



## **BWXT Medical Submits Drug Master File for Actinium-225 API to U.S. Food and Drug Administration**

June 7, 2024

OTTAWA, Ontario--(BUSINESS WIRE)-- BWXT Medical Ltd. has submitted a Drug Master File (DMF) to the U.S. Drug and Food Administration (FDA) for No Carrier Added (n.c.a.) Actinium-225 (Ac-225) Active Pharmaceutical Ingredient.

Ac-225 is an alpha-emitting isotope used in targeted alpha therapies (TATs) that combine the isotope with specific tumor-seeking targeting vectors to kill cancer cells while minimizing the impact to healthy tissues.

There is growing demand for the isotope, but there are a limited number of suppliers that are currently able to produce meaningful quantities of high purity actinium. One such technology is high-energy proton spallation of thorium targets that are produced and irradiated in collaboration with TRIUMF. Irradiation at high energy favors the production of Ra-225, which can be isolated and loaded onto a generator. Elution of this generator yields high purity Ac-225, which does not contain the long-lived impurity Ac-227.

Jonathan Cirtain, president and chief executive officer of BWXT Medical, stated, "Our submission of a Drug Master File to the FDA marks a significant milestone for our company. This filing underscores our unwavering commitment to quality and regulatory excellence, ensuring that our medical isotopes meet the highest standards of safety and efficacy. It represents not just our dedication to advancing healthcare, but also our readiness to support our customers and partners in delivering critical treatments to patients in need."

The FDA is responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health. Drug master files (DMFs) are submissions to FDA used to provide confidential, detailed information about facilities, processes or articles used in the manufacturing, processing, packaging and storing of human drug products.

An active DMF enables clinical investigators or pharmaceutical companies to reference the filing in their regulatory submissions. BWXT Medical's Ac-225 has been used in an early clinical study, and the DMF is now ready for reference to support later stage clinical studies and, ultimately, new drug applications.

### **Forward Looking Statements**

*BWX Technologies, Inc. ("BWXT") cautions that this release contains forward-looking statements, including statements relating to expectations for the development, production, performance, demand, timing and impact of Ac-225. These forward-looking statements involve a number of risks and uncertainties, including, among other things, changes in market demand, delays in the development and automation of our production, regulatory approvals and potential supply chain issues. If one or more of these or other risks materialize, actual results may vary materially from those expressed. For a more complete discussion of these and other risk factors, please see BWXT's annual report on Form 10-K for the year ended December 31, 2023 and subsequent quarterly reports on Form 10-Q filed with the Securities and Exchange Commission. BWXT cautions not to place undue reliance on these forward-looking statements, which speak only as of the date of this release, and undertakes no obligation to update or revise any forward-looking statement, except to the extent required by applicable law.*

### **About BWXT Medical**

*BWXT Medical Ltd. manufactures custom radiopharmaceuticals, radiotherapies and medical isotopes in an 80,000-square-foot cGMP manufacturing facility in Ottawa and at the state-of-the-art commercial cyclotron facility within TRIUMF, Canada's particle acceleration centre. BWXT Medical Ltd. is a subsidiary of BWX Technologies, Inc. (NYSE: BWXT). BWXT is a manufacturing and engineering innovator that provides safe and effective nuclear solutions for global security, clean energy, environmental restoration, nuclear medicine and space exploration. Learn more at [www.bwxmedical.com](http://www.bwxmedical.com) and follow us on [LinkedIn](#).*



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