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Actinium Announces FDA Clearance of Iomab-ACT Targeted Conditioning IND Application for Sickle Cell Disease Patients Undergoing Bone Marrow Transplant in Collaboration with Columbia University

- Sickle cell disease affects approximately 100,000 patients in the U.S. annually and is a debilitating and life-threatening condition with high unmet need

- Current conditioning with non-targeted chemotherapies provides limited access to potentially curative bone marrow transplant and recently approved gene therapies for sickle cell disease patients

- Initial trial focused on conditioning for bone marrow transplant intended to inform subsequent gene therapy conditioning study and provide broader access to cellular therapy for sickle cell patients

NEW YORK, July 25, 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 FDA clearance of an Investigational New Drug (IND) application to study Iomab-ACT for targeted conditioning prior to a bone marrow transplant (BMT), in patients with sickle cell disease. The study will be conducted in collaboration with the Columbia University and led by Markus Mapara, M.D., Ph.D., Professor of Medicine, Columbia University Irving Medical Center, Director, Bone Marrow Transplantation and Cell Therapy Program, Vagelos College of Physicians and Surgeons. This trial will evaluate the safety of Iomab-ACT in patients with sickle cell disease who are to receive an allogeneic BMT. If successful, the trial is expected to inform a clinical trial to evaluate Iomab-ACT as a targeted conditioning agent prior to gene therapy for which there are two approved agents for patients with sickle cell disease, Casgevy (Vertex Pharmaceuticals, Inc.) and Lyfgenia (Bluebird Bio, Inc.). This collaboration with Dr. Mapara is intended to enable patients with sickle cell disease broader access to allogeneic BMT and gene therapy, potentially curable cellular therapies, via Iomab-ACT. 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 replacing the non-targeted chemotherapy and total body irradiation that is currently used for conditioning. It is the only CD45 targeting conditioning agent in clinical development.

Dr. Mapara, stated, "Undergoing chemotherapy- or total body irradiation-based conditioning for curative allogeneic bone marrow transplant or gene therapy often brings severe side effects for patients with sickle cell disease. These toxicities include organ damage, infections, infertility, and the potential for secondary malignancies. Leveraging extensive data from CD45 ARC conditioning in allogeneic bone marrow transplants, I am thrilled to lead this pioneering study using Iomab-ACT, a non-chemotherapeutic targeted radiotherapy conditioning, for patients with sickle cell disease. This innovative approach aims to minimize toxicity while ensuring complete donor hematopoiesis engraftment. Success in this trial could revolutionize treatment, enabling the use of a low-toxicity method for the engraftment of genetically engineered autologous stem cells in SCD patients."

Sandesh Seth, Actinium's Chairman and CEO, added, "We are honored to collaborate with Dr. Mapara on this important initiative to address the significant number of patients with sickle cell disease who do not pursue or are not able to access transplant or gene therapies due to the required chemotherapy-based conditioning and its severe toxicities. Sickle cell disease represents a large and high unmet need that needs better treatment options and outcomes. This exciting program in sickle cell disease adds to our recently announced commercial CAR-T trial addressing the large patient population with blood cancers that can also benefit from broader access to cellular therapy via targeted conditioning. We look forward to further expanding Iomab-ACT's already large addressable patient opportunity in transplant, cell therapy and gene therapy conditioning."

Targeted Radiotherapy Conditioning Opportunity

The opportunity exists for better conditioning in other areas of cellular therapy, such as CAR-T as well as gene therapies. The pipeline of CAR-T and gene therapies has rapidly expanded, with the addressable patient population expected to nearly double and reach approximately 93,000 patients in the U.S. by 2030 based on the current pipeline of cellular therapies. The CAR-T market size in terms of revenue is estimated to grow at a CAGR of approximately 11% over the next 5 plus years. Currently, there are six CAR T-cell therapies approved by the FDA that are used to treat patients with lymphomas, leukemia, and multiple myeloma, which collectively had total sales of over $3.5 billion in 2023 and two gene therapies approved by the FDA for patients with sickle cell disease. The addressable market for Iomab-ACT is in line with the patient population for cell and gene therapies as all patients must receive some type of conditioning prior to these treatments. We will continue to develop Iomab-ACT, our next-generation conditioning program for rapidly growing cell and gene therapies based on early promising results, ultimately with the value proposition of improving overall access and outcomes for patients who need cellular or gene therapies. A potential blockbuster revenue opportunity exists for Iomab-ACT assuming it can provide one or more clinical benefits related to lower cytokine release syndrome (CRS), less immune effector cell-associated neurotoxicity syndrome (ICANS), longer duration of response with selective lymphodepletion or a higher overall success rate of cell and gene therapies due to benefits of targeted conditioning.

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 (National Cancer Institute CRADA), 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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