GE Healthcare announces first patient dosed in phase III clinical trial for new dopamine transporter imaging radiopharmaceutical

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- *First patient dosed in Phase III clinical trial for PET radiopharmaceutical*
- *Next stage clinical study also proceeding for SPECT radiopharmaceutical*
- *Both imaging agents aim to assist in the evaluation of adult patients with suspected Parkinsonian syndromes, support research and improve patient care*
- *Builds on market leadership with SPECT agent DaTscan™ (Ioflupane I 123 Injection), to offer increased choice for nuclear medicine community*

Marlborough, US — 28March 2022: GE Healthcare has today announced the first patient dosed in the Phase III clinical trial for a Positron Emission Tomography (PET) radiopharmaceutical imaging agent which aims to assist in the evaluation of adult patients with suspected Parkinsonian syndromes, support research and improve patient care. Already a global leader with DaTscan ([123I]-ioflupane), used in Single-Photon Emission Computed Tomography (SPECT) imaging across more than 40 countries worldwide, GE Healthcare is now planning to bolster its portfolio with two pipeline radiopharmaceuticals, one for PET and one for SPECT.

The multi-center Phase III clinical trial of a PET radiopharmaceutical is underway in France. In addition to offering a potentially shorter patient workflow, the clinical trial is comparing PET for striatal dopamine transporter visualization with DaTscan. PET technology offers higher spatial resolution than SPECT, which may result in a clearer image to aid visual interpretation and diagnosis. This PET radiopharmaceutical was originally developed by Zionexa, a French company specializing in innovative radiopharmaceuticals which was acquired by GE Healthcare's Pharmaceutical Diagnostics business last year.

Speaking about the clinical trial, Professor Olivier Rascol, Professor of Clinical Pharmacology at Toulouse University Hospital, said: "We are excited to conduct this multi-center Phase III study which represents a significant milestone in the development of this radiopharmaceutical. Having a PET option for dopamine transporter imaging in patients with Parkinsonian syndromes could be highly relevant for an early differential diagnosis."

A next stage clinical study for a SPECT dopamine transporter imaging agent will also be underway this year in the United States. Licensed from Boston-based brain imaging specialist, LikeMinds, it has the potential to reduce overall procedure time, to optimize imaging center workflow and help improve patient comfort. GE Healthcare has obtained exclusive global rights to the product.

Dr John Seibyl, Board Chairman and Distinguished Scientist, Institute for Neurodegenerative Disorders, New Haven, Connecticut, said: "This new SPECT agent may offer a faster imaging workflow which could provide more convenience for patients with suspected Parkinsonian syndromes and greater efficiency for the imaging clinic. It also holds promise in potentially making dopamine transporter imaging more accessible if approved."

2021 marked ten years for GE Healthcare's DaTscan in the U.S., used across the neurology community to aid clinical differentiation between conditions with nigrostriatal dopaminergic neurodegeneration, such as Parkinson's disease, and those without, such as Essential Tremor. Imaging with DaTscan occurs between three and six hours after radiotracer injection.

Julia Casey, Molecular Imaging General Manager for GE Healthcare Pharmaceutical Diagnostics, said: "More than one million doses of DaTscan have already been used around the world in the clinical evaluation of Parkinsonian syndromes. Building on our leadership in this space, and to complement DaTscan, we are aiming to offer our customers, in both clinical and research settings, a wider choice of diagnostic tracers across PET and SPECT to suit all needs. We continue to invest in products that enable precision health and may help improve clinical outcomes."

Globally, the number of people with Parkinson's disease is estimated to double from 6.9 million in 2015 to 14.2 million in 2040 [1]. Early and accurate diagnosis helps patients, their families and care givers to identify appropriate resources and support as well as plan for the future and access treatment.

GE Healthcare's Pharmaceutical Diagnostics unit is a global leader in imaging agents used to support around 100 million procedures per year globally, equivalent to three patients every second.

