PRESS RELEASE

Global Regulatory Partners Japan Partners with IRE ELiT to Bring ^{68}Ge/^{68}Ga Generator for PET Imaging to Japan

GRP appointed as Japanese Marketing Authorization Holder partner for IRE ELiT's ^{68}Ge/^{68}Ga Generator

Tokyo, Japan — November 17th, 2026 — Global Regulatory Partners GK (GRP Japan) today announced a strategic partnership with IRE ELiT, the radiopharmaceutical innovation subsidiary of Belgium-based IRE Group, to support the registration and future commercialization of IRE ELiT's ^{68}Ge/^{68}Ga Generator in Japan.

Under the partnership, GRP Japan has been officially appointed as the Japanese Marketing Authorization Holder (MAH) partner for the ^{68}Ge/^{68}Ga Generator and will provide the support to launch the generator in Japan.

About the Germanium-68/Gallium-68 (^{68}Ge/^{68}Ga) Generator

IRE ELiT's Germanium-68/Gallium-68 (^{68}Ge/^{68}Ga) Generator is a radiopharmaceutical generator designed to produce Gallium-68 chloride solution for the radiolabelling of suitable carrier molecules, in accordance with the applicable European product information.[1]

Gallium-68-labelled radiopharmaceuticals are used in positron emission tomography (PET) molecular imaging, supporting advances in precision diagnostics and nuclear medicine.

IRE ELiT's Ga-68 generator has been available in Japan for several years through ATOX Co., Ltd., primarily for use in clinical trials and early access programs.

Dr. Suzan Davis, Chief Executive Officer, Global Regulatory Partners GK, said:

> "GRP has proudly supported IRE ELiT as its in-country representative in Japan for the past seven years, and we are delighted to take this longstanding relationship to the next level by officially becoming its Marketing Authorization Holder (MAH) partner.
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> This partnership represents an important milestone in expanding GRP's capabilities in radiopharmaceuticals and nuclear medicine, while reinforcing our commitment to bringing innovative healthcare technologies to patients in Japan.
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> By combining IRE ELiT's expertise in radiopharmaceutical innovation with GRP's established regulatory infrastructure and local capabilities, we look forward to supporting the successful introduction and long-term management of its ^{68}Ge/^{68}Ga Generator in the Japanese market."

Mr. Jean Bonnet, Head of R&D, Strategy and Marketing of IRE Elite said

> “It has been more than 7 years since IRE Elit initiated its generator recording project in Japan. This has allowed us to understand, integrate and above all respect this attitude for which "The path counts more than the destination, and the process counts more than the result
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> Japan is a reference market for nuclear medicine due to the quality of its scientific community and its infrastructure. And IRE Elit is committed to bringing its $^{68}Ge/^{68}Ga$ generator to the Japanese market.
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> It was always obvious that we would do so with the support of a partner who was an expert in local regulatory constraints radiopharmaceuticals, and capable of a credible dialogue with the various authorities involved in importation and registration with a strong local presence.
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> Having stated this, GRP was clearly the partner of choice for this long-term project, and we are pleased with the quality of this collaboration”

NOTES TO EDITORS

About IRE and IRE ELiT

IRE is a public-interest foundation specializing in the production of radioisotopes for diagnostic and therapeutic applications in nuclear medicine. IRE is the world's leading producer of Molybdenum-99 and Iodine-131, two of the most widely used isotopes in nuclear medicine.

Founded in 2010, IRE ELiT is IRE's innovation-focused subsidiary dedicated to the end-to-end development of radiopharmaceutical medicinal products for imaging and cancer treatment. The company's flagship product, the Galli Ad® Gallium-68 Generator, is a leading solution supporting diagnostic and theranostic applications in nuclear medicine worldwide.

IRE and IRE ELiT are also expanding their CDMO capabilities, with new state-of-the-art production lines that will support partners from early-stage development through to commercial manufacturing.

Together, IRE and IRE ELiT employ more than 300 people.

Website : www.ire.eu

About Global Regulatory Partners GK

Global Regulatory Partners GK (GRP Japan) is the Japanese affiliate of Global Regulatory Partners, Inc. and a licensed Marketing Authorization Holder (MAH) headquartered in Tokyo, Japan. Operating in Japan since 2016, GRP Japan supports international pharmaceutical, biotechnology, and healthcare companies in the registration, launch, commercialization, and lifecycle management of products in Japan.

GRP Japan provides integrated regulatory, quality, safety, medical information, supply chain, and commercialization capabilities, serving as a bridge between global healthcare innovation and the Japanese market. GRP’s mission is to accelerate access to innovative healthcare products and technologies for patients in Japan.

Reference

1. IRE ELiT. $^{68}Ge/^{68}Ga$ 1.85 GBq radionuclide generator — Summary of Product Characteristics (SmPC). European product information.

Regulatory Notice

The $^{68}Ge/^{68}Ga$ Generator described in this press release is not currently approved for marketing in Japan. Product information presented in this release is based on European product information and is provided for informational purposes only.