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Actinium's Four Presentations at ASH Highlight the Positive Outcomes for Iomab-B and Actimab-A in Patients with Relapsed or Refractory Acute Myeloid Leukemia

- Oral presentation highlighted Iomab-B improves overall survival in patients with TP53 mutation with active, relapsed or refractory AML
- Eighth oral presentation of the Phase 3 SIERRA results at ASH continues to build broad exposure for Iomab-B across key medical and scientific communities globally

NEW YORK, Dec. 11, 2023 /PRNewswire/ --**Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) (Actinium or the Company), a leader in the development of targeted radiotherapies, today highlighted four presentations at the 65th Annual American Society of Hematology Annual Meeting & Exposition (ASH) detailing results from the Phase 3 SIERRA trial of Iomab-B and Phase 1 trial of Actimab-A in combination with Venetoclax in patients with relapsed or refractory acute myeloid leukemia (r/r AML). Iomab-B and Actimab-A are the only two clinical stage targeted radiotherapies in development for patients with AML, which is known to be highly sensitive to radiation.



Sandesh Seth, Actinium's Chairman and CEO, said, "Earlier in 2023 we presented data from both Iomab-B and Actimab-A highlighting positive outcomes in patients with relapsed or refractory AML. We are particularly excited by these results as our trials enrolled patients with difficult to treat disease as they were heavily pre-treated, elderly in age, or had adverse cytogenetic or molecular mutations. As evidenced by the data presented at ASH in the oral presentation of the Phase 3 SIERRA trial results, Iomab-B produced improved outcomes in patients with a TP53 mutation, which is associated with dismal outcomes. We are proud to have showcased Iomab-B and Actimab-A at ASH and excited by the enthusiasm for which the data were received. We look forward to progressing both programs with key BLA and MAA filings for Iomab-B next year and advanced development for Actimab-A."

ASH Presentations and Highlights:

¹³¹I-Apamistamab-Led Allogeneic Hematopoietic Cell Transplant Significantly

Improves Overall Survival in Patients with TP53 Mutated R/R AML

- Patients receiving lomab-B had significantly greater median overall survival of 5.49 months compared to 1.66 months in patients on the control arm that received conventional care
- 24% of patients (37/153) enrolled on the SIERRA trial had a TP53 mutation, which is associated with the worst outcomes
- lomab-B produced response rates and overall survival in these very high-risk patients similar to those observed in patients without a TP53 mutation

¹³¹I-Apamistamab Effectively Achieved Durable Responses in Patients with R/R AML Irrespective of the Presence of Multiple High-Risk Factors

- Patients receiving lomab-B were able to receive a BMT and achieve durable Complete Remission (dCR), the primary endpoint in the SIERRA trial, irrespective of having multiple high-risk factors
- lomab-B met the dCR rate primary endpoint with high statistical significance ($p < 0.0001$) with 22% dCR rate in the lomab-B arm vs. 0% dCR rate in the control arm
- 53% of patients had 2-3 high-risk factors and 29% had 4-5 high-risk factors that included adverse-risk cytogenetics, age >65, prior treatment failure with Venetoclax, BMT comorbidity index > 3, and Karnofsky Performance Status < 90
- There was no statistical difference in the rate of dCR in patients receiving lomab-B across the high risk-factor categories (0-1, 2-3 & 4-5)

High-Dose Targeted Radiation with ¹³¹I-Apamistamab Prior to HCT Demonstrated a Dose-Response for Durable Complete Remission in Patients with R/R AML

- Patients with higher bone marrow/liver absorbed dose ratios experienced considerably higher rates of dCR demonstrating a dose dependent response
- 27% of patients achieving dCR when receiving > 22 Gy to the liver vs 13.5% dCR rate in patients receiving ≤ 22 Gy to the liver; maximum tolerable dose in SIERRA was 24 Gy administered to the liver
- Rates of Grade 3 \geq treatment emergent events were similar between patients receiving < 22 Gy to the liver and those receiving > 22 Gy to the liver
- lomab-B led BMT produced to significantly higher rates of dCR with patients achieving dCR having a 92% 1-year overall survival and 60% 2-year overall survival
- These results demonstrate the importance of maximizing the dose to target tissues within the established dose tolerances

Updated Results from Phase 1 Study of Targeted Radiotherapy with Lintuzumab-Ac225 in Combination with Venetoclax in Relapsed/Refractory AML

- Actimab-A dosed up to 2.0 $\mu\text{Ci/kg}$ with Venetoclax in patients with relapsed/refractory AML was well-tolerated, with a manageable adverse event profile
- Maximum tolerated dose was not reached with no dose-limiting toxicities observed at the 3 highest dose levels (1.0, 1.5 & 2.0 $\mu\text{Ci/kg}$)
- Complete responses were achieved including a complete response in a patients with prior Venetoclax treatment and a TP53 mutation
- These results support the continued evaluation of Actimab-A in combination with Venetoclax-based treatment

About Actinium Pharmaceuticals, Inc.

Actinium develops targeted radiotherapies to meaningfully improve survival for people who have failed existing oncology therapies. Advanced pipeline candidates lomab-B (pre-BLA), an induction and conditioning agent prior to bone marrow transplant, and Actimab-A (National Cancer Institute CRADA pivotal development path), a therapeutic, have demonstrated potential to extend survival outcomes for people with relapsed and refractory acute myeloid leukemia. Actinium plans to advance lomab-B for other blood cancers and next generation conditioning candidate lomab-ACT to improve cell and gene therapy outcomes. Actinium's technology platform is the basis for collaborations with Astellas Pharma for solid tumors, AVEO Oncology/LG Chem Life Sciences for HER3 solid tumors, and several internal programs in solid tumors. Actinium holds more than 220 patents and patent applications.

For more information, please visit: <https://www.actiniumpharma.com/>


Forward-Looking Statements

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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Sources: Granowicz EM, Jonas BA. Targeting *TP53*-Mutated Acute Myeloid Leukemia: Research and Clinical Developments. *Onco Targets Ther.* 2022 Apr 21;15:423-436. doi: 10.2147/OTT.S265637. PMID: 35479302; PMCID: PMC9037178.

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