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## **Actinium Presents New Pivotal Phase 3 SIERRA Trial Data Showing Rapid Peripheral Blast Reduction and Anti-Leukemic Effect with Single Agent lomab-B in Older Patients with Active, Relapsed or Refractory Acute Myeloid Leukemia at 2019 ASCO Annual Meeting**

- **Lower circulating leukemia tumor burden achieved prior to bone marrow transplant with single agent lomab-B with 98% peripheral blast reduction by day 3 and 100% peripheral blast reduction by day 8**
- **Rapid peripheral blast clearance, as seen here after lomab-B administration, has been demonstrated as being predictive of Complete Response and Relapse-Free Survival in patients with Acute Myeloid Leukemia after chemotherapy in multiple studies**

NEW YORK, June 4, 2019 /PRNewswire/ -- **Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) ("Actinium") presented new data from the ongoing pivotal Phase 3 SIERRA study of lomab-B's single agent effect in patients with active, relapsed or refractory AML or Acute Myeloid Leukemia age 55 and above. The data was presented by SIERRA investigator Benjamin Tomlinson, M.D., Adult Hematologic and Stem Cell Transplant Section, Seidman Cancer Center, University Hospitals Case Medical Center (Cleveland, OH) in a poster presentation at the 2019 ASCO or American Society of Clinical Oncology Annual Meeting that is being held from May 31<sup>st</sup> – June 4<sup>th</sup> at the McCormick Place, Chicago.



Dr. Tomlinson, said, "Older patients with active, relapsed or refractory AML are an underserved patient population. These patients, particularly those with high blast counts as

seen in the SIERRA trial, are not typically considered candidates for transplant, which is a potentially curative treatment for AML, and have a poor prognosis with other therapeutic options. lomab-B has uniquely demonstrated an ability to effectively condition these patients for transplant with robust engraftment. We hypothesized that this successful engraftment is due to the myeloablation and anti-leukemic effect of lomab-B, since these patients had a median of 30% bone marrow blasts prior to transplant. Therefore, we are highly encouraged to observe that lomab-B as a single agent has a significant anti-leukemic effect and rapidly reduces peripheral blasts."

The poster can be accessed on Actinium's website ([Click Here](#)).

The poster evaluated data from the first 25% of patients (38) from the SIERRA trial where a total of 29 patients received lomab-B. This included 19 patients who received lomab-B directly and 10 patients who received lomab-B via crossover after conventional care salvage chemotherapy failed to produce a complete response. Previously presented preliminary feasibility data from the SIERRA trial demonstrated that all patients receiving lomab-B had robust BMT or Bone Marrow Transplant donor engraftment and donor chimerism without delay. The new data presented at ASCO evaluated lomab-B's effect as a single agent on white blood cells, lymphocytes and peripheral blasts. Of the 16 patients for whom data was available, there was a median reduction of peripheral blasts of 98% by day 3 and 100% reduction by day 8 following lomab-B administration and prior to any other pre-BMT conditioning. Rapid reduction of peripheral blasts has been observed as an independent prognostic marker that is predictive of both CR or Complete Response and RFS or Relapse-Free Survival in patients with AML after receiving cytotoxic chemotherapy. Gianfaldoni et al<sup>1</sup> performed an analysis of 30 newly diagnosed AML patients who were treated with cytotoxic induction chemotherapy and found that a rapid reduction of peripheral leukemia blasts correlated with responses and all patients that achieved CR had a rapid reduction of their peripheral blasts. Elliot et al<sup>2</sup>, performed a retrospective analysis of 86 adult patients with AML and identified time to clearance of circulating leukemia blasts as an independent prognostic marker of RFS that superseded all other known risk factors including karyotype and number of cycles of induction therapy needed to achieve CR.

"We are delighted that lomab-B continues to generate encouraging data in the SIERRA trial," said Dr. Mark Berger, Actinium's Chief Medical Officer. "This is the first time single agent lomab-B clinical data has been presented and we are quite excited by the rapid peripheral blast reduction that has been observed thus far. Peripheral blast reduction is a highly relevant clinical measure and we are optimistic that it will have a positive impact on durable complete response rates, which is the primary endpoint of the SIERRA trial. We are confident that this data will be well received by SIERRA investigators and will add to the strong engraftment data that has been already reported at ASH and TCT. Collectively, we are encouraged that lomab-B is continuing to exemplify best-in-class transplant conditioning potential for this difficult to treat patient population."

