

April 3, 2023



# Actinium Pharmaceuticals Reports 2022 Financial Results and Highlights Recent and Upcoming Clinical Data and Milestones

- Announced positive results from the pivotal Phase 3 SIERRA trial of lomab-B in r/r AML patients ages 55+; achieved primary endpoint of dCR with high statistical significance ( $p < 0.0001$ )
- On track to commence Early Access Program and file a BLA submission for lomab-B in 2H:2023
- *Actimab-A + CLAG-M demonstrated 59% 1-year and 32% 2-year survival in r/r AML patients subset that failed venetoclax; NCI CRADA provides broad support including late-stage trials expected to be balance sheet sparing*
- Strong balance sheet expected to fund operations through 2025

NEW YORK, April 3, 2023 /PRNewswire/ -- **Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) ("Actinium" or the "Company"), a leader in the development of targeted radiotherapies, today reported its financial results for the quarter and year ended December 31, 2022, and provided a corporate update.



"The clinical results from lomab-B and Actimab-A taken together set the stage for an exciting future for Actinium", said Sandesh Seth, Chairman and CEO. "lomab-B pivotal phase 3 trial results were highly positive, demonstrating that lomab-B facilitates unprecedented access to a Bone Marrow Transplant (BMT) and produces improved outcomes, including long-term survival in patients are not considered for transplant in routine clinical practice today and that have a life expectancy of approximately three months. The Actimab-A+CLAG-M proof-of-concept trial showed improved overall survival (OS) with an impressive, one- and two-year survival of 59 and 32 percent, respectively, in patients failing venetoclax, who typically live two to four months. These highly impressive improvements in survival of high-risk relapsed and refractory (r/r) acute myeloid leukemia (AML) patients were demonstrated by each product candidate in a complementary fashion across the patient journey. lomab-B facilitates

transplants for currently not transplantable, unfit patients and Actimab-A+CLAG-M provides a better therapeutic option for fit, high-risk patients. Based on these results, Actinium intends to forge ahead with the development and commercialization of lomab-B and Actimab-A to build a specialty radiotherapeutics company that can offer AML patients an opportunity for extended survival that just does not exist currently."

Mr. Seth continued, "With these consequential clinical results in hand, we will initiate an Early Access Program and file a BLA for lomab-B in 2H:2023. We will also leverage our National Cancer Institute (NCI) Cooperative Research and Development Agreement (CRADA) and announce plans for advanced development of Actimab-A in 2H:2023 in keeping with our objective of developing this mutation-agnostic agent as a backbone in combination with other therapies in AML, which is characterized by a high degree of mutations. We are also on track for a clinical data readout from the Memorial Sloan Kettering Cancer Center (MSKCC)/National Institutes of Health (NIH) CAR-T trial with lomab-ACT, our low-dose conditioning program for cell and gene therapy. Our research in solid tumors with our collaborators is progressing well and we anticipate showcasing results from key programs this year as well. Our balance sheet strength enables us to fund operations through 2025 enabling us to prepare for the launch of lomab-B, assuming approval, and the Company is well positioned to achieve these value creating milestones on the way to realizing our mission of materially improving the survival of r/r AML patients."

#### **Fourth Quarter and Recent Business Highlights**

- **Full Data From the Pivotal SIERRA Trial-** In February 2023, we presented full trial results from the Company's pivotal Phase 3 SIERRA trial of lomab-B in patients age 55 and above with active r/r AML, which demonstrated unprecedented access, improved outcomes and better safety and tolerability with double 1-year and median OS with lomab-B compared to the control arm during the 2023 Transplantation & Cellular Therapy Meetings of the American Society for Transplantation and Cellular Therapy (ASTCT) and the Center for International Blood & Marrow Transplant Research (CIBMTR). These data are expected to support the planned Biologics License Application (BLA) submission for lomab-B to the FDA in 2H:2023, and if approved, the Company intends to commercialize the product in the U.S. The Company believes these data show lomab-B could become a new standard of care.
- **Data From Actimab-A Combination Trials** - In December 2022, the Company presented the Phase 1 results from the Actimab-A CLAG-M combination trial in high-risk r/r AML patients at the American Society of Hematology (ASH) Annual Meeting & Exposition that showed high response rates and minimal residual disease (MRD) negativity, translating to a meaningful survival benefit of 53 percent and 32 percent at one and two years in all patients (1 and 2 year overall survival of 59 and 32 percent in venetoclax failed patients who are typically expected to live two to four months). At the same meeting, the Company shared Phase 1 data showing that the combination of Actimab-A + venetoclax was well-tolerated with responses, including a Complete Remission (CR) and a partial response in early dose escalation cohorts. These data are encouraging and represent a significant improvement compared to available therapies for these patients, especially in the TP53 mutant and Venetoclax treated patients.

