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# Actinium Pharmaceuticals Highlights Antibody Radiation Conjugate Program Developments and Reports Financial Results for the Third Quarter 2024

- Aligned with FDA on operationally seamless Phase 2/3 trial for Actimab-A + CLAG-M in relapsed/refractory acute myeloid leukemia
- Actimab-A selected for National Cancer Institute's recently opened myeloMATCH precision medicines program for patients with acute myeloid leukemia and myelodysplastic syndromes
  - Two lomab-ACT INDs cleared by FDA: Commercial CAR-T trial at University of Texas Southwestern and sickle cell transplant trial at Columbia University; proof-of-concept safety and efficacy data expected in 2025
  - Actinium seeking U.S. strategic partner for lomab-B to conduct dose optimization and head-to-head Phase 3 trial based on FDA guidance in adult patients with active relapsed or refractory acute myeloid leukemia
- Accomplished biopharma industry executive June Almenoff, M.D., Ph.D., appointed to Actinium's Board of Directors
- Cash and cash equivalents of approximately \$78.6 million as of September 30, 2024, is expected to fund operations into 2027

NEW YORK, Nov. 18, 2024 /PRNewswire/ -- **Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) (Actinium or the Company), a leader in the development of Antibody Radiation Conjugates (ARCs) and other targeted radiotherapies, today highlighted recent regulatory and development updates for its lomab-B, Actimab-A and lomab-ACT ARC clinical programs as well as its financial results for the third quarter ended September 30, 2024. lomab-B is a first in class CD45 targeted conditioning agent to enable bone marrow transplant (BMT) and has been studied in over four hundred patients including the completed Phase 3 SIERRA trial for patients with relapsed or refractory acute myeloid leukemia (r/r AML). Actimab-A is a targeted radiotherapeutic that uses the Actinium-225 (Ac-225) isotope payload directed against CD33 with broad potential for development in AML and other myeloid indications including in collaboration with the National Cancer Institute (NCI) under a Cooperative Research and Development Agreement (CRADA). lomab-ACT is a next-generation CD45 targeted conditioning agent being developed for cell and gene therapies for both malignant and non-malignant hematologic indications. Actinium is executing cutting-edge R&D focused on ARCs and other targeted radiotherapies for blood cancer and solid tumor indications leveraging its strong intellectual property portfolio of 230 patents and patent applications including several patents related to the manufacture of the

isotope Ac-225 in a cyclotron.



Sandesh Seth, Actinium's Chairman and CEO, stated, "During the third quarter and over the last several weeks, we have made significant progress with our three ARC clinical programs. Actinium is now positioned to advance exciting clinical trials for Actimab-A and lomab-ACT in large indications with high unmet needs that can deliver impactful clinical data in 2025. Actimab-A's backbone therapy potential is poised to be realized with the operationally seamless Phase 2/3 trial following alignment with the FDA, additional clinical trials being planned under the NCI CRADA including the myeloMATCH program and via our R&D efforts to further elucidate Actimab-A's mutation agnostic mechanism of action. The clinical data anticipated from lomab-ACT in 2025 from the commercial CAR-T and sickle cell transplant trials has the potential to establish lomab-ACT as a best-in-class targeted conditioning agent for both malignant and non-malignant hematology indications. In addition, our recent meeting with the FDA regarding lomab-B established a clear development pathway, which will be incredibly valuable in securing a U.S. strategic partner. Finally, I am delighted to welcome Dr. June Almenoff to our Board of Directors, who brings over 25 years of biopharma industry experience with a proven track record of leading drug development through approvals and executing value enhancing business development transactions."

### **Actimab-A Regulatory and Development Update**

- Actinium met with the FDA in the third quarter and aligned with the FDA on an operationally seamless randomized Phase 2/3 trial to study Actimab-A + CLAG-M
- In the Phase 2 portion of the study, the Actimab-A dose will be optimized in combination with CLAG-M
- The Phase 3 portion will study the optimized dose of Actimab-A + CLAG-M versus CLAG-M alone in patients with r/r AML
- Operationally seamless trial design is expected to reduce the required time and resources compared to separate Phase 2 and Phase 3 trials
- Actinium continues to evaluate and develop additional Actimab-A clinical trials under its CRADA with the NCI, investigator initiated, or Actinium sponsored studies
- Actimab-A selected by NCI for recently opened myeloMATCH precision medicine program for patients with AML and myelodysplastic syndrome (MDS)

### **lomab-ACT Program Update**

- In the third quarter, the FDA cleared the investigational new drug (IND) applications for both the commercial CAR-T study led by the University of Texas Southwestern (UTSW) and the sickle cell trial being led by Columbia University
- The UTSW commercial CAR-T trial expected to initiate patient enrollment in 1Q 2025 with proof-of-concept clinical data expected by year end
- Commercial CAR-T sales exceeded \$3.5 billion in 2023 with multiple CAR-T therapies approved for patients with lymphomas, leukemias and multiple myeloma

