



## **Actinium Pharmaceuticals Highlights Analysis of Pivotal lomab-B Phase 3 SIERRA Trial Presented in Oral Session at ASH Annual Meeting**

- Key highlights include near universal engraftment and no 100-day non-relapse mortality in patients randomized to lomab-B arm; 79% of patients in the control arm failed to achieve a complete response necessary for conventional bone marrow transplant
- 67% (10/15) of patients eligible for crossover successfully transplanted with lomab-B
- Interim results strongly support feasibility of lomab-B for targeted conditioning in patients 55 years or older with active, relapsed or refractory Acute Myeloid Leukemia
- SIERRA trial is the only ongoing Phase 3 trial to offer a bone marrow transplant for this patient population

NEW YORK, Dec. 4, 2018 /PRNewswire/ --**Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) announced today that additional data from an updated analysis of the pivotal lomab-B Phase 3 SIERRA trial were highlighted last night in an oral presentation at the 60<sup>th</sup> American Society of Hematology (ASH) Annual Meeting. The SIERRA trial is the only ongoing Phase 3 trial offering a bone marrow transplant (BMT) to patients 55 years of age or older with active, relapsed or refractory acute myeloid leukemia (AML). Data in the table below were presented in the oral session and are updated from those at the time of abstract submission. Preliminary data strongly support the feasibility and safety of re-induction and targeted conditioning with lomab-B prior to a BMT.

**Preliminary Feasibility and Safety Data**

	Randomized to lomab-B Study Arm (N=19)	Randomized to Conventional Care (N=19)	Randomized to Conventional Care, No Remission, and Crossed Over (N=10)
Number of Patients Receiving BMT after receiving therapy	100% (18/18) (1 patient did not receive therapeutic lomab-B dose)	21% (4/19)	100% (10/10)

Blast % at Randomization	Median: 30% Range: 4* -74	Median: 26% Range: 6-97	At Randomization 24% (6-70) At Crossover 45% (10-70)
Days to BMT (post-randomization)	Median: 28 Range: 23-38	Median: 67 Range: 66-86	Median: 66 Range: 57-161
Days to Absolute Neutrophil Engraftment	Median:13 Range: 9 – 22	Not entered	Median:13 Range: 9 - 20
Days to Platelet Engraftment	Median: 16 Range: 13 – 26	Not entered	Median:17 Range: 10 – 20
100-Day Non- Relapse Mortality	0% (0/18)	25% (1/4 – septic shock)	10% (1/10 – diffuse alveolar hemorrhage)

\*1 patient with 4% blasts in the marrow had circulating AML blasts

### Other Key Highlights:

- 15 of 19 (79%) patients in the control arm failed to achieve a complete response
- 67% (10/15) of patients eligible for crossover successfully transplanted with lomab-B
- All patients receiving lomab-B engrafted despite active disease with high blast count (median 30%, or median 45% for crossover patients)
- Patients receiving lomab-B received a BMT more quickly post-randomization (28 days) than patients receiving conventional care (67 days)
- In the conventional care arm, there was no difference in time to BMT for patients that crossed over to lomab-B (66 days) compared to those achieving complete remission with conventional care (67 days)
- No Grade 3 or 4 lomab-B infusion related reactions with all lomab-B infusions completed
- No non-relapse mortality in patients randomized to lomab-B arm

Abstract #1017: Targeted Conditioning of lomab-B (131I-anti-CD45) Prior to Allogeneic Hematopoietic Cell Transplantation Versus Conventional Care in Relapsed or Refractory Acute Myeloid Leukemia (AML): Preliminary Feasibility and Safety Results from the Prospective, Randomized Phase 3 Sierra Trial

Dr. Edward Agura, Medical Director of Bone Marrow Transplantation at Baylor University Medical Center said, "Given that more than two thirds of patients who are diagnosed with AML are 55 years of age or older, there exists a significant unmet medical need to broaden transplant access and improve outcomes for these patients. The data from the SIERRA trial thus far are highly encouraging as they demonstrate that lomab-B can enable a potentially curative transplant in patients with active disease, including those patients with progressing disease who did not achieve a response on conventional care. The nearly universal and rapid engraftment of patients receiving lomab-B, together with no 100-day non-relapse mortality, is particularly compelling as these results have not been achieved with conventional care."

The 150 patient SIERRA study is a multi-center randomized trial that will compare outcomes of patients who receive lomab-B and a BMT to those patients receiving physician's choice of salvage chemotherapy, defined as conventional care, as no standard of care exists for this patient population. AML patients with active, relapsed or refractory AML have dismal prognoses and are typically not offered curative transplant as an option. This is largely because salvage treatments have a limited ability to produce a complete remission, which is necessary prior to BMT if conventional BMT is to be successful. However, with lomab-B

targeted conditioning, a complete remission prior to starting the lomab-B conditioning is not necessary for a successful transplant.