Sources:

1) Gianfaldoni et al. clearance of leukemic blasts from peripheral blood during standard induction treatment predicts the bone marrow response in acute myeloid leukemia: a pilot study. *British Journal of Haematology*, 2006 March 16; 134, 54-57.

2) Elliott et al. Early peripheral blood blast clearance during induction chemotherapy for acute myeloid leukemia predicts superior relapse-free survival. *Blood*. 2007 Dec 15; 110(13):4172-4. Epub 2007 Oct 1.

### **About lomab-B**

lomab-B is an ARC or Antibody Radiation-Conjugate comprised of the anti-CD45 antibody apamistamab and the radioisotope iodine-131 that is intended to be a re-induction and conditioning agent prior to a BMT or bone marrow transplant. lomab-B was developed at the Fred Hutchinson Cancer Research Center and has been studied in over 300 patients in multiple hematologic indications across 12 clinical trials in addition to the ongoing SIERRA study in older patients with active, relapsed or refractory AML or Acute Myeloid Leukemia prior to patients receiving an allogeneic BMT or bone marrow transplant. lomab-B is Actinium's lead targeting conditioning ARC in its multi-target, multi-indication targeted conditioning pipeline that includes the lomab-B and Actimab-MDS programs for BMT and the lomab-ACT program that will study a lower dose of lomab-B for lymphodepletion prior to CAR-T and other cellular therapies.

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

Actinium Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on improving patient access and outcomes to cellular therapies such as BMT or Bone Marrow Transplant and CAR-T with its proprietary ARC or Antibody Radiation-Conjugate targeted conditioning technology. 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 indications. It is developing a multi-disease, multi-target pipeline of clinical-stage ARC's targeting the antigens CD45 and CD33 for targeting 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 (AML), Myelodysplastic Syndrome (MDS) and Multiple Myeloma (MM). Actinium's lead product candidate, lomab-B, is in a pivotal Phase 3 trial for re-induction and conditioning prior to a BMT for patients with active relapsed or refractory AML or Acute Myeloid Leukemia. BMT is the only curative treatment option for this patient population and currently no standard of care exists. Actimab-MDS is its second pivotal program for targeted conditioning that will study the ARC comprised of the anti-CD33 monoclonal antibody lintuzumab linked to the radioisotope actinium-225 in patients with high-risk MDS in combination with RIC or Reduced Intensity Conditioning prior to a BMT. Its lomab-ACT program utilizes a lower dose of lomab-B (CD45 – I-131) that is intended to be used for targeted conditioning or lymphodepletion prior to CAR-T and adoptive cell therapies as a replacement to non-optimized chemotherapies, such as Flu/Cy or fludarabine and cyclophosphamide, that is used in standard practice today. Actinium also has multiple clinical trials ongoing, in startup phase, or in planning, to use its CD33 ARC in combination with other therapeutic modalities such as chemotherapy, targeted agents or immunotherapy. It has initiated several combination trials, including a doublet combination trial with its CD33 ARC and venetoclax, a BCL-2 inhibitor, for patients with relapsed or refractory AML, a triplet combination trial with venetoclax and an HMA or hypomethylating agent and in combination with the salvage chemotherapy regimen CLAG-M (cladribine, cytarabine, filgrastim and mitoxantrone) for patients with relapsed or refractory AML. Actinium is also studying its

CD33 ARC as single agent for patients with penta-refractory multiple myeloma. Its AWE technology platform 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 110 patents covering composition of matter, formulations, methods of use, the DOTA linker technology for actinium-225 applications and methods of manufacturing the actinium-225 radioisotope in a cyclotron.

### **Forward-Looking Statements for Actinium Pharmaceuticals, Inc.**

The information in this press release contains forward-looking statements regarding future events, including statements about Actinium's expectations regarding the terms of the offering or completion of the offering. Actinium intends such forward-looking statements to be covered by the safe harbor provisions contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include, without limitation, risks and uncertainties related to market and other conditions, the satisfaction of customary closing conditions related to the offering and the impact of general economic, industry or political conditions in the United States or internationally. There can be no assurance that Actinium will be able to complete the offering on the anticipated terms, or at all. More information about the risks and uncertainties faced by Actinium are more fully detailed under the heading "Risk Factors" in Actinium's Annual Report on Form 10-K for the year ended December 31, 2018 filed with the SEC. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this press release. Except as required by law, Actinium assumes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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