



IRE Elit and Isologic announce the approval of the Gallium-68 generator, Galli Eo[®], as a drug in Canada

December 5th, 2019 - Fleurus, Belgium & Montreal, Canada: IRE ELIT, Belgian radiopharmaceutical company, has just received the Notice of Compliance (NOC) from Health Canada for its drug Galli Eo, the generator of Germanium/Gallium-68; which until now had a type II Drug Master File.

Very good news for ISOLOGIC, a Canadian company dedicated to nuclear medicine, partner of IRE Elit and **exclusive distributor of Galli Eo[®] in Canada**, which will be able to meet the growing demand for Ga-68 tests for patients.

Galli Eo[®] is approved in Canada for **in vitro radiolabeling of radiopharmaceuticals ligands for diagnostic procedures using positron emission tomography (PET) and represents a major advance for specialists in nuclear medicine and functional molecular medical imaging.** Already authorized since 2018 in 13 European countries (Galli Ad[®]) and in the United States (Galli Eo[®]), the Germanium-68/Gallium-68 generator provides easy and flexible access for radiopharmacies and nuclear medicine services.

The gallium-68 is used in particular for the labelling of molecular vectors used in the diagnosis of **neuroendocrine cancers**, which are particularly difficult to detect early. It is also used for the clinical development of other molecular vectors in **the diagnosis of prostate cancer (recurrent forms)**, the most common cancer in men.

IRE ELIT has developed a new generation of generator that meets user demands for ease of use, operator safety and cost savings for radiopharmacies.

Jean Bonnet, Strategy Director at IRE ELIT commented: *"We are proud to strengthen our global footprint by bringing our Germanium-68/Gallium-68 generator to Canada, the result of our research, entirely developed and produced in Fleurus. Thanks to Isologic, our trusted partner in Canada, this authorization will allow wide access to Gallium-68 for the benefit of patients."*

"ISOLOGIC is proud to be part of this important news whereas physician will now have easy access to this new breakthrough technology to assist them in the diagnosis and treatment of patient with different life-threatening ailments. The approval of Galli Eo[™] 68Ge/ 68Ga generator is an important advancement and is the logical outcome to our investment in the field" said André Gagnon, President of ISOLOGIC.

About IRE ELIT

IRE ELIT is a radiopharmaceutical company and the innovation subsidiary of the IRE founded in 2010, with the support of SFPI (Société Fédérale de Participation et d'Investissement) to fully develop radiopharmaceuticals used in molecular imaging and therapy. In 2018, IRE ELIT devoted 18% of its turnover to R&D, a percentage that has been constantly increasing since the company was founded. The IRE and IRE ELIT currently employ 230 people. More information on www.ire.eu

About ISOLOGIC

Isologic Innovative Radiopharmaceuticals (ISOLOGIC) is a Canadian company dedicated to nuclear medicine and the science of radiopharmaceutical production. ISOLOGIC's commitment in these areas includes cyclotron centers, SPECT and PET radiopharmaceutical manufacturing facilities across Canada. We use our increased experience, expertise and radiopharmaceutical network to provide our customers and patients reliable, safe and high quality radiopharmaceutical products and services. ISOLOGIC's radiopharmaceutical drug and medical device offers flexibility of choice, providing its clients with access to all radiopharmaceuticals that have Health Canada's market authorization.

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