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Curium Announces New Indication for Ioflupane I 123 Injection in the U.S.

(St. Louis, MO – November 22, 2022) – Curium, the world's leading nuclear medicine company, announced today that it intends to submit updated labeling to the U.S. Food and Drug Administration (FDA) for its generic version of DaTscan™ (Ioflupane I 123 Injection) to include a new indication and updated safety information. The additional indication will be to assist in the evaluation of adult patients for striatal dopamine transporter visualization using single photon emission computed tomography (SPECT) brain imaging with suspected dementia with Lewy bodies (DLB). Curium intends to match the labeling recently approved by the FDA for GE Healthcare's DaTscan on November 3, 2022 as generic drugs are required to have the same labeling as the reference listed drug (DaTscan). Curium will