- Columbia University sickle cell transplant trial to study lomab-ACT for targeted conditioning prior to BMT for the first time in a non-malignant hematology setting, which is a rapidly growing indication for BMT; patient enrollment expected to commence in the first half of 2025

### **lomab-B Regulatory Status and Program Update**

- Actinium is seeking a U.S. strategic partner to advance clinical development of lomab-B including the Phase 3 trial
- Actinium met with the FDA in the fourth quarter and aligned on the patient population for the head-to-head Phase 3 trial to evaluate allogeneic BMT using lomab-B plus a reduced intensity conditioning regimen of fludarabine and total body irradiation (Flu/TBI) versus allogeneic BMT using reduced intensity conditioning comprised of cyclophosphamide plus Flu/TBI
- Head-to-head Phase 3 trial to enroll adult patients aged 18 and above with active AML with blasts counts greater than 5% and less than 20%, representing a broader patient population than that in the SIERRA trial
- Dose optimization trial to be completed prior to initiating the head-to-head Phase 3 trial to determine the dose for lomab-B based on radiation to the bone marrow rather than the maximum tolerable dose of 24 Gy of radiation to the liver as was done in the SIERRA trial based on several interactions with the FDA before starting the SIERRA trial

Mr. Seth added, "We are excited by our recent progress and committed to delivering on several milestones in the near-term and throughout 2025. Our current balance sheet provides strong runway into 2027, which enables us to deliver important clinical data and further realize our vision of being a leading fully integrated specialty radiopharmaceutical company."

### **Third Quarter 2024 Financial Results**

Cash and cash equivalents of approximately \$78.6 million as of September 30, 2024. Based on Actinium's current operating plan, cash and cash equivalents are expected to fund operations into 2027.

### **Research and Development Expense, net of reimbursements**

Research and development expenses of \$9.8 million for the three months ended September 30, 2024 decreased \$1.8 million from \$11.6 million for the three months ended September 30, 2023. The decrease is primarily a result of a decline in Chemistry, manufacturing and controls, or CMC, expenses of \$5.5 million and lower consulting expenses of \$0.5 million, both due to lower activity in 2024 related to lomab-B. These declines were partially offset by increased preclinical expenses of \$3.9 million.

### **General and administrative expense**

General and administrative expenses of \$2.8 million for the three months ended September 30, 2024 increased by \$0.1 million from \$2.7 million for the three months ended September 30, 2023, primarily due to higher non-cash stock compensation expense of \$0.5 million, partially offset by lower compensation expense of \$0.3 million due to lower headcount.

In the third quarter of 2024, our overall headcount reduced by approximately twenty percent, with a majority of these former employees being from our clinical and CMC groups. As a result of these departures, we expect our personnel expenses to be reduced by approximately \$3.7 million in 2025, which may be offset by additional hires or consultants. We do not expect these departures to have a material impact on our operations or ability to execute our operating plan and we are actively seeking a strategic partner for lomab-B in the U.S. to advance the clinical development activity for lomab-B including the planned Phase 3 trial.

### **Other income**

Other income is comprised of net interest income in both reporting periods. The amount for the three months ended September 30, 2024 and 2023 of \$1.0 million in each reporting period was virtually unchanged from the same time period in the prior year.

### **Net loss**

Net loss of \$11.6 million for the three months ended September 30, 2024 decreased by \$1.7 million from \$13.3 million for the three months ended September 30, 2023 due to lower research and development expenses partially offset by higher general and administrative expenses.

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

Actinium develops Antibody Radiation Conjugates (ARCs) and other targeted radiotherapies intended to meaningfully improve outcomes for people who have failed existing oncology therapies. The company continues to advance its development for product candidate Actimab-A, a therapeutic agent that has demonstrated potential activity in r/r AML patients. In addition, Actinium is engaged with the National Cancer Institute (NCI) under the Cooperative Research and Development Agreement (CRADA) for development of Actimab-A in AML and other myeloid malignancies. lomab-ACT, Actinium's next generation conditioning candidate, is being developed with the goal of improving patient access and outcomes for potentially curative cell and gene therapies. lomab-B is an induction and conditioning agent prior to bone marrow transplant in patients with relapsed and refractory acute myeloid leukemia (r/r AML), which Actinium is seeking a potential strategic partner for in the U.S. In addition, the company's R&D efforts are primarily focused on advancing several preclinical programs for solid tumor indications. Actinium holds 230 patents and patent applications including several patents related to the manufacture of the isotope Ac-225 in a cyclotron.

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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