



IRE ELiT and ROTOP Pharmaka enter into a distribution partnership in Germany for ^{68}Ge Germanium / ^{68}Ga Gallium generator

Fleurus (Belgium), Dresden (Germany)– 6th January 2021. IRE ELiT and ROTOP Pharmaka, two innovative radiopharmaceuticals companies focused on diagnostics and therapeutics announce today they have entered into an exclusive commercial agreement for the distribution of Galli Ad (the $^{68}\text{Ge}/^{68}\text{Ga}$ generator from IRE ELiT) in Germany.

This strategic decision is an important step to increase the presence of Galli Ad generators in Germany, representing the leading market in Europe for Gallium-68 development.

The switch over from distributorship will be effective early 2021, with total continuity of supply and support to our current customers. The practical modalities will be communicated to them soon.

Erich Kollegger CEO of IRE ELiT stated *“We believe that there is a real and mutual interest for IRE ELiT and ROTOP to partner. The combination of our expertise and the reputation of ROTOP will work for the benefit of the patients and nuclear medicine professionals. This partnership will strengthen our position on the European market and contribute to the global development of this essential radiopharmaceutical.”*

Jens Junker Managing Partner at ROTOP Pharmaka stated *“We are proud to enter into the partnership with IRE ELiT, one of the leading European radiopharmaceutical companies, which is driving innovation for the benefit of patients and nuclear medicine. With the Galli Ad generators ROTOP enhances its portfolio of radiopharmaceuticals in Germany and continues the strategy of offering a wide range of radiopharmaceuticals.”*

About Galli Ad ® generator

Galli Ad is a $^{68}\text{Ge}/^{68}\text{Ga}$ generator, approved in Europe for the in vitro radiolabeling of specific vector molecules that have been specifically developed and authorized for radiolabeling with this radionuclide for positron emission tomography (PET) diagnostic imaging.

The innovation of the Galli Ad 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-99m generators (another diagnostic radionuclide used very easily with cold kits for SPECT imaging).

This innovation is based on three unique aspects:



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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
2. A unique chromatographic column: dry, on which the $^{68}\text{Germanium}$ (^{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 simplify and reduce the steps for the preparation of radiopharmaceuticals; ensure their reproducibility and contribute to operator safety;

For further information on $^{68}\text{Germanium}/^{68}\text{Gallium}$ generator please consult the SmPC (Summary of Product Characteristics) of the product available on our website www.ire.eu

About IRE ELIT

IRE ELiT is a radiopharmaceutical company and the innovation subsidiary of the IRE founded in 2010, to fully develop radiopharmaceuticals used in molecular imaging and therapy. IRE ELiT works closely with its clients in a «test & learn» spirit as well as with globally recognized universities and research centers. Today, IRE ELiT is one of only two global suppliers of germanium-68 (Ge-68) / gallium-68 (Ga-68) generator to be approved for use as a drug in Europe and as an active pharmaceutical ingredient (API) in the USA. The IRE and IRE ELiT currently employ 250 people. More information on www.ire.eu

About ROTOP Pharmaka

ROTOP Pharmaka is a leading German pharmaceutical company that produces cGMP compliant radiopharmaceuticals for diagnostics and therapy in Nuclear Medicine and Molecular Imaging and distributes them in more than 30 countries worldwide. With more than 20 years of experience in the development, production, authorization and distribution of sterile kits for radiolabeled pharmaceuticals ROTOP continuously expands its product portfolio by developing new products and entering new strategic partnerships. The portfolio includes a GMP Kit production facility, the ROTOP Innovation Center (RIC) with full CRO Services, incl. API and Kit development, the ROTOP Radiopharmacy with I-123 compounds and a worldwide distribution network. More information on www.rotop-pharmaka.de

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