





ITM and CNL Announce the Launch of Actineer, a New Joint Venture in the Global Production of Actinium-225

New company will advance Actinium-225 technologies, quickly secure supply, and construct a new production facility in Canada to produce industrial-scale quantities of rare medical isotope

Garching / Munich, Germany and Chalk River, Ontario, Canada, October 18, 2023 – ITM Isotope Technologies Munich SE (ITM), a leading radiopharmaceutical biotech company, and Canadian Nuclear Laboratories (CNL), which manages and operates the national laboratory at Chalk River, Ontario on behalf of <u>Atomic Energy of Canada Limited</u> (AECL), today announced the launch of Actineer[™] Inc., a new joint venture company between CNL and ITM for the industrial scale production of Actinium-225 (²²⁵Ac).

As a rare alpha-emitting medical radioisotope, ²²⁵Ac is quickly gaining attention across the precision oncology field due to its significant potential as a powerful new weapon in the fight against cancer. The joint venture will fulfill the unmet global manufacturing and production needs of this coveted radioisotope.

Under terms of the agreement, Actineer will advance ²²⁵Ac production and processing technologies to establish short-term production capabilities of the medical isotope that will significantly boost international supplies, while working long-term towards the construction of a new Actinium Production Facility (APF) that will feature dedicated large-scale infrastructure to produce ²²⁵Ac.

The collaboration also encompasses the development and implementation of the manufacturing process to be used at the APF. CNL will provide the starting material for irradiation and initially manage the production process during the interim scale of radiochemical grade ²²⁵Ac supply, while ITM will further process the resulting ²²⁵Ac to pharmaceutical grade under Good Manufacturing Process (GMP) specifications. ITM will also be responsible for global marketing, sales, and distribution, which will be supported by its well-established global sales network. The joint venture remains subject to further closing conditions expected to be satisfied in early 2024. Further details of the agreement were not disclosed.

"Targeted alpha therapies based on Actinium-225 are gaining increasing importance in addition to the well-established beta emitters such as our highly-pure non-carrier-added (n.c.a.) Lutetium-177. Joining forces with CNL provides us the opportunity to extend our therapeutic portfolio as we continue striving to meet the needs of healthcare professionals and cancer patients worldwide," commented **Steffen Schuster, CEO of ITM**.

"Working with ITM, CNL has already made significant progress towards our goal of bringing a next-generation medical radioisotope to the world market. With the launch of Actineer, we are poised to establish a reliable and large-scale supply of ²²⁵Ac that we believe will unlock ground-breaking new cancer treatments," commented **Joe McBrearty, CNL's President and CEO**. "The entire team at CNL looks forward to applying their radiochemical expertise to the development of the new production process for Actinium-225, and to working with ITM to advance new and exciting cancer treatments."

AECL, a Crown corporation with its vision to realize benefits to Canadians by driving nuclear innovation in Canada, welcomes this venture as part of its efforts to foster collaboration and advance isotope development to the benefit of patients in Canada and around the world:

"We are pleased to support the joint venture between CNL and ITM with shared values to bring this potentially lifesaving therapy to the world," said **Fred Dermarkar, President, and CEO of AECL**. "It is our role to drive nuclear innovation in Canada, to bring private and public expertise together to spark these new initiatives that will ultimately benefit the health of Canadians and bring new jobs to Canada. We are building on decades of Canada's world-leading isotope innovation, and have found the key to success is collaboration, partnership, and strong leadership."

Using existing materials handling facilities and supporting infrastructure at the Chalk River Laboratories, <u>CNL and ITM are also collaborating with other key strategic service providers</u> to establish an interim supply of ²²⁵Ac. This project will deliver significant quantities of the high-demand radioisotope to healthcare professionals and patients before the APF is completed.

Targeted alpha therapy is attracting growing interest from scientists and medical practitioners. Alphaemitters, particularly ²²⁵Ac, are in high demand for their ability to cause damage to cancer cells. Notably, ²²⁵Ac emits high-energy alpha particles with a short penetration range, which potentially enable precise treatment of tumor cells, including hard-to-target micro metastases, with minimal impact to surrounding healthy tissue. In preclinical studies, targeted alpha therapies have shown remarkable results, destroying cancer cells by effectively breaking the bonds in their DNA. ²²⁵Ac can be labelled to a variety of peptide ligands or antibodies to specifically target cancer cells in a wide range of tumor indications.

About Targeted Alpha Therapy

Targeted Alpha Therapy is an emerging class of cancer therapeutics, which seeks to deliver alpha radiation directly to the tumor while minimizing radiation exposure to normal tissue. Targeted radiopharmaceuticals are created by linking a therapeutic radioisotope to a targeting molecule (e.g., peptide, antibody, small molecule) that can precisely recognize tumor cells and bind to tumor-specific characteristics, like receptors on the tumor cell surface. As a result, the radioisotope accumulates at the tumor site and decays, releasing a small amount of ionizing radiation, thereby destroying tumor tissue. The highly precise localization enables targeted treatment with minimal impact to healthy surrounding tissue.

About ITM Isotope Technologies Munich SE

ITM, a leading radiopharmaceutical biotech company, is dedicated to providing a new generation of radiomolecular precision therapeutics and diagnostics for hard-to-treat tumors. We aim to meet the needs of cancer patients, clinicians and our partners through excellence in development, production and global supply. With improved patient benefit as the driving principle for all we do, ITM advances a broad precision oncology pipeline, including two phase III studies, combining the company's high-quality radioisotopes with a range of targeting molecules. By leveraging our nearly two decades of pioneering radiopharma expertise, central industry position and established global network, ITM strives to provide patients with more effective targeted treatment to improve clinical outcome and quality of life. www.itm-radiopharma.com

About AECL

AECL drives nuclear innovation to deliver clean energy technologies and improve the quality of life of Canadians while caring for the land.

As a federal Crown corporation, AECL's mandate is to enable nuclear science and technology, derive optimal value for Canada from AECL's CANDU intellectual property and to protect the environment by fulfilling the Government of Canada's radioactive waste and decommissioning responsibilities.

AECL delivers its mandate through a Government-owned, Contractor-operated model, whereby a privatesector organization, Canadian Nuclear Laboratories, is responsible for managing and operating AECL's sites.

Under the Government-owned, Contractor-operated model, AECL owns the sites, facilities, assets, intellectual property and responsibility for nuclear science and technology, environmental remediation and radioactive waste management. Canadian Nuclear Laboratories is responsible for the day-to-day management and operations of the sites.

To learn more about AECL, please visit <u>www.aecl.ca</u>.

About CNL

As Canada's premier nuclear science and technology laboratory, and working under the direction of Atomic Energy of Canada Limited (AECL), CNL is a world leader in the development of innovative nuclear science and technology products and services. Guided by an ambitious corporate strategy - Vision 2030, CNL fulfills three strategic priorities of national importance – restoring and protecting the environment, advancing clean energy technologies, and contributing to the health of Canadians.

By leveraging the assets owned by AECL, CNL also serves as the interface between government, the nuclear industry, the broader private sector and the academic community. CNL works in collaboration with all these sectors to advance innovative Canadian products and services for real-world use, including clean energy, cancer treatments and other therapies, non-proliferation technologies and waste management solutions.

To learn more about CNL, please visit <u>www.cnl.ca</u>.

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