- Development Agreement with NCI** - Entered into a CRADA with the NCI, part of the NIH, to develop Actimab-A for the treatment of patients with AML and other hematologic malignancies. NCI Cancer Therapy Evaluation Program (CTEP), which sponsors approximately two thirds of all combination cancer studies, will be accepting Letters of Intent (LOIs) or concepts for Phase 1, 2 or 3 studies of Actimab-A in AML and other hematological malignancies. The CRADA will be balance sheet sparing as NCI will fund the clinical development expenses associated with trials conducted under the CRADA while Actinium will supply drug. Actinium has the rights to all data generated under the CRADA and assuming Actimab-A gains approval, there are no royalties or other economics due to the NCI. The Company believes the promise of the data presented at the Actimab-A CLAG-M combination trial in December paved the way for this agreement. Through the CRADA, Actimab-A will be available at over 2,000 clinical trial sites under the Experimental Therapeutics Clinical Trials Network (ETCTN) and the National Clinical Trials Network (NCTN) that includes leading oncology network groups such as Eastern Cooperative Oncology Group and the American College of Radiology Imaging Network (ECOG-ACRIN), Southwest Oncology Group (SWOG) and the Alliance for Clinical Trials in Oncology. Actimab-A studies may also be conducted through NCI's MyeloMATCH program.
- Anti-cancer Activity of Next-Generation Targeted Radiotherapies** - Presenting data at the American Association for Cancer Research (AACR) 2023 Annual Meeting that will highlight the multifaceted anti-cancer activity and enhanced anti-tumor effect of HER3-targeted, radiotherapy being developed in collaboration with AVEO Oncology, an LG Chem Company (LG Chem). These data further showcase a first-in-class HER3 radiotherapy in preclinical models of cancers with unmet therapeutic needs.
- Columbia University Research Collaboration** - Entered a research collaboration with Columbia University to study Actimab-A, its clinical-stage CD33 targeting radiotherapeutic, with engineered hematopoietic stem cells (eHSCs) modified by CRISPR/Cas9 gene editing technology to knock out CD33 expression. Under this collaboration, Actimab-A will be administered following transplantation of the eHSCs with the goal of eliminating any CD33 positive residual AML cells. eHSCs are intended to engraft and reconstitute the blood and immune systems with cells that do not express cancer-specific targets such as CD33. The eHSC technology is intended to allow a patient to receive CD33 targeting therapy post-transplant to eradicate any residual CD33 positive leukemia cells and prevent relapse while sparing newly formed blood cells that do not express CD33.
- Growing R&D Pipeline** - The Company's pipeline is further exemplified by its next-generation lomab-ACT conditioning program for rapidly growing cell and gene therapies, as well as its solid tumor and immunotherapy collaborations with Astellas Pharma Inc., LG Chem and EpicentRx, Inc. In addition, Actinium has several other programs in solid tumors at the pre-clinical stage with investigational new drug enabling studies ongoing and the Company extensive intellectual property portfolio includes over 200 issued patents and pending patent applications worldwide.
- Key Commercial Leader Hired.** - Expanded the commercial leadership, CMC and clinical leadership teams during the fourth quarter, which includes the appointed Caroline Yarbrough as Chief Commercial Officer. She brings the Company broad

commercial expertise that spans several leading global organizations, including Novartis where she most recently oversaw a product portfolio with over \$1.0 billion in revenue, led the successful launches in a variety of cancer treatment settings, including hematology, and led account management for the launch of the CAR-T cellular therapy, Kymriah.