[1] The Parkinson Pandemic – A Call to Action

E. Ray Dorsey, MD1; Bastiaan R. Bloem, MD, PhD2

JAMA Neurol. 2018;75(1):9-10. doi:10.1001/jamaneurol.2017.3299

IMPORTANT SAFETY INFORMATION FOR DATSCAN (IOFLUPANE I 123 INJECTION)

CONTRAINDICATIONS

- DaTscan is contraindicated in patients with known hypersensitivity to the active substance, any of the excipients, or iodine

WARNINGS AND PRECAUTIONS

- **Hypersensitivity Reactions**: Hypersensitivity reactions, generally consisting of skin erythema and pruritus, have been reported following DaTscan administration

  Thyroid Accumulation: The DaTscan injection may contain up to 6% of free iodide (iodine 123 or I-123). To decrease thyroid accumulation of I-123, block the thyroid gland at least one hour before administration of DaTscan; failure to do so may increase the long-term risk for thyroid neoplasia

ADVERSE REACTIONS

- In clinical trials, headache, nausea, vertigo, dry mouth, or dizziness of mild to moderate severity were reported. In postmarketing experience, hypersensitivity reactions and injection-site pain have been reported

DRUG INTERACTIONS

- Drugs that bind to the dopamine transporter with high affinity may interfere with the DaTscan image. The impact of dopamine agonists and antagonists on DaTscan imaging results has not been established

USE IN SPECIFIC POPULATIONS

- **Pregnancy**: Radioactive iodine products cross the placenta and can permanently impair fetal thyroid function. Administration of a thyroid blocking agent is recommended before the use of DaTscan in a pregnant woman. All radiopharmaceuticals have potential to cause fetal harm. There are no available data on DaTscan use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. Advise pregnant woman of the potential risks of fetal exposure to radiation with the administration of DaTscan

  Lactation: Iodine 123 (I 123), the radionuclide in DaTscan, is present in human milk. There is no information on the effects on breastfed infants or on milk. Advise a lactating woman to interrupt breastfeeding and pump and discard breast milk for at least 6 days after DaTscan administration to minimize radiation exposure to a breastfeeding infant

  Pediatric Use: The safety and efficacy of DaTscan have not been established in pediatric patients

  Geriatric Use: There were no differences in responses between elderly patients and younger patients that would require a dose adjustment

  Renal and Hepatic Impairment: The effect of renal or hepatic impairment on DaTscan imaging has not been established. The kidney excretes DaTscan; patients with severe renal impairment may have increased radiation exposure and altered DaTscan images

OVERDOSAGE

- It is unknown whether or not ioflupane is dialyzable. The major risks of overdosage relate to increased radiation exposure and long-term risk for neoplasia. In case of radioactivity overdosage, frequent urination and defecation should be encouraged to minimize radiation exposure to the patient

PROCEDURE — Radiation Safety

- DaTscan emits radiation and must be handled with safety measures to minimize radiation exposure to clinical personnel and patients

Prior to DaTscan administration, please read the full Prescribing Information for additional Important Safety Information.

To report SUSPECTED ADVERSE REACTIONS, contact GE Healthcare at 800 654 0118 (option 2, then option 1) or the FDA at 800 FDA 1088 or www.fda.gov/medwatch.

About GE Healthcare:

GE Healthcare is the $17.7 billion* healthcare business of GE (NYSE: GE). As a leading global medical technology, pharmaceutical diagnostics and digital solutions innovator, GE Healthcare enables clinicians to make faster, more informed decisions through intelligent devices, data analytics, applications and services, supported by its Edison intelligence platform. With over 100 years of healthcare industry experience and around 47,000 employees globally, the company operates at the center of an ecosystem working toward precision health, digitizing healthcare, helping drive

productivity and improve outcomes for patients, providers, health systems and researchers around the world.

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Media Contact:

Debbie Leven

Debbie.Leven@ge.com

+44 7785 456999