February 21, 2020

Actinium Presents Positive Findings from Mid-Point Analysis of Pivotal SIERRA Trial of Iomab-B at 2020 Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR (TCT)

- Substantially lower rates of febrile neutropenia and sepsis in patients receiving Iomab-B compared to patients receiving salvage chemotherapy in the control arm

- 78 percent of patients in the Iomab-B arm are potentially evaluable for the primary endpoint compared to 13 percent in the control arm after factoring in 100-day non-relapse transplant related mortality

- Key protocol amendment allowing patients failing venetoclax induction therapy to enroll in the SIERRA trial is expected to increase eligible patient pool

NEW YORK, Feb. 21, 2020 /PRNewswire/ --**Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) ("Actinium") announced today findings from the SIERRA trial that were presented at the 2020 Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR (TCT) in Orlando, FL. Dr. Boglarka Gyurkocza, the principal investigator from Memorial Sloan Kettering Cancer Center, revealed that there were key differences in side effects reported in patients treated in the Iomab-B and control arms of the study with rates of febrile neutropenia, sepsis and mucositis being markedly lower in the Iomab-B arm.

The oral presentation also featured updated results from the fifty percent enrollment mid-point analysis including BMT access rates, engraftment and 100-day non-relapse transplant related mortality (TRM). After accounting for these factors, the results showed that, on an intent-to-treat or ITT basis, 78 percent of patients in the Iomab-B arm are potentially evaluable for the primary endpoint compared to 13 percent in the control arm. In addition, an important and recent protocol amendment was highlighted; the approximately 30 percent

of patients who are expected to fail induction therapy with venetoclax plus hypomethylating agents[1] are now eligible for enrollment in the SIERRA trial. The change is expected to increase the addressable patient population of the study given that this combination is now recommended as part of the NCCN or National Comprehensive Cancer Network guidelines, is widely used and expected to become the treatment of choice.

Key Interim Results:

The data tables that follow summarize key findings that were presented as part of the TCT proceedings. As highlighted in the table below, patients receiving Iomab-B showed lower rates of key adverse events relevant in the BMT setting in compared to patients randomized to receive physician's choice of salvage chemotherapy on the control arm. For example, patients receiving Iomab-B had a much lower incidence of sepsis of 3 percent compared to the 42 percent incidence in the control arm.

Adverse Event* N (%)	Randomized to Iomab-B and received BMT (N=31)	Randomized to Control Arm and received BMT (N=7)
Febrile Neutropenia	8 (25.8)	3 (42.8)
Sepsis/Septic Shock	1 (3.2)	3 (42.8)
Stomatitis (mucositis)	3 (9.7)	2 (28.6)
Pneumonia/Lung Infection	4 (12.9)	1 (14.3)
Hypertension	6[1] (19.4)	1 (14.3)
Decreased Appetite	5 (16.1)	0 (0.0)
Device related infection	4 (12.9)	1 (14.3)
Hypophosphatemia	2 (6.5)	1 (14.3)

* All adverse events reported irrespective of attribution to protocol-directed procedures

1) 5 patients had hypertension considered unrelated to Iomab-B and 1 patient had hypertension possibly related to Iomab-B

"This detailed safety data from SIERRA is highly encouraging, particularly in this patient population, as neutropenia and sepsis are hallmark toxicities associated with chemotherapy-based conditioning regimens that next to relapse are leading causes of morbidity and mortality post-transplant," said Dr. Vijay Reddy, Vice President, Clinical Development and Head of BMT at Actinium. "Chemotherapy-based conditioning damages normal organs, such as the gastrointestinal tract, which allows gut bacteria to cause serious infections. The data showing less mucositis, febrile neutropenia, and sepsis are consistent with the targeted nature of Iomab-B, since a lack of damage to the gastrointestinal track would lead to a reduction in these adverse events. BMT is the only curable treatment option for older patients with active, relapsed or refractory AML. Yet these patients face restricted access and suboptimal outcomes due to reliance on chemotherapy-based conditioning regimens and perceptions in the hematologist community around safety and eligibility for BMT. With the SIERRA trial, our goals are to eliminate these barriers leading to more patients receiving BMT and with better patient outcomes. With this additional safety data in hand, we have even greater confidence in our ability to change the perceptions around BMT and are excited to update the transplant and hematology communities on Iomab-B's potential to positively impact patients through improved access to BMT and better outcomes."

The presentation highlighted that 100 percent (31/31) of patients receiving a therapeutic dose of Iomab-B achieved successful BMT engraftment with only a 6 percent (2/31) TRM rate compared to the control arm where 18 percent (7/38) achieved engraftment with a 29 percent (2/7) TRM rate. At the 100-day post BMT time point, on an ITT basis, there were 29 patients from the Iomab-B study arm potentially evaluable for the primary endpoint of durable Complete Remission (dCR) at 180 days compared to 5 patients in the control arm.

By this measure, 78 percent of patients in the Iomab-B arm are potentially eligible for the dCR primary endpoint compared to 13 percent of patients in the control arm. The mid-point analysis and data presented at TCT can be viewed here.