### **Upcoming 2023 Milestones**

- The Company intends to submit a BLA for lomab-B to the FDA in 2H:2023
- The Company plans to launch an Early Access Program in 2H:2023 to make lomab-B available anticipating FDA approval
- The Company expects to initiate under the NCI CRADA the late-stage development including a potential pivotal trial of Actimab-A in combinations as a backbone therapy for r/r AML in the 2H:2023
- The Company intends to present clinical proof-of-concept data from its NIH-funded lomab-ACT collaboration with MSKCC and provide a program update for additional development opportunities for cell and gene therapy
- The Company is working with its partner Immedica to support the Marketing Authorization Application (MAA) and commercialization of lomab-B in the EU

### **Financial Highlights for the Year Ended December 31, 2022**

**Cash & Investment Position:** The Company reported cash and cash equivalents of \$108.9 million as of December 31, 2022, which is projected to fund operations through 2025

**R&D Expenses:** Research and development expenses increased by \$5.1 million to \$23.1 million for the year ended December 31, 2022, compared with \$18.0 million for the year ended December 31, 2021. Higher expenses were primarily due to increased CMC activity related to lomab-B, as well as increased compensation of \$1.0 million resulting from increased headcount.

**G&A Expenses:** General and administrative expenses increased by \$3.9 million to \$12.0 million for the year ended December 31, 2022, compared with \$8.1 million for the year ended December 31, 2021. Higher expenses were primarily due to increased compensation of \$0.9 million, increased non-cash equity compensation of \$1.0 million, higher professional fees and consulting fees including recruitment costs, and higher legal fees.

**Net Loss:** Net loss increased by \$8.2 million to \$33.0 million for the year ended December 31, 2022, compared with \$24.8 million for the year ended December 31, 2021, primarily due to higher research and development expenses and general and administrative expenses, partially offset by other income.

**Shares Outstanding:** Common shares outstanding were approximately 25.7 million as of March 31, 2022.

### **About lomab-B and the Pivotal Phase 3 SIERRA Trial**

lomab-B is a first-in-class targeted radiotherapy intended to improve patient access to potentially curative BMT by simultaneously and rapidly depleting blood cancer, immune and bone marrow stem cells that uniquely express CD45. Multiple studies have demonstrated

increased survival in patients receiving BMT, however, an overwhelming majority of patients with blood cancers do not receive BMT as current approaches do not produce a remission, which is needed to advance to BMT, or are too toxic. Studied in over 400 patients, prior studies with lomab-B have demonstrated nearly universal access to BMT, increased survival and tolerability in multiple clinical trials including the recently completed pivotal Phase 3 SIERRA trial in patients with active (leukemic blasts >5%), relapsed or refractory acute myeloid leukemia (r/r AML) age 55 and above.

lomab-B met the primary endpoint of durable Complete Remission (dCR) of 6 months after initial remission post-BMT in the pivotal Phase 3 SIERRA trial with high statistical significance ( $p < 0.0001$ ). lomab-B produced a 75% post-BMT CR rate (44/59 patients), which is 12-times greater than the post-BMT rate of 6.3% (4/64 patients) in the control arm. Patients receiving lomab-B had a 78% lower probability of an event, defined as not achieving a CR/CRp, crossover, not receiving a BMT, relapse or death, with a Hazard Ratio of 0.22 ( $p < 0.0001$ ). lomab-B doubled 1-year overall survival with 26.1% compared to 13.1% in the control arm for patients who did not crossover as well as median overall survival with 6.4 months vs 3.2 months. Overall survival statistics are confounded by the crossover arm. Crossover patients had a 35.8% 1-year overall survival rate. Due to its targeted nature, lomab-B was well tolerated with four times lower rates of sepsis compared to the control arm (6.1% vs. 28.6%) and lower rates of BMT associated adverse events including febrile neutropenia, mucositis and graft versus host disease (GVHD). Actinium intends to submit a Biologics License Application (BLA) seeking approval for lomab-B in 2023 to address patients age 55+ with r/r AML who cannot access BMT with currently available therapies. lomab-B has been granted Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) and has patent protection into 2037.

The pivotal Phase 3 SIERRA (Study of lomab-B in Elderly relapsed or refractory AML) is a 153-patient, randomized, multi-center clinical trial, studying lomab-B compared to the control arm of physician's choice of salvage therapy. Control arm options included chemotherapies like cytarabine and daunorubicin and targeted agents such as a Bcl-2 inhibitor (Venetoclax), FLT3 inhibitors and IDH 1/2 inhibitors. The SIERRA control arm reflects real-world treatment of r/r AML patients with over 20 agents used alone or in combination as no standard of care exists for this patient population. The SIERRA trial enrolled patients at 24 leading transplant centers in the United States and Canada that perform over 30% of AML BMTs.