Dr. Mark Berger, Actinium's Chief Medical Officer said, "We believe that lomab-B represents a potentially disruptive modality for targeted conditioning. The preliminary data from the SIERRA trial presented at ASH exceeded our expectations regarding feasibility and safety, which adds to the already extensive body of research and data demonstrating the utility of lomab-B for targeted conditioning in multiple hematologic indications. With this data in hand we are highly motivated to complete the SIERRA trial, which will serve as the beachhead for our multi-target, multi-disease pipeline for targeted conditioning, where we are committed to expanding our leadership position."

### **About Actinium Pharmaceuticals, Inc.**

Actinium Pharmaceuticals Inc. is focused on improving patient access and outcomes to cellular therapies such as bone marrow transplant (BMT) and CAR-T with its proprietary, chemotherapy free or sparing, targeted conditioning technology. Actinium is the only company with a multi-disease, multi-target, drug development pipeline focused on targeted conditioning. Its targeted conditioning technology is enabled by ARC's or Antibody Radiation Conjugates that combine the targeting ability of monoclonal antibodies with the cell killing ability of radioisotopes. Actinium's pipeline of clinical-stage targeted conditioning ARCs target the antigens CD45 and CD33 for patients with a broad range of hematologic malignancies including acute myeloid leukemia (AML), myelodysplastic syndrome (MDS) and multiple myeloma (MM), acute lymphoblastic leukemia (ALL), Hodgkin's lymphoma and Non-Hodgkin's lymphoma. Actinium's lomab-ACT program is designed to be a universal lymphodepletion technology intended to eliminate the need for chemotherapy-based conditioning prior to CAR-T or other adoptive cellular therapies.

lomab-B, Actinium's lead targeted conditioning product candidate, is currently enrolling patients in the pivotal Phase 3 SIERRA trial in patients age 55 or older, with active, relapsed or refractory AML. Iodine-131-apamistamab (lomab-B), combines the anti-CD45 monoclonal antibody labeled with iodine-131 for myeloablation prior to a bone marrow transplant. CD45 is expressed on leukemia, lymphoma and normal immune cells. lomab-B has been studied in over 500 patients in 10 clinical trials in numerous hematologic diseases. Actinium's lomab-ACT program is an expansion of its CD45 program that is intended to be a universal, chemotherapy-free solution for targeted lymphodepletion prior to CAR-T. Through targeted lymphodepletion, the lomab-ACT program is expected to improve CAR-T cell expansion, reduce CAR-T related toxicities and expand patient access to CAR-T treatment and potentially other adoptive cell therapies. Due to its lower payload dose, lymphodepletion with the lomab-ACT program can be accomplished through a single outpatient infusion. Actinium intends to advance its lomab-ACT program with CAR-T focused collaborators from academia and industry.

Actinium's pipeline also includes a potentially best-in-class CD33 program with its ARC comprised of the anti-CD33 antibody lintuzumab labeled with the alpha-particle emitter actinium-225. Its CD33 program is currently being studied in multiple clinical trials for targeting conditioning and as a therapeutic in multiple diseases and indications including AML, MDS and MM. Actinium applies its CD33 program at high doses to target CD33+ cells of the myeloid lineage in combination with reduced intensity conditioning (RIC), which together are intended to result in myeloablative outcomes with a more benign and well

tolerated profile than high intensity chemotherapy myeloablation. Actinium is focused on applying its CD33 program at low doses in combination with other therapeutic modalities including chemotherapy, targeted agents and immunotherapies.

Actinium is also developing its proprietary AWE or Antibody Warhead Enabling technology platform which utilizes radioisotopes including iodine-131 and the highly differentiated actinium-225 coupled with antibodies to target a variety of antigens that are expressed in hematological and solid tumor cancers. The AWE technology enables Actinium's internal pipeline and with the radioisotope Actinium-225 is being utilized in a collaborative research partnership with Astellas Pharma, Inc. Actinium's clinical programs and AWE technology platform are covered by a portfolio of 75 patents covering composition of matter, formulations, methods of use and also methods of manufacturing the radioisotope Actinium-225 in a cyclotron.

More information is available at [www.actiniumpharma.com](http://www.actiniumpharma.com) and our Twitter feed @ActiniumPharma, [www.twitter.com/actiniumpharma](https://www.twitter.com/actiniumpharma).

### **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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