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Actinium Expands Patent Coverage Over Iomab-ACT, its Next-Generation Targeted Radiotherapy Conditioning Agent, for Gene Edited Stem Cell-Based Therapies for Non-Malignant Indications

- Newly issued U.S. patent augments Actinium's existing composition of matter patent coverage over Iomab-B and Iomab-ACT targeted radiotherapy conditioning programs

- Pertains to the use of Iomab-ACT with genetically engineered hematopoietic stem cells for treating non-malignant diseases including sickle cell disease, severe combined immunodeficiency disease, β-thalassemia and Fanconi's anemia

NEW YORK, Aug. 1, 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 announced the issuance of U.S. Patent No. 11,912,780 titled, "Anti-CD45-Based Conditioning Methods and Uses Thereof in Conjunction with Gene-Edited Cell Based Therapies" by the United States Patent and Trademark Office (USPTO). This patent extends into 2040 and covers methods using Iomab-ACT for conditioning patients prior to the administration of gene-edited hematopoietic stem cell (HSC) therapy to treat non-malignant disorders, such as sickle cell disease, severe combined immunodeficiency disease (SCID), β-thalassemia and Fanconi's anemia. Iomab-ACT is an ARC that targets CD45, a marker expressed on blood cancer cells and immune cells that is intended to enable conditioning prior to cell and gene therapies such as CAR T-cell therapy and replace the non-targeted chemotherapy that is currently used for conditioning.

Sandesh Seth, Actinium's Chairman and CEO, stated, "The field of gene-edited stem cell therapies is rapidly evolving, with the potential to transform or even cure debilitating diseases. Recognizing this emerging field, we are excited to further strengthen our intellectual property portfolio, demonstrating our commitment to innovation in targeted radiotherapy. We aim to establish Iomab-ACT as a universal, non-chemotherapy targeted

conditioning regimen for use across cell and gene therapies for both malignant and non-malignant indications. Current conditioning regimens use high doses of cytotoxic chemotherapies such as busulfan and others that are associated with infertility and other toxicities posing barriers for patients seeking gene therapy for non-cancerous diseases. Collectively, the indications covered under this patent afflict over one hundred thousand patients each year, and we are committed to improving access and outcomes for these patients via Iomab-ACT as is evidenced by our recent clinical collaborations with leading academic institutions to determine the potential of Iomab-ACT as a conditioning regimen prior to a cellular therapy".

Actinium's intellectual property portfolio also includes a family of issued composition of matter patents covering Iomab-B and Iomab-ACT, extending into 2037. The term of newly issued U.S. Patent No. 11,912,780 extends patent protection over Iomab-ACT aspects until 2040. The Company is pursuing further patent coverage for Iomab-ACT in the U.S. and internationally.

Iomab-ACT is currently being studied in a clinical trial at Memorial Sloan Kettering Cancer Center with a CD19 CAR-T therapy in patients with relapsed or refractory B-cell Acute Lymphoblastic Leukemia (r/r B-ALL) or Diffuse Large B-cell Lymphoma (DLBCL) that is supported by grant funding from the National Institutes of Health (NIH). Initial proof of concept data showed that Iomab-ACT produced transient depletion of peripheral blood lymphocytes and monocytes and that CAR-T cells persisted up to eight weeks post infusion. Minimal non-hematologic toxicities have been observed to date. Specifically, there were no (0/4) cases of immune effector cell-associated neurotoxicity syndrome (ICANS) of any grade, a major safety measure of the study, as ICANS is observed in 25% or more of patients with r/r B-ALL and DLBCL treated with various CAR-T cell products. Iomab-ACT is being studied in a Phase 1 trial as conditioning prior to treatment with a commercial CAR-T therapy in collaboration with the University of Texas Southwestern (UTSW) as well as a Phase 1 trial to condition patients with sickle cell disease prior to a stem cell transplant in collaboration with Columbia University that is expected to inform a gene therapy conditioning trial in patients with sickle cell disease. IND applications have been cleared by the FDA for both the commercial CAR-T and sickle cell disease Phase 1 trials and patient enrollment is expected to commence.

About Actinium Pharmaceuticals, Inc.

Actinium develops targeted radiotherapies to meaningfully improve survival for people who have failed existing oncology therapies. Advanced pipeline candidates Iomab-B (pre-BLA & MAA (EU)), an induction and conditioning agent prior to bone marrow transplant, and Actimab-A (Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute), a therapeutic agent, have demonstrated potential to extend survival outcomes for people with relapsed and refractory acute myeloid leukemia. Actinium plans to advance Iomab-B for other blood cancers and next generation conditioning candidate Iomab-ACT to improve cell and gene therapy outcomes. Actinium holds more than 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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