Detailed engraftment data is presented in the table below:

BMT Feasibility and Outcome Data	Randomized to Study Arm (N=37)	Randomized to Control Arm (N=38)	
	Received Therapeutic Dose of Iomab-B and received BMT (N=31)[1]	Achieve CR and received standard BMT (N=7)	Did not Achieve CR (N=31/38)[2] Crossed over from to Iomab-B and received BMT (N=20)
BMT Engraftment Rate (%, N)	100% (31/31)	18% (7/38)	100% (20/20)
Median Bone Marrow Blasts % at randomization (%, range)	29% (5-88)	26% (5-97)	At crossover: 31% (6-87) At randomization: 35% (5-75)
Median Days to BMT post randomization (days, range)	30 (23-50)	67 (51-86)	64 (44-161)
Median Days to Absolute Neutrophil Count Engraftment (days, range)	15 (9-22)[3]	18 (13-82)[4]	14 (10-37)[5]
Median Day to Platelet Engraftment (days, range)	20 (4-39)[3]	22 (9-35)[4]	19 (13-38)[5]
100-day non-relapse transplant related mortality (%, N)	6% (2/31)	29% (2/7)	10% (2/20)[6]

1) No therapeutic dose (6) due to: declining Karnofsky Performance Scale (PFS) (3), Infusion reaction (1), unfavorable biodistribution (1), post-randomization eligibility (1)
2) Ineligible for crossover (9) due to: hospice care/progression (4), declined/ineligible for BMT (2), died pre-crossover (3), eligible for crossover (2) did not receive Iomab-B due to declining status
3) Absolute Neutrophil Count engraftment data not available (1), platelet engraftment data not available (4)
4) ANC and platelet engraftment data not available (1), engraftment failure (1)
5) ANC engraftment data not available (1) out of 20, platelet engraftment data not available (3)
6) 1 patient at 161 days had delayed transplant due to infection and respiratory failure, received Iomab-B and BMT when stable

Dr. Mark Berger, Actinium's Chief Medical Officer, stated, "As we approach critical enrollment milestones in the SIERRA trial, our focus turns to bringing Iomab-B to as many patients as possible that can benefit from this product candidate and as expeditiously as possible. Consequently, we made an important amendment to the SIERRA protocol to expand the potential patient pool by including in the eligibility criteria patients who fail induction therapy with venetoclax plus hypomethylating agents. As targeted agents such as venetoclax and others have gained approval, the acute myeloid leukemia treatment landscape has evolved with a significant percentage of patients being treated with these agents in frontline and relapsed settings. In fact, as of mid-2019, venetoclax plus hypomethylating agents have been included as part of the AML National Comprehensive Cancer Network guidelines and medical practice is embracing these regimens widely. However, these regimens are not curative, nor do they eliminate the need for BMT. Indeed, approximately thirty percent of patients fail to achieve a remission after two cycles of induction therapy with venetoclax and most patients ultimately relapse with a median duration of response of less than one year. This amendment has already had a positive impact on the trial that we expect to continue through the remaining portion of enrollment. Most importantly, if Iomab-B gains approval, this amendment will support its use for the significant and growing number of patients receiving and failing venetoclax as induction therapy instead of traditional 7+3 induction chemotherapy. We look forward to continuing to provide key updates as SIERRA reaches key milestones and completes enrollment in 2020."

Sources:
1) DiNardo et al. Venetoclax combined with decitabine or azacitidine in treatment-naïve, elderly patients with acute myeloid leukemia. Blood 2019 133(1): 7-17 https://doi.org/10.1182/blood-2018-08-868752

About the SIERRA Trial

The SIERRA trial (**S**tudy of **I**omab-B in **E**lderly **R**elapse/**R**efractory **A**cute Myeloid Leukemia) 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. The SIERRA trial is a 150-patient, multicenter randomized trial that studying Iomab-B compared to physician's choice of salvage chemotherapy. The primary endpoint of the SIERRA trial is durable Complete Remission of 180 days and the secondary endpoint is 1-year overall survival. Iomab-B is an ARC or 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. For more information, visit www.sierratrial.com.

About Transplantation & Cellular Therapy Meetings™ (TCT)

TCT, formerly known as the BMT Tandem Meetings, are the combined annual meetings of the American Society for Blood and Marrow Transplantation (ASBMT) and the Center for International Blood & Marrow Transplant Research (CIBMTR). Each year the conference brings together several thousand investigators, clinicians, researchers, nurses and other allied health professionals from over 500 transplant centers from over 50 countries around a full scientific program focused on bone marrow transplant and cellular therapies.

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 (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. The SIERRA trial is over fifty percent enrolled and positive single-agent, feasibility and safety data has been highlighted at ASH, TCT, ASCO and SOHO annual meetings. I-131 apamistamab will also be studied as a targeted conditioning agent in a Phase 1/2 anti-HIV stem cell gene therapy with UC Davis and is expected to be studied with a CAR-T therapy in 2020. 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.

Contacts:

Investors:
Hans Vitzthum
LifeSci Advisors, LLC
Hans@LifeSciAdvisors.com
(617) 535-7743

Media:
Alisa Steinberg, Director, IR & Corp Comms
asteinberg@actiniumpharma.com
(646) 237-4087

View original content to download multimedia:http://www.prnewswire.com/news-releases/actinium-presents-positive-findings-from-mid-point-analysis-of-pivotal-sierra-trial-of-iomab-b-at-2020-transplantation--cellular-therapy-meetings-of-astct-and-cibmtr-tct-301009012.html

SOURCE Actinium Pharmaceuticals, Inc.