DATSCAN™ (Ioflupane I 123 Injection) indication expanded to include use in patients with suspected Dementia with Lewy Bodies (DLB)

November 3, 2022

- DaTscan is first radiopharmaceutical diagnostic tracer approved by U.S. FDA for use in patients with suspected Dementia with Lewy Bodies (DLB)
- Builds on DaTscan market leadership globally with over one million doses already used around the world in the clinical evaluation of Parkinsonian syndromes
- One in five patients with dementia suffers from DLB, the second most common form of degenerative dementia after Alzheimer's Disease [i]

Marlborough, MA, US – 3rd November 2022: GE Healthcare's DaTscan has been approved by the U.S. Food and Drug Administration (FDA) for use in patients with suspected Dementia with Lewy Bodies (DLB). This new indication is in addition to its use with single photon emission computed tomography (SPECT) imaging to visualize dopamine transporters (DaT) in the brains of adult patients with suspected Parkinsonian syndromes. With the expanded indication, DaTscan is now available to more patients, including those with suspected DLB, in the United States.

The clinical signs and symptoms of DLB can be atypical and overlap with other forms of dementia, leading to up to 70% of patients with DLB being misdiagnosed, often as having Alzheimer's Disease [ii]. This new indication enables clinicians to use DaTscan to help differentiate DLB from other forms of dementia. Early and accurate diagnosis of DLB can help ensure specific appropriate treatment and specialized care for patients, while enabling them and their caregivers to more effectively manage the disease and plan for the future[iii].

Approximately one in five patients with dementia suffers from DLB, making it the second most common form of degenerative dementia after Alzheimer's Disease [i].

Professor James E. Galvin, MD, MPH, Consultant, University of Miami Miller School of Medicine, U.S., said: "Misdiagnosis is a significant issue for those patients with suspected Dementia with Lewy Bodies, causing untold anxiety for the patient and family as well as potentially placing the patient at higher risk of adverse events due to delayed diagnosis. The label expansion for DaTscan moves patients a step closer to an earlier, more accurate, diagnosis which is beneficial for them and their families, setting them on the right treatment path sooner and helping to avoid medications and treatments that could be potentially harmful."

Mark Hibberd, Chief Medical Officer 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. We have built on our scientific and medical leadership with DaTscan to pave the path for this new indication, that supports our customers and their patients with more accurate diagnoses of DLB."

The approval of the use of DaTscan in DLB is the culmination of significant work, including clinical trials, compilation and analysis of data and collating evidence for submission to the U.S. FDA, all demonstrating GE Healthcare's continued commitment and investment in this space.

Earlier this year, GE Healthcare announced plans to bolster its Molecular Imaging neurology portfolio by complementing DaTscan with two pipeline radiopharmaceuticals, one for Positron Emission Tomography (PET) and another for SPECT, aiming to offer customers, in both clinical and research settings, a wider choice of diagnostic tracers to help evaluate adult patients with suspected Parkinsonian syndromes.

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 patient procedures every second. Its Molecular Imaging portfolio combines established proprietary products across cardiology, neurology and oncology, with an innovative pipeline, all aimed at enabling better diagnosis and monitoring for improved therapy decision-making and clinical outcomes.

References:

[i] Barker, Warren W et al. "Relative frequencies of Alzheimer disease, Lewy body, vascular and frontotemporal dementia, and hippocampal sclerosis in the State of Florida Brain Bank." Alzheimer disease and associated disorders vol. 16,4 (2002): 203-12. doi:10.1097/00002093-200210000-00001

[ii] Warr et al. Q J Nucl Med Mol Imaging; 2012; 56: 39-54

[iii] Zweig and Galvin Alzheimer's Research & Therapy 2014, 6.21; http://alzres.com/content/6/2/21

Product Indications and Important Safety Information – DaTscan

PRODUCT INDICATION AND USE

DATSCAN is indicated as an adjunct to other diagnostic evaluations for striatal dopamine transporter visualization using single photon emission computed tomography (SPECT) brain imaging in adult patients with:

- suspected Parkinsonian syndromes (PS) or
- suspected dementia with Lewy bodies (DLB).

Important Safety Information About DaTscan™ (ioflupane I 123 injection)

CONTRAINDICATIONS

• DaTscan is contraindicated in patients with known serious hypersensitivity to ioflupane I 123.

WARNINGS AND PRECAUTIONS

• **Hypersensitivity Reactions:** Hypersensitivity reactions, including dyspnea, edema, rash, erythema, and pruritus, have been reported following DATSCAN administration.

• **Thyroid Accumulation:** DaTscan may contain up to 6% of free iodide (iodine-123). Thyroid uptake of iodine-123 may result in an increased long-term risk for thyroid neoplasia. To decrease thyroid accumulation of iodine-123, block the thyroid gland before administration of DaTscan.

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 observed in the parkinsonian syndrome studies.

• **Renal Impairment:** DaTscan is excreted by the kidney and patients with severe renal impairment may have increased radiation exposure and altered DaTscan images

OVERDOSAGE

• The risks of overdose relate predominantly to increased radiation exposure, with the long-term risks for neoplasia. In case of overdosage of radioactivity, 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 DaTscan

DaTscan is a radiopharmaceutical imaging agent that works by binding to dopamine transporters (DaT) in the brain. A specific marker for DaT, DaTscan produces images that provide visual evidence based on the density of dopamine transporters.

DaTscan was the first FDA-approved radiopharmaceutical adjunct imaging agent to help physicians evaluate patients with suspected Parkinsonian syndromes (PS), such as Parkinson's disease (PD).

DaTscan has been available in the US since 2011 and has been used in more than 1 million patients in 40 countries.

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 48,000 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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