



Fleurus, May 17, 2018

Cancer imaging: The submitted file of IRE ELiT's $^{68}\text{Ge}/^{68}\text{Ga}$ generator has been accepted in 13 European countries

- The young Belgian biotechnology company IRE ELiT, a subsidiary of IRE (Institute for Radioelements), has just taken a key step towards the conquest of the radiopharmaceuticals market.
- IRE ELiT's radiopharmaceutical new generation, $^{68}\text{Ge}/^{68}\text{Ga}$ generator, developed entirely in Fleurus (Belgium), has been accepted by RMS^[1] and all CMS^[2] of 13 European countries. The commercialization will be allowed for the first of these 13 countries within the next one to two months.
- This generator opens up significant possibilities in the diagnosis of neuroendocrine cancers and of recurrent forms of prostate cancer.

On May 9th, IRE ELiT, a subsidiary and innovation hub of IRE (Institute for Radioelements), received the acceptance of RMS and all CMS for its radiopharmaceutical Germanium-68/Gallium-68 generator which represents a major breakthrough in the world of nuclear medicine and medical imaging.

Gallium-68 is the isotope which, when accompanied by a cold vector, is used in oncology for the diagnosis of neuroendocrine cancers, particularly difficult to detect at the early stage. It is also used in clinical development of highly specific diagnostic agents such as for the diagnosis of prostate cancer (recurrent forms), the most common cancer in men.

Nuclear medicine uses the properties of the radiation emitted by a radioactive isotope for diagnostic and therapeutic purposes. In oncology, radiopharmaceutical diagnoses can determine the number and aggressiveness of tumours and metastases. Today, radiopharmaceutical diagnosis accompanied by their therapeutic counterpart open a new era in the field of personalised medicine (theranostic: "the right treatment for the right patient").

Five years of research and development

Five years ago, IRE ELiT launched the project to develop a next generation generator. There were four generators on the market at the time, and users' expectations were not being fully met, in particular in terms of ease of use.

^[1] RMS = Reference Member State

^[2] CMS = Concerned Member States

After five years of research and development, IRE ELiT developed a generator that responds to these demands, with due regard for operator safety and for the cost to the hospital.

Erich Kollegger, CEO of IRE and IRE ELiT: *“Our Germanium-68/Gallium-68 generator enables simplified and reliable usage while optimising costs for hospitals. Our goal is to offer innovative solutions to meet patients’ needs regarding cancer diagnosis and treatment.”*

Michel Baijot, Board Director IRE ELiT: *“We are proud to be able to offer to the market our Germanium-68/Gallium-68 generator, the result of our research, entirely developed and produced in Fleurus. This radiopharmaceutical product is destined for a great future. This acceptance will accelerate the growth of IRE ELiT on the main markets, based on partnerships for sales and marketing activities, such as the one already in place with Cardinal Health in the USA or those in place on the European markets. The goal is to have as wide access as possible for the benefit of patients.”*

About IRE ELiT

IRE ELiT, founded by the Institute for Radioelements (Fleurus) in 2010 to develop new diagnostic and therapeutic applications in the area of radiopharmaceuticals, is the IRE’s innovation subsidiary.

In 2017, IRE ELiT allocated 16.2% of its turnover to R&D, a percentage which has constantly increased since the company’s creation. In 2017 and this year, in 2018, several million euros have been and will be invested to support its production capacity, which it plans to double and then quadruple.

IRE ELiT employed over 40 people at the end of 2017.

Further information at www.ire.eu

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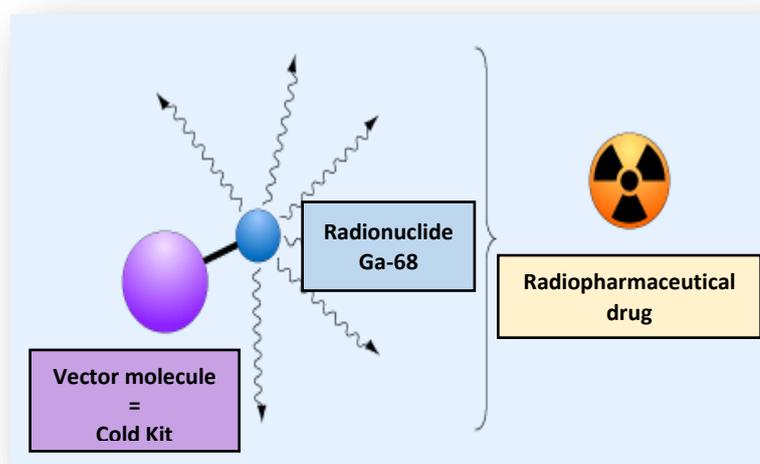
Technical information sheet

The indication for which Germanium-68/Gallium-68 generator has been accepted is the following:

The eluate (Gallium chloride (^{68}Ga) solution) is used for the in vitro radiolabelling of specific vector molecules that have been specifically developed and authorised for radiolabelling with this radionuclide for positron emission tomography (PET) diagnostic imaging.

The Germanium-68/Gallium-68 generator facilitates the routine use of Gallium-68 for PET imaging in radiopharmacy.

A radiopharmaceutical product consists of a radionuclide, a radioactive element called a “hot” tracer, and a “cold” (non-radioactive) vector molecule called a vector. The vector molecule can be provided in the form of “cold kits” and will then be combined with the appropriate quantity of Gallium-68 from the generator before being injected into the patient to carry out the examination.



The innovation of the Germanium-68/Gallium-68 generator is having been specifically designed, due to its technical properties, to be combined with cold kits in order to get closer to the best practice in nuclear medicine using Technetium-99 generators (another diagnostic radionuclide used very easily with cold kits for SPECT imaging).

This innovation is based on three unique aspects:

1. An innovative elution mechanism delivering a very small and always fixed amount of eluate: 1.1 ml of a Gallium (^{68}Ga) chloride solution for radiolabelling (European Pharmacopoeia).
2. A unique chromatographic column: dry, on which the Germanium-68 (^{68}Ge) is adsorbed.
3. A ready-to-use system integrating the eluent pouch which is pre-connected to the inside of the generator.

These characteristics make it possible, among other things, to:

- Simplify and reduce the steps for the preparation of radiopharmaceuticals;

- Ensure their reproducibility and maintain their specifications throughout the lifetime of the generator;
- Ensure operator safety;
- Enable hospitals to control costs.

For further information on Germanium-68/Gallium-68 generator please consult the SmPC (Summary of Product Characteristics) of the product available on our website www.ire.eu
