

ITM and Bruce Power successfully complete feasibility study

Key requirements met to start Ytterbium-176 irradiation at Bruce Power's facilities for the production of ITM's no-carrier-added Lutetium-177 for cancer therapy

Garching/Munich, Germany, and Tiverton, ON, Canada, September 30, 2019

ITM Isotopen Technologien München AG (ITM), a biotechnology and radiopharmaceutical group of companies, and Bruce Power, a Canadian-based nuclear generator and isotope supplier, announced today that they have successfully completed a joint feasibility study at Bruce Power's Nuclear Facilities for the irradiation of Ytterbium-176. Ytterbium-176 is the source material of ITM's medical radioisotope no-carrier-added (n.c.a.) Lutetium-177 (EndolucinBeta®). The intermediate material to be generated at Bruce Power will be processed to the high purity medical radioisotope n.c.a. Lutetium-177 at ITM's global network of radiopharmaceutical production facilities.

ITM and Bruce Power have come to the conclusion that Bruce Power and its partners Framatome and Kinectrics, following regulatory and other approvals, are uniquely positioned to fulfil the necessary requirements to establish isotope production units at the Bruce Power Reactors that meet the high standards required for ITM's proprietary n.c.a. Lutetium-177 production process.

"We are very pleased about the successful completion of our feasibility study and being able to meet ITM's high standards", said James Scongack, Executive Vice-President Corporate Affairs and Operational Services. "Through our partnership with Kinectrics and Framatome, we look forward to becoming part of a global network providing the highly pure medical radioisotope n.c.a. Lutetium-177 to a growing number of cancer patients worldwide."

The feasibility study examined factors such as technical, medical and nuclear regulatory requirements, radiation protection and waste management. The study also verified the specific requirements of compatibility with ITM's target and processing technology.

"After the excellent results of our joint feasibility study with Bruce Power and its partners Framatome and Kinectrics we are looking forward to the start of the construction of the irradiation facilities at Bruce Power shortly" added Steffen Schuster, CEO of ITM. "We are delighted that with Bruce Power we have found a strong and reliable partner, with whom we can ensure security of supply of no-carrier-added Lutetium-177 for cancer patients worldwide used in Targeted Radionuclide Therapy."

N.c.a. Lutetium-177 is a key radiopharmaceutical component which is successfully applied in Targeted Radionuclide Therapies (TRT) for the treatment of a growing variety of cancers such as neuroendocrine tumors, prostate cancer or bone metastases. N.c.a. Lutetium-177 provides the highest specific activity and an unrivalled level of radionuclidic purity, as it contains no metastable Lutetium-177m impurities.* This is especially important in an increasing number of countries and regions that are subject to strict radiation protection regulations with a release limit of Lutetium-177m into the environment. In such places, the radioisotope form containing Lutetium-177m can, in most cases, not be used. On August 21, new regulations by the Environmental Protection Agency (EPA) for the disposal of hazardous drugs by healthcare institutions, providers and pharmacies came into force in the United States. According to these

new rules, flushing hazardous waste pharmaceuticals into the sewage system is prohibited by law.

The installation of the irradiation equipment at Bruce Power, by Framatome and Kinectrics, will be consistent with ITM's specifications and is currently planned for late-2021. Bruce Power will provide the infrastructure and be responsible for the irradiation as it currently does with Cobalt. ITM will deliver Ytterbium-176 targets to the irradiation site, while Framatome and Kinectrics will be responsible for handling and preparing the Ytterbium-176 targets according to ITM requirements.

- Ends -

About n.c.a. Lutetium-177

No-carrier-added (n.c.a) Lutetium-177 is used in Targeted Radionuclide Therapy for cancer treatment. It is a radiopharmaceutical precursor, used for radiolabeling of disease-specific carrier molecules. N.c.a. Lutetium-177 exhibits high radionuclidic purity, with no metastable Lu-177m, thus, there is no need for storage or disposal of long-lived radioactive waste. N.c.a. Lutetium-177 is GMP certified and has marketing authorization by the European Medicines Agency under the name: EndolucinBeta®.

