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# **Actinium's Late Breaking Oral Presentation at 2019 TCT Meetings Reports New Data on Donor Chimerism Indicating Deep Engraftment in All Iomab-B Treated Patients in the Pivotal Phase 3 SIERRA Trial**

- All patients receiving Iomab-B achieved transplant engraftment and Donor Chimerism with 92% achieving Full Donor Chimerism prior to day 100**
- SIERRA Trial is the only pivotal trial offering Bone Marrow Transplant as an option to patients with active, relapsed or refractory Acute Myeloid Leukemia age 55 and above**

NEW YORK, Feb. 25, 2019 /PRNewswire/ -- Actinium Pharmaceuticals, Inc. (NYSE American: ATNM), announced today that new data from the ongoing pivotal Phase 3 SIERRA trial for Iomab-B was reported in a late breaking oral presentation at the 2019 Transplantation & Cellular Therapy Meetings™ of ASBMT and CIBMTR (TCT Meetings) that was held on February 20<sup>th</sup> – 24<sup>th</sup>. Dr. Sergio Giralt, Chief, Adult Bone Marrow Transplant Service at Memorial Sloan Kettering Cancer Center presented the late breaking oral presentation. It was reported that all patients who received Iomab-B, received a BMT or Bone Marrow Transplant with 100% (28/28) of patients achieving engraftment and Donor Chimerism. The new data indicated that 92% (26/28) of these patients achieved Full Donor Chimerism prior to day 100, which is defined as at least 95% of donor cells being engrafted in the recipient. Full Donor Chimerism prior to day 100 is a clinically significant outcome that indicates acceptance of donor cells and transplant success.

"We are excited that data from the SIERRA trial continue to demonstrate strong engraftment, particularly in this patient population who have limited access to BMT, which is the only curative treatment option, with current chemotherapy based conditioning approaches", said Dr. Mark Berger, Actinium's Chief Medical Officer. "Full Donor Chimerism is an important metric in this setting that indicates patients receiving Iomab-B are having successful transplants, which is significant for the SIERRA trial. I am delighted that we were able to report these new data on strong donor chimerism to the transplant

community at the TCT Meetings after reporting at ASH in December that all patients receiving lomab-B received a BMT and achieved engraftment. We are motivated by the positive reception that the engraftment, safety and feasibility data have received from trial investigators and referring physicians. These data from the SIERRA trial will serve us well as we work to complete enrollment of the SIERRA trial and bring this important therapy to patients with significant unmet needs."

The SIERRA trial (**S**tudy of lomab-B in **E**lderly **R**elapsed or **R**efractory **A**ML) is a 150-patient pivotal Phase 3 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. The primary endpoint of the SIERRA trial is dCR or durable Complete Remission of 6 months. The SIERRA trial is currently enrolling patients at 18 sites in the U.S and Canada including many of the leading BMT sites based on volume. Patients with active, relapsed or refractory AML have dismal prognoses and are typically not offered potentially curative transplant as an option, largely because salvage treatments have a limited ability to produce a complete remission, which is necessary prior to conventional 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. lomab-B is an ARC or Antibody Radiation-Conjugate that targets CD45, an antigen expressed on leukemia, lymphoma and immune cells, and delivers Iodine-131 that kills targeted cells via linear energy transfer. Safety and feasibility data from the first 38 patients (25% of planned enrollment) in the SIERRA trial including donor chimerism data that were presented in a late breaking oral session at TCT can be accessed [here](#). Additional safety and feasibility analyses will occur when 50% and 75% of patients have been enrolled. The SIERRA trial also permits ad hoc interim analyses that may be requested at Actinium's discretion to assess safety and efficacy when 70 and 110 patients have reached the primary endpoint of 6-month dCR. However, these interim analyses will not expend meaningful alpha and re-powering of the study is not required as trial size cannot be increased after an Ad-hoc interim analysis.

Key highlights from the SIERRA Trial presented at ASH and the TCT Meetings include:

- All patients receiving a therapeutic dose of lomab-B engrafted despite active disease with high blast count (median 30%, or median 45% for crossover patients)
- 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 after lomab-B treatment
- 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 100-Day non-relapse mortality in patients randomized to lomab-B arm
- All patients receiving lomab-B and a BMT (28/28) achieved Donor Chimerism prior to day 100

- 94% of patients initially randomized to receive lomab-B and a BMT (17/18) achieved Full Donor Chimerism > 95% prior to day 100 with 1 patient achieving 65% donor chimerism
- 90% of patients who crossed-over to receive lomab-B and a BMT (9/10), after salvage chemotherapy in the control arm failed to produce a CR or Complete Response, also achieved Full Donor Chimerism > 95% prior to day 100 with 1 patient achieving 86% donor chimerism

Sandesh Seth, Actinium's Chairman and CEO said, "lomab-B has been studied extensively across multiple clinical trials and disease indications where it has consistently demonstrated the ability to condition patients for BMT in a well-tolerated manner with high engraftment rates and improved clinical outcomes including a survival benefit. As the lead candidate in our pipeline, it is heartening to see interim safety and feasibility data consistent with prior clinical evidence as the trend of strong engraftment with lomab-B continues in the pivotal multi-center SIERRA trial. In addition, our other posters at TCT supporting the value proposition of lomab-B from a healthcare economics perspective are also illuminative of the potential opportunity available. We are also excited to note the strong data from the lomab-ACT program for targeted lymphodepletion prior to CART and other adoptive cell therapies supportive of clinical advancement that was presented at this TCT Meeting. We look forward to providing additional updates as we continue to build and advance our industry leading, multi-asset, multi-indication targeted conditioning portfolio."

### **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, 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 ARCs 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 AML or Acute Myeloid Leukemia, MDS or Myelodysplastic Syndrome and MM or Multiple Myeloma.

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. lomab-B (Iodine-131 apamistamab), 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 300 patients and 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, chemo-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 Phase 1 clinical trials for targeting conditioning, in combinations and as a therapeutic in multiple diseases and indications including AML, MDS and MM.

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 over 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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