



Cardinal Health™ Nuclear & Precision Health Solutions and IRE ELiT support the growing demand for Ga-68 labeled radiopharmaceuticals

IRE ELiT submitted Drug Master File (DMF) to the U.S. Food and Drug Administration (FDA) for the 100 mCi Ge68/Ga68 Galli Eo® generator.

DUBLIN, OHIO and FLEURUS, BELGIUM – AUGUST 26, 2021 – Cardinal Health (NYSE: CAH) and IRE ELiT (the radiopharmaceutical subsidiary of IRE Group) are working to expand patient access to novel radiopharmaceuticals for Positron Emission Tomography (PET) imaging as demand in the United States (U.S.) continues to grow. Cardinal Health is the preferred U.S. distributor of the IRE ELiT 100 mCi Germanium-68/Gallium-68 radionuclide generator (Ge-68/Ga-68 Galli Eo® generator) in support of clinical investigational trials, pre-commercial research and post-approval commercial sales in the U.S. and its territories, including Puerto Rico.

Designed for the on-site preparation of Ga-68 radiolabeled pharmaceuticals, IRE ELiT modified its Ge-68/Ga-68 Galli Eo® generator to double its activity from 50 mCi to 100 mCi. This activity enhancement will enable the Nuclear & Precision Health Solutions business of Cardinal Health to increase preparation of Ga-68 radiolabeled pharmaceuticals, which are approved and under investigation for many cancers.

The new, higher-activity 100 mCi generator provides users with more flexibility by increasing the number of daily elutions and the activity in each elution, ultimately increasing the number of patients that can be served. “As a leading U.S. provider of Ga-68 radiopharmaceuticals, Cardinal Health commends IRE ELiT for their efforts to increase the activity of Ge-68/Ga-68 Galli Eo® generators,” said Mike Pintek, president of Cardinal Health™ Nuclear & Precision Health Solutions. “Ultimately, this will allow us to better supply medical providers, and their patients, with current and future novel Ga-68 diagnostics.”

“Increasing the activity of our Galli Eo® generator is a critical part of our plan to meet the exponential demand for Ga-68 radiolabeled pharmaceuticals in the U.S.,” said Erich Kollegger, chief executive officer of IRE ELiT. “Combining the expertise of our R&D department with the experience of our production team, IRE ELiT is prepared to produce and supply Cardinal Health with these high-activity generators.”

While the activity of the Ge-68/Ga-68 Galli Eo® generator has increased, the footprint of each unit will remain the same to ensure Cardinal Health can seamlessly transition to the new 100 mCi Ge-68/Ga-68 Galli Eo® generators without impact to the pharmacy.

Cardinal Health currently has the majority of its more than 130 nuclear pharmacies licensed for Gallium-68 and plans to license them all to expand patient access to PET imaging.

About Cardinal Health

Cardinal Health is a distributor of pharmaceuticals, a global manufacturer and distributor of medical and laboratory products, and a provider of performance and data solutions for health care facilities. With 50 years in business, operations in more than 35 countries and approximately 44,000 employees globally, Cardinal Health is essential to care. Information about Cardinal Health is available at cardinalhealth.com.

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About IRE ELiT

IRE ELiT, the innovation subsidiary of the IRE, is a radiopharmaceutical company 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) generators approved for use as a drug in Europe and as an active pharmaceutical ingredient (API) in the U.S. IRE and IRE ELiT currently employ 250 people. More information is available at www.ire.eu.

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