



Actinium Announces Positive Interim Results from Iomab-B Pivotal Phase 3 SIERRA Trial at 50% of Total Patient Enrollment

- All patients in the study arm receiving a therapeutic dose of Iomab-B were successfully transplanted
- High failure rate of control arm with 18% complete remission rate despite incorporation of recently approved targeted therapies including venetoclax
- Iomab-B 50% data strongly tracking trends of high BMT engraftment shown at 25% interim results and historical data from several Iomab-B trials
- Management and Dr. Sergio Giralt to discuss results on a call scheduled for today, October 28, 2019 at 12:00 PM Eastern Time

NEW YORK, Oct. 28, 2019 /PRNewswire/ --Actinium Pharmaceuticals, Inc. (NYSE AMERICAN: ATNM) ("Actinium") today announced key interim findings from the pivotal Phase 3 SIERRA trial of Iomab-B, including feasibility and safety data, at 50% of total patient enrollment. The SIERRA trial (**S**tudy of Iomab-B in **E**lderly **R**elapse/**R**efractory **A**cute **M**yeloid **L**eukemia) is a 150-patient, 1:1 randomization Phase 3 pivotal trial that is studying Iomab-B (Iodine-131 apamistamab) compared to physician's choice of salvage chemotherapy in patients age 55 and above with active, relapsed or refractory AML (Acute Myeloid Leukemia). These interim data provide information on safety and feasibility of using Iomab-B to enable a BMT (Bone Marrow Transplant), the only curative treatment option in this patient population that is not typically considered eligible for BMT.



Key findings from the first 75 patients enrolled (50% of total enrollment) in the trial

include:

- Patients enrolled in the SIERRA trial were a median age of 64 (55-76) and had active disease with a median bone marrow blast percentage at randomization of 28 percent (5-97%). All patients were intermediate or poor, adverse risk groups. Two-thirds (68%) of the patients enrolled were in the poor prognostic, adverse cytogenetic and molecular risk group.
- All patients receiving a therapeutic dose of lomab-B (31/31) in the study arm received a bone marrow transplant and engrafted rapidly without delay in blood count recovery.
- Only 7/38 patients (18%) randomized to the control arm achieved an initial complete response (CR) and were able to proceed to a conventional bone marrow transplant.
- Of the 31 patients who failed the primary endpoint in the control arm (82% failure), 20 (64%) were considered eligible for potential rescue by treatment with lomab-B followed by a BMT. All 20 patients (100%) who crossed over and received a therapeutic dose of lomab-B followed by a BMT achieved engraftment without delay in blood count recovery despite high blast count burden prior to transplant (median 35%).
- 12/38 patients (32%) randomized to the control arm received targeted agents all of which were recently approved. 11/12 patients (92%) received the Bcl-2 inhibitor venetoclax with either an hypomethylating agent or low dose cytarabine. Of these, only 3/11 patients (27%) achieved a CR.
- 100-day Non-Relapse Transplant Related Mortality remains lower in the lomab-B arm (1/31 patients or 3%) compared to patients in the control arm who received conventional transplants (2/7 or 29%). Of the 31 patients who received lomab-B in the study arm, 30 are potentially evaluable for the primary endpoint compared to 5 in the control arm. This difference between study arm and control arm remains consistent with that reported at the interim update at 25% of enrollment.
- The SIERRA trial remains the only randomized Phase 3 clinical trial to offer BMT as an option for patients age 55 and above with active, relapsed or refractory AML.

Sergio Giralt, M.D., Chief of Adult BMT, Memorial Sloan Kettering Cancer Center; Chair, Myeloma Service, said, "The results from the first 50% of patients to be enrolled in the SIERRA trial continue to be highly encouraging, particularly lomab-B's ability to enable a transplant in this patient population that would otherwise be ineligible. Despite eight new therapies having been approved for patients with AML, better outcomes for patients with AML are needed, in particular for the large number of relapsed and refractory patients. Newly approved targeted agents are not curative and as seen in the SIERRA trial do not enable a high rate of potentially curative BMT."

Feasibility and Safety Data from First 75 patients in the SIERRA trial

Key Patient Characteristics Median (range)	Randomized to lomab-B Study Arm (N=37)	Randomized to Conventional Care Arm (N=38)
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Median Age	65 (55-77)	64 (55-76)	
Molecular & Cytogenetic Risk ¹	Favorable: 0% , Intermediate: 32% , Adverse: 68%	Favorable: 0% , Intermediate: 32% , Adverse: 68%	
Bone Marrow Blast % median	30 (5-88) ²	26 (5-97)	
Results Median (range)	Received Therapeutic Dose of lomab-B & Transplanted (N=31)³	CR after salvage therapy (N=7)	No CR after salvage therapy (N=31)⁴
Cross-over Rate	N/A	N/A	65% (20/31) ⁴
% Transplanted	100% (31/31)	18% (7/38)	100% (20/20) ⁵
Bone Marrow Blast % at baseline	29 (5-75) ¹	9 (6-81)	30 (5-97)
Bone Marrow Blast % Pre-transplant	29 (5-75) ¹	1 (0-3)	35 (5-89) ¹
Days to Absolute Neutrophil Count (ANC) Engraftment	15 (9-22) ⁶	18 (12-19) ⁷	13 (9-35) ⁸
Days to Platelet Engraftment	18 (4-39) ⁶	22 (9-35) ⁷	17 (10-38) ⁸
Days to HCT (From day of Randomization)	30 (23-50)	67 (51-86)	64 (44-161) ⁹
100-day non-relapse Transplant-Related Mortality ¹⁰	3% (1/31)	29% (2/7)	13% (2/16)
Radiation Dose to Bone Marrow	15.6 (4.6-32) Gy	N/A	14.3 (6.3 – 30) Gy
	616 (397-1027) mCi		560 (313-1008) mCi

