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Actinium Announces Positive Interim Results from Iomab-B Pivotal Phase 3 SIERRA Trial at 75% of Total Patient Enrollment at the 62nd American Society of Hematology Annual Meeting

NEW YORK, Dec. 7, 2020 /PRNewswire/ --**Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) ("Actinium" or the "Company") today announced that interim data from its ongoing pivotal Phase 3 trial in patients with relapsed or refractory Acute Myeloid Leukemia (R/R AML) were presented in an oral presentation at the 62nd American Society of Hematology (ASH) annual meeting. Through 75% of patient enrollment, 100% (49/49) of patients receiving a therapeutic dose of Iomab-B in SIERRA have successfully proceeded to Bone Marrow Transplant (BMT) compared to 16% (9/56) of patients in the control arm who received physician's choice of salvage therapies. The control arm includes a wide range of salvage therapies, including targeted agents, as there is no standard of care in this setting. Of the 84% (47/56) of patients that did not achieve complete remission on the control arm, 64% (30/47) of patients crossed over to receive Iomab-B with 100% (30/30) of those patients successfully proceeding to BMT. In total, 78% (88/113) of patients enrolled on the SIERRA trial were able to receive a BMT despite this being a patient population not typically considered for BMT.

At the 100-day post BMT time point, on an ITT basis, there were 43 patients from the Iomab-B study arm potentially evaluable for the primary endpoint of durable Complete Remission (dCR) at 180 days compared to 7 patients in the control arm. By this measure, 77 percent of patients in the Iomab-B arm are potentially eligible for the dCR primary endpoint compared to 12 percent of patients in the control arm, a greater than 6-times difference, which is consistent with results at the 25% and 50% interim feasibility and safety analyses.

The SIERRA trial is the only randomized Phase 3 trial to offer Bone Marrow Transplant (BMT) as an option for patients over the age of 55 with active R/R AML. BMT remains the only therapeutic option with curative potential for this patient population. Iomab-B is intended to simultaneously be a targeted induction and conditioning agent that allows patients to proceed to BMT in days after receiving Iomab-B compared to current chemotherapy-based approaches that require a patient to first achieve a complete remission

before proceeding to additional conditioning and a BMT.

Dr. Mark Berger, Actinium's Chief Medical Officer, said, "Results from SIERRA continue to show that Iomab-B can enable a potentially curative bone marrow transplant to older patients with high leukemia burden who are not typically considered for BMT. The stark contrast between the 100% of patients successfully receiving a BMT with Iomab-B compared to the 16% of patients able to proceed to BMT with today's standard approaches gives us great enthusiasm for the eventual outcome of the SIERRA trial and the potential of Iomab-B. This, together with Iomab-B's targeted nature and therefore lower rates of serious adverse events as highlighted in our other ASH oral presentation and lower rates of non-relapse transplant related mortality, give Iomab-B a clinical profile not matched by any other therapeutic candidates we see in development. We are honored to have had the opportunity to showcase Iomab-B and SIERRA, as well our Actimab-A combination trials, at ASH and now focus our complete attention on the ad hoc interim analysis that will be complete in the coming weeks."

Detailed results from 75% of enrollment presented in the oral presentation are highlighted in the table below:

ASH Oral Presentation: *Personalized Targeted Radioimmunotherapy with Anti-CD45 Iodine (^{131}I) Apamistamab [Iomab-B] in Patients with Active Relapsed or Refractory Acute Myeloid Leukemia Results in Successful Donor Hematopoietic Cells Engraftment with the Timing of Engraftment Not Related to the Radiation Dose Delivered*

Phase 3 SIERRA – 75% Enrollment Results			
Baseline Characteristics	**Iomab-B Arm (N=56)**	**Conventional Care (CC) Arm (N=57)[1]**	
Age (yrs, median, range)	63 (55-77)	65 (55-77)	
Cytogenetic and Molecular Risk[2,3]	Favorable: 4% Intermediate: 33% Adverse: 63%	Favorable: 5% Intermediate: 30% Adverse: 64%	
% Transplanted Intent-to-Treat Group	88% (49/56)	16% (9/56)	64% (30/47)
Results	**Underwent Iomab-B based Conditioning and HCT (N=49)[4]**	**Achieved CR and received standard of care HCT (N=9)**	**Randomized to Conventional Care and Crossed Over to Iomab-B with HSCT (N=30)[5]**
Cross-over Rate	n/a	n/a	Received Therapeutic Dose of Iomab-B (N=30) Transplanted (N=30) 64% (30/47)
% Transplanted	100% (49/49)	16% (9/56)	100% (30/30)
BM Blast % @ randomization (median, range)	30% (5-95)[6]	20% (5-97)	22% (6-87)
Days to ANC Engraftment	14 (9-22)[7]	17 (13-83)[8]	14 (10-37)[9]
Days to Platelet Engraftment	18 (4-39)[7]	22 (8-35)[8]	19 (1-38)[9]
Days to HCT (Post Randomization)	30 (23-60)	66 (51-86)	64 (36-100)[10]
Myeloablative Dose Delivered to Bone Marrow	14.8 (4.6-32) Gv 641 (354-1027) mCi	n/a	15.5 (6.3-42) Gv 607 (313-1013) mCi
100-day non-Relapse Transplant-Related Mortality[11]	4% (2/45 Evaluable)	22% (2/9 Evaluable)	12% (3/26 Evaluable)

