization, 83% (44/53) of Conventional Care (CC) patients failed salvage therapy, including 45% (24/53) who received targeted agents. 44 CC patients were evaluated for crossover, with a median 33% marrow blasts, 59% (26/44) crossed over to lomab-B followed by allogeneic HCT and 100% (26/26) of those patients engrafted.
- Median time to neutrophil and platelet engraftment were 14 days (range 9-22) and 17 days (range 4-39) respectively, with 91% of evaluable patients achieving full donor chimerism (>95% by day 100). Neither the radiation dose delivered to the marrow (median 14.7 Gy; range, 4.6-32 Gy) nor the total administered activity (median 632 mCi; range, 354-1027 mCi) showed correlation with the time to neutrophil (p value=0.525) or platelet engraftment (p value=0.952).
- Regression analyses, considering all of the variables individually, did not indicate a statistically significant correlation ( $p > 0.1$ ) between days to engraftment and radiation dose delivered to the marrow.

Phase 3 SIERRA – Preliminary Results			
Baseline Characteristics	Randomized to lomab-B (N=53)	Randomized to Conventional Care (CC) (N=53)	
Age (yrs, median, range)	64 (55-77)	65 (55-77)	
Molecular & Cytogenetic Risk	Favorable: 2% Intermediate: 33% Adverse: 65%	Favorable: 4% Intermediate: 30% Adverse: 66%	
% Transplanted Intent-to-Treat Group	87% (46/53)	17% (9/53)	59% (26/44)

Results	Received Therapeutic dose of lomab-B & Transplanted (N=46)****	Eligible to Receive Std. of Care Transplant Post-Salvage (N=9)	Evaluated for Crossover (N=44)*****
Cross-over Rate	n/a	n/a	Received Therapeutic Dose of lomab-B (N=26) Transplanted (N=26) 59% (26/44)
% Transplanted	100% (46/46)	17% (9/53)	100% (26/26)
BM Blast % @ baseline (median, range)	26 (4-95)	14 (5-97)	30 (6-87)
BM Blast % pre-HCT (median, range)	26 (4-95)	1 (0-3)*	32.5 (2-75)
Days to ANC Engraftment	14 (9-22)***	17 (13-83)#	14 (10-37)**
Days to Platelet Engraftment	17 (4-39)***	22 (8-35)#	19 (1-38)**
Days to HCT (Post Randomization)	30 (23-60)	66 (51-86)	65 (36-161)^
Myeloablative Dose Delivered to Bone Marrow	14.7 (4.6-32) Gv	n/a	14.4 (6.3-30) Gv
	632 (354-1027) mCi		540 (313-1008) mCi
Chimerism >= 95% by D100	91% (39/43^ Evaluable)	67% (4/6^^ Evaluable)	87% (20/23^^^ Evaluable)
100-day non-Relapse Transplant-Related Mortality	5% (2/40 Evaluable)	25% (2/8 Evaluable)	8% (2/24 Evaluable)
*1 pt with 8% BM blasts on D42 with CRp on D50, ** ANC engraftment data not available (N=3), platelet engraftment data not available (N=4); *** ANC engraftment data not available (N=4), platelet engraftment data not available (N=9), ^ 1 patient at 161 days had delayed transplant due to infection and respiratory failure, received lomab & transplant when stable, # ANC and platelet engraftment data not available (N=2)			
**** No Therapy Dose (7) due to: Declining KPS (4), Infusion Reaction (1), Unfavorable Biodistribution (1), Post-Randomization Eligibility (1); 1 Pending Treatment.			
*****Ineligible for lomab-B HCT after crossover evaluation - 13: due to Hospice Care/Progression (4), Declined/Ineligible for HCT (5), Died Pre-Crossover (4). 4 Received Dosimetry but No Therapy Dose due to Declining KPS; 2 Pending Evaluation for Crossover.			
^ Did not achieve ≥95% chimerism (4); Data pending (2); Died (1); ^^ Did not achieve ≥95% chimerism (4); Data pending (1); ^^ Did not achieve ≥95% chimerism (4); Data pending (2);			

Oral Presentation Title: High Doses of Targeted Radiation with Anti-CD45 Iodine (<sup>131</sup>I) 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

Publication Number: 135

Session Name: 721. Clinical Allogeneic Transplantation: Conditioning Regimens, Engraftment, and Acute Transplant Toxicities

Session Date: Saturday, December 5, 2020

Presentation Time: 9:30 AM PT / 12:30 PM ET

- The median dose of lomab-B administered was 603 mCi (range 313-1027 mCi) and the median radiation dose delivered to the marrow in the lomab-B group was 14.7 Gy (range 4.6 – 32 Gy).
- All patients (n=45, median age 64) treated with a therapeutic dose of lomab-B achieved neutrophil engraftment after a median of 14 days post-HCT (range 9-22), despite presenting with a median 26% marrow blasts prior to initiation of therapy.
- No correlation between adverse events (AE) (FN, mucositis, sepsis) and administered lomab-B activity (p=0.08), nor with dose delivered to GI tract (p=0.09) was observed. Furthermore, these AEs were not related to the dose of radiation received by the small intestine (median 2.7 Gy range 1.1-6.8 Gy) large intestine (median 2.6 Gy range 0.9-6.5 Gy), nor an average of 4 GI sites (median 2.8 Gy range 1.6-6.8 Gy).

## **About lomab-B**

lomab-B via the monoclonal antibody BC8, targets CD45, an antigen widely expressed on leukemia and lymphoma cancer cells, B cells and stem cells. BC8 is linked to the radioisotope iodine-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, 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 AML can be found at [sierratrial.com](http://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 (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 [sierratrial.com](http://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 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 100 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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