*Footnotes for table can be found below Conference Call and Webcast information

Mark Berger, M.D., Actinium's Chief Medical Officer, said, "We are thrilled that data from the halfway point of the SIERRA trial validate the promising interim safety and feasibility results from the first 25% of patients in this trial. It is particularly gratifying for me to see that these relapsed, refractory patients with heavy disease burden who received a therapeutic dose of lomab-B were successfully transplanted. In addition, it is heartening that lomab-B can be an effective pathway to transplant even when the recently approved targeted therapies unfortunately fail, as shown by our control arm and crossover data. With the first half of the trial behind us and with strong data in hand, we are focused on taking this message to hematologists and transplant physicians. We look forward to continuing to execute on our strategies to bring lomab-B to patients as quickly as possible."

Conference Call and Webcast Information

Time and Date: 12:00 PM ET on Monday, October 28th

Registration Link: <https://platform.cinchcast.com/ses/kSO55A9SLNGFoAvv1hgHpg~~>

U.S./Canada Toll Free Dial-in: (855) 698-6739

Participant Dial-in: (646) 402-9440

Conference ID: 0417

A replay of the call will be available on the [Investor Relations](#) page of the Company's website.

Table Footnotes:

1. Data available on 31 patients per arm
2. 1 patient with circulating blasts and bone marrow <5% not included in median/range
3. No therapeutic dose (6) due to: declining KPS (3), infusion reaction (1), unfavorable biodistribution (1), post-randomization eligibility (1)
4. Ineligible for crossover (9) due to: hospice care/progression (4), declined/ineligible for BMT (2), died pre-crossover (3). Eligible for crossover (2), received dosimetry but not Iomab-B therapy due to declining status
5. Crossed-over and received therapeutic dose of Iomab-B
6. ANC engraftment data not available (1), platelet engraftment data not available (5)
7. ANC and platelet engraftment data not available (1), engraftment failure (1)
8. ANC engraftment data not available (2), platelet engraftment data not available (4)
9. 1 patient at 161 days had delayed transplant due to infection and respiratory failure, received Iomab-B and BMT when stable
10. Data available on: Iomab-B study arm (30), CR after salvage therapy (7) and no CR after salvage crossed-over received Iomab-B and transplanted (16)

About the SIERRA Trial

The SIERRA trial (**S**tudy of Iomab-B in **E**lderly **R**elapse/**R**efractory **A**cute **M**yeloid **L**eukemia) is the only randomized Phase 3 trial that offers BMT (Bone Marrow Transplant) as an option for older patients with active, relapsed or refractory AML or acute myeloid leukemia. BMT is the only potentially curative treatment option for older patients with active relapsed or refractory AML and there is no standard of care for this indication other than salvage therapies. Iomab-B is an ARC (Antibody Radiation-Conjugate) comprised of the anti-CD45 antibody apamistamab and the radioisotope I-131 (Iodine-131). The 20 active SIERRA trial sites in the U.S. and Canada represent many of the leading bone marrow transplant centers by volume.

About Actinium Pharmaceuticals, Inc.

Actinium Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing ARC's or Antibody Radiation-Conjugates, which combine the targeting ability of antibodies with the cell killing ability of radiation. Actinium's lead application for our ARC's is targeted conditioning, which is intended to selectively kill patient's cancer cells and certain immune cells prior to a BMT or Bone Marrow Transplant, CAR-T and other cell therapies. 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, Iomab-B is being studied in the ongoing pivotal Phase 3 Study of Iomab-B in Elderly Relapsed or Refractory Acute Myeloid Leukemia (SIERRA) trial for BMT conditioning. Beyond Iomab-B, we are developing a multi-disease, multi-target pipeline of clinical-stage ARC's 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 AML (Acute Myeloid Leukemia), MDS (Myelodysplastic Syndrome), MM (Multiple Myeloma). 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 ARC's 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.

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.

Contacts:

Actinium Pharmaceuticals, Inc.

Steve O'Loughlin

Principal Financial Officer

investorrelations@actiniumpharma.com

Hans Vitzthum

LifeSci Advisors, LLC

Hans@LifeSciAdvisors.com

(617) 430-7578

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