

## **IRE Elit files marketing authorisation (MAA) application for Galli Eo™**

**Fleurus, Belgium November 2th, 2016** - IRE Elit, the IRE subsidiary specialised in the production of radiopharmaceuticals, is pleased to announce the filing of a marketing authorisation (MAA) application with the European Medicines Agency (EMA) for the *Galli Eo™*, a radiopharmaceutical <sup>68</sup>Germanium/<sup>68</sup>Gallium generator that constitutes major progress in the availability and routine use of Gallium-68 by nuclear medicine centres.

This application is the culmination of a major effort made by the company to propose a new generation Gallium-68 generator which, thanks to its innovative design, facilitates the use of Gallium-68 in PET imaging, in full compliance with nuclear and pharmaceutical safety standards, for the benefit of patients and users.

This next-generation generator not only enables cost optimisation, but also innovates by providing health professionals with greater ease of use. This innovation will contribute to the development of personalised medicine.

*"This innovation marks a major stage in the development of IRE Elit and the awarding of an MAA will open up new markets and excellent growth prospects for us,"* said Jean-Michel Vanderhofstadt, CEO – General Manager IRE – IRE ELiT

*Galli Eo™* is currently used in the preclinical stages in European university hospitals with which the IRE-ELiT works very closely, and also benefits from the status as a Medicine for Clinical Trials for research centres. The generator is already registered as an API outside Europe and was acclaimed by the **EANM** (European Association of Nuclear Medicine) **Congress**, held recently in Barcelona from 15 to 19 October. It will also be presented internationally during **Theranostics Congress** dedicated to Gallium-68, in Melbourne from 7-9 November 2016.

### About MN:

Nuclear Medicine was introduced shortly after radioactivity was discovered. After 50 years of experience and practice, today Nuclear Medicine plays a key role in the evolution of medicine concerning both diagnostic and therapeutic techniques.

### About 68 Ge /Ga 68 generator:

Germanium-68/Gallium-68 Generator is a device used to extract the positron-emitting isotope <sup>68</sup>Ga of Gallium from a source of decaying Germanium-68 used for diagnostic procedures. Its major application domain is oncology, where development and availability of new <sup>68</sup>Ga-agents, like prostate-specific membrane antigen (PSMA) for prostate cancer detection, have increased drastically during last years.

### **About IRE – IRE ELiT**

IRE or the Institute of Radioelements is a non-profit foundation, whose main activity is the production of radio-isotopes for diagnostic and therapeutic applications in the field of nuclear medicine. These products are the active agents in many radiopharmaceutical

medicines. IRE ELiT, an IRE subsidiary, produces several radiopharmaceutical derivatives used in the treatment of certain cancers and palliative care. IRE ELiT, in addition to its production activities, contributes to the protection of the environment via its services for measurement of radioactivity in various samples, the radiological characterisation of waste and contaminated elements, consultancy and technical assistance projects in the radiological and nuclear fields, and the dismantling of sealed radioactive sources. Each year, over 6 million nuclear medicine examinations are carried out using medical radio-isotopes produced by IRE.

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