Developed at the Fred Hutchinson Cancer Research Center, a pioneer in the field of BMT, lomab-B is supported by data in six disease indications including leukemias, lymphomas and multiple myeloma, which afflict over 100,000 patients annually. Actinium intends to pursue additional indications for lomab-B beyond AML. Actinium also intends to pursue international regulatory approvals independently and through partnerships. In April 2022, Actinium licensed the European, Middle East and North African commercial rights for lomab-B to Immedica AB, a fully-fledged independent pharmaceutical company headquartered in Sweden. In exchange, Actinium received an upfront payment of \$35 million USD with the potential for an additional \$417 million USD in regulatory and sales milestones and mid-twenty percent royalties. Europe represents a commercial opportunity double the size of the United States by number of patients with AML receiving BMT. lomab-B has been granted Orphan Drug Designation by the European Medicines Agency (EMA) and has received positive Scientific Advice from the Committee for Medicinal Products for Human Use (CHMP) of the EMA indicating that the Phase 3 SIERRA trial design, primary endpoint and planned

statistical analysis are acceptable as the basis for a Marketing Authorization Application.

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

Actinium Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing targeted radiotherapies to deliver cancer-killing radiation with cellular level precision to treat patients with high unmet needs. Actinium's clinical pipeline is led by targeted radiotherapies that are being applied to targeted conditioning, which is intended to selectively deplete a patient's disease or cancer cells and certain immune cells prior to a bone marrow transplant (BMT), gene therapy or adoptive cell therapy, such as CAR-T, to enable engraftment of these transplanted cells with minimal toxicities. Our lead product candidate, lomab-B (I-131 apamistamab) has been studied in over four hundred patients, including the pivotal Phase 3 Study of lomab-B in Elderly Relapsed or Refractory Acute Myeloid Leukemia (SIERRA) trial for BMT conditioning. The SIERRA trial was positive with lomab-B meeting the primary endpoint of durable Complete Remission of 6-months with high statistical significance ( $p < 0.0001$ ). Lomab-B enabled 100% of patients to access a BMT and produced higher rates of post-BMT CR. Lomab-B produced positive results for the secondary endpoints of the SIERRA trial including reducing the probability of an event by 78% resulting in an Event-Free Survival (EFS) Hazard Ratio of 0.22 ( $p < 0.0001$ ), doubled 1-year overall survival and median overall survival. Lomab-ACT, low dose I-131 apamistamab, is being studied as a targeted conditioning agent in a Phase 1 study with a CD19 CAR T-cell Therapy with Memorial Sloan Kettering Cancer Center with NIH funding. Actimab-A, our second most advanced product candidate has been studied in approximately 150 patients with Acute Myeloid Leukemia or AML, including in combination trials with the chemotherapy regimen CLAG-M and with venetoclax, a targeted therapy. Actimab-A or lintuzumab-Ac225 is an Actinium-225 based antibody radiation conjugate targeting CD33, a validated target in AML. Actinium has entered into a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI) to develop Actimab-A as a single agent or combination with chemotherapy, targeted agents or immunotherapy in Phase 1, 2 or 3 trials. The NCI will fund clinical trial expenses under the CRADA while Actinium will supply Actimab-A. The NCI is currently accepting proposals for non-clinical and clinical studies with Actimab-A. Actinium is a pioneer and leader in the field of Actinium-225 alpha therapies with an industry leading technology platform comprising over 190 patents and patent applications including methods of producing the radioisotope AC-225. Our technology and expertise have enabled collaborative research partnerships with Astellas Pharma, Inc. for solid tumor theranostics, with AVEO Oncology Inc. to create an Actinium-225 HER3 targeting radiotherapy for solid tumors, and with EpicentRx, Inc. to create targeted radiotherapy combinations with their novel, clinical stage small molecule CD47-SIRP $\alpha$  inhibitor. More information is available on Actinium's 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.*

**Investors:**

Hans Vitzthum

LifeSci Advisors, LLC

[Hans@LifeSciAdvisors.com](mailto:Hans@LifeSciAdvisors.com)

(617) 430-7578

 View original content to download multimedia <https://www.prnewswire.com/news-releases/actinium-pharmaceuticals-reports-2022-financial-results-and-highlights-recent-and-upcoming-clinical-data-and-milestones-301787907.html>

SOURCE Actinium Pharmaceuticals, Inc.