

February 6, 2023



# Actinium Signs Cooperative Research and Development Agreement with National Cancer Institute to Further Enhance Clinical and Non-clinical Development of Actimab-A for the Treatment of Acute Myeloid Leukemia and Other Hematologic Malignancies

- National Cancer Institute will sponsor and oversee clinical trials of Actimab-A under the terms of the Cooperative Research and Development Agreement
- Collaboration will provide Actimab-A and other necessary support to study Actimab-A alone or in combinations with chemotherapy, immunotherapy and/or targeted agents aligned with Actinium's development strategy
- Over 2,000 institutions within NCI funded extramural clinical networks will have access to Actimab-A for conducting clinical and non-clinical research and development
- CRADA Clinical Studies will be performed utilizing NCI's *Experimental Therapeutics Clinical Trials Network (ETCTN)* and *National Clinical Trials Network (NCTN)*

NEW YORK, Feb. 6, 2023 /PRNewswire/ -- **Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) (Actinium or the Company), a leader in the development of targeted radiotherapies, today announced that it has entered into a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI), part of the National Institutes for Health (NIH), to develop Actimab-A for the treatment of patients with acute myeloid leukemia (AML) and other hematologic malignancies. Under the terms of the CRADA, the NCI will serve as the regulatory sponsor for any clinical trials mutually approved by both parties to study Actimab-A while Actinium will be responsible for supplying and distributing Actimab-A to participating clinical sites and providing additional support as needed. The CRADA will provide broad support for the development of Actimab-A alone or in combination with chemotherapy, immunotherapy, targeted agents and other novel combinations, in line with Actinium's strategy of leveraging Actimab-A's targeted radiotherapy mechanism to elicit synergistic effects.



The CRADA studies will be overseen by NCI in collaboration with Actinium's clinical development team. 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. 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.

Sandesh Seth, Actinium's Chairman and CEO, said, "We are incredibly honored to be collaborating with NCI and excited that they share our vision for Actimab-A's potential for the treatment of AML and other blood cancers. The CRADA will allow Actimab-A's broad applicability to be fully studied and developed by leading oncology network groups as well as NCI's leading-edge MyeloMATCH program in ways Actinium could not do independently. NCI's sponsorship will also allow us to accelerate novel Actimab-A combinations and broaden its use in AML and other hematological indications, while the collaboration with NCI, who funds and maintains the largest centralized clinical trial support systems in the United States, will help preserve our balance sheet for additional corporate priorities."

Dr. Avinash Desai, Chief Medical Officer of Actinium Pharmaceuticals, commented, "NCI's broad support under the CRADA is a strong encouragement for us to together explore Actimab-A's potential for the treatment of AML and other hematologic malignancies. As the only CD33 targeting radiotherapy in development, Actimab-A is uniquely positioned to address the challenges in treating relapsed or refractory AML patients who do not respond well to front line therapies and those whose disease stops responding to traditional cytotoxic or available targeted therapies. We are highly encouraged by the high rates of responses, minimal residual disease negativity and strong survival benefit at 1 and 2 years in heavily treated patients, including prior Venetoclax treatment and/or transplant, and those with adverse cytogenetics, including TP53 mutations, recently reported from the Actimab-A CLAG-M combination study. We look forward to working collaboratively with the NCI and all investigators through this CRADA to complete multiple clinical trials to further realize Actimab-A's therapeutic potential."

### **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 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, I-131 apamistamab (Iomab-B) has been studied in over four hundred patients, including the pivotal Phase 3 Study of Iomab-B in Elderly Relapsed or Refractory Acute Myeloid Leukemia (SIERRA) trial for BMT conditioning. Topline data from the SIERRA trial was positive with the study meeting its primary endpoint with a high statistical significance ( $p < 0.0001$ ). Full results from the SIERRA trial will be presented in a late-breaker presentation at the 2023 Tandem Meetings: Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR on February 18, 2023. Iomab-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 ongoing 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 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-signs-cooperative-research-and-development-agreement-with-national-cancer-institute-to-further-enhance-clinical-and-non-clinical-development-of-actimab-a-for-the-treatment-of-acute-myeloid-leukemia-and-other-hematologic-m-301739011.html](https://www.actiniumpharma.com/press-releases/actinium-signs-cooperative-research-and-development-agreement-with-national-cancer-institute-to-further-enhance-clinical-and-non-clinical-development-of-actimab-a-for-the-treatment-of-acute-myeloid-leukemia-and-other-hematologic-m-301739011.html)

SOURCE Actinium Pharmaceuticals, Inc.