About Targeted Radionuclide Therapy

Targeted Radionuclide Therapy (TRT) is a medical specialty where small amounts of radioactive compounds, called radiopharmaceuticals, are used to treat diseases such as cancer. TRT uses a medical isotope bound to a targeting molecule to selectively deliver ionizing radiation to the site of disease while sparing healthy tissue and minimizing negative side effects. TRT is often combined with diagnostic imaging through use of a Theranostic facilitating the application of personalized medicine in the field of precision oncology.

About ITM

ITM Isotopen Technologien München AG is a privately held biotechnology and radiopharmaceutical group of companies dedicated to the development, production and global supply of targeted diagnostic and therapeutic radiopharmaceuticals and radionuclides for use in cancer treatment. Since its foundation in 2004, ITM and its subsidiaries have established GMP manufacturing and a robust global supply network of a novel, first-in-class medical radionuclides and generator platform for a new generation of targeted cancer diagnostics and therapies. Furthermore, ITM is developing a proprietary portfolio and growing pipeline of targeted treatments in various stages of clinical development, which address a range of cancers such as neuroendocrine cancers and bone metastases. ITM's main objectives, together with its scientific, medical and industrial collaboration partners worldwide, are to significantly improve outcomes and quality of life for cancer patients while at the same time reducing side effects and improving health economics through a new generation of Targeted Radionuclide Therapies in Precision Oncology. For more information please visit: www.itm.ag

About Bruce Power

Formed in 2001, Bruce Power is an electricity company based in Bruce County, Ontario. We are powered by our people. Our 4,200 employees are the foundation of our accomplishments and are proud of the role they play in safely delivering clean, reliable, low-cost nuclear power to families and businesses across the province. Bruce Power is also a significant source of Cobalt-60, a radioisotope used for the sterilization of medical equipment around the world as well as a specialized form of cancer treatment called the Gamma Knife.

Bruce Power is also part of the newly-established Canadian Nuclear Isotope Council (CNIC), which will ensure Canada remains a world leader in the production of life-saving radioisotopes by raising awareness and supporting long-term policies at the domestic and international level. Over 30 leading organizations from Canada and around the world have joined the council, which will develop collective solutions to maintain Canada's leadership position on the global isotope stage. Learn more at www.brucepower.com and follow us on [Facebook](#), [Twitter](#), [LinkedIn](#), [Instagram](#) and [YouTube](#).

About Framatome

Framatome is a major international player in the nuclear energy market recognized for its innovative solutions and value-added technologies for designing, building, maintaining, and advancing the global nuclear fleet. The company designs, manufactures and installs components, fuel and instrumentation and control systems for nuclear power plants and offers a full range of reactor services. With 14,000 employees worldwide, every day Framatome's expertise helps its customers improve the safety and performance of their nuclear plants and achieve their economic and societal goals. Join the energy conversation with Framatome on Twitter: [@Framatome](#), Facebook: [@FramatomeUS](#) and LinkedIn: [@Framatome](#).

About Kinectrics

Kinectrics is the category leader in providing life cycle management services for the electricity industry. Trusted by clients worldwide, our expertise in engineering, testing, inspection, and certification is backed by our independent laboratory and testing facilities, a diverse fleet of field inspection equipment and an award-winning team of over 1,000 engineers and technical experts. From initial design and type testing to operational deployment and maintenance services, Kinectrics collaborates closely with customers to ensure that utility assets perform safely, reliably and efficiently throughout their entire life cycle. Learn more at www.kinectrics.com and follow us on [LinkedIn](#), [Twitter](#), and [YouTube](#).

ITM Contact:

Nicola Scharrer
Head of Marketing
Phone: +49 89 3298986-151
Email: Nicola.Scharrer@itm.ag

Bruce Power Duty Media:

519-361-6161
BNPDdutymedia@brucepower.com

Reference

* Lebedev, N. A. et al. (2000) Radiochemical separation of no-carrier-added ^{177}Lu as produced via the $^{176}\text{Yb}(n,\gamma)^{177}\text{Yb} \rightarrow ^{177}\text{Lu}$ process. *Applied Radiation and Isotopes* 53: 421-425.