1)	Data unavailable for one (1) patient.
2)	Iomab-B arm: data unavailable (4) and patient was excluded (1), conventional care arm: data unavailable (1)

3)	Per NCCN guidelines version 3. 2020
4)	No therapy dose (7) due to: declining KPS (4), Infusion reaction (1), unfavorable biodistribution (1), post-randomization eligibility (1). Two (2) did not receive DI and five (5) received DI without proceeding to TI.
5)	Thirteen (13) patients ineligible for crossover due to: hospice care/progression (4), declined/ineligible for HCT (5), died pre-crossover (4). Additionally, four (4) patients were eligible for crossover and did not receive Iomab-B due to declining KPS.
6)	One (1) patient with 4% blasts in the marrow had circulating AML blasts
7)	ANC engraftment data not available (3), platelet engraftment data not available (6)
8)	ANC engraftment data not available (2), platelet engraftment data not available (1)
9)	ANC engraftment data not available (3), platelet engraftment data not available (4)
10)	One (1) patient at 161 days had delayed transplant due to infection & respiratory failure, received Iomab & transplant when stable, not included in range
11)	Iomab-B arm: Four (4) patients unevaluable; Conventional Care arm: Four (4) patients unevaluable (4). Rates of NRM were not significantly different between any 2 groups

Dr. Vijay Reddy, Head of Transplant, VP, Clinical Development of Actinium, said, "As a transplant physician, I know firsthand the difficulty in treating older patients with R/R AML, especially with highly active disease like those in SIERRA. Unfortunately, many older patients with R/R AML have no possibility of ever receiving a BMT as current chemotherapy-based conditioning regimens are too toxic to withstand or unable to produce the complete remission necessary for the patient to proceed to BMT. With Iomab-B, we are working to create a paradigm shift that will enable significantly more patients with R/R AML to gain access to potentially curative BMT that we believe can change the practice of AML patient care. We are greatly encouraged by the data from this latest update and the steady trends in differences between the control and study groups we have witnessed at the 25 percent, 50 percent, and now the 75 percent interim analysis."

About Iomab-B

Iomab-B (I-131 apamistamab) via the monoclonal antibody apamistamab, targets CD45, an antigen widely expressed on leukemia and lymphoma cancer cells, B cells and stem cells. Apamistamab is linked to the radioisotope iodine-131 (I-131) and once attached to its target cells emits energy that travels about 100 cell lengths, destroying a patient's cancer cells and ablating their bone marrow. By carrying iodine-131 directly to the bone marrow in a targeted manner, Actinium believes Iomab-B will avoid the side effects of radiation on most healthy tissues while effectively killing the patient's cancer and marrow cells.

Iomab-B is currently being studied in the pivotal Phase 3 SIERRA (Study of Iomab-B in Relapsed or Refractory AML) trial, a 150-patient, randomized controlled clinical trial in patients with relapsed or refractory Acute Myeloid Leukemia (AML) who are age 55 and above. The SIERRA trial is being conducted at preeminent transplant centers in the U.S. with the primary endpoint of durable Complete Remission (dCR) at six months and a secondary endpoint of overall survival at one year. Upon approval, Iomab-B is intended to prepare and condition patients for a bone marrow transplant, also referred to as a hematopoietic stem cell transplant, in a potentially safer and more efficacious manner than the non-targeted intensive chemotherapy conditioning that is the current standard of care in bone marrow transplant conditioning. A bone marrow transplant is often considered the only potential cure for patients with certain blood-borne cancers and blood disorders. Additional information on the Company's Phase 3 clinical trial in R/R can be found at www.sierratrial.com.

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 seventy-five percent enrolled and positive single-agent, feasibility and safety data has been highlighted at ASH, TCT, ASCO and SOHO annual meetings. More information on this Phase 3 clinical trial can be found at www.sierratrial.com. I-131 apamistamab will also be studied as a targeted conditioning agent in a Phase 1 study with a CD19 CAR T-cell therapy and in a Phase 1/2 anti-HIV stem cell gene therapy with UC Davis. 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 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 130 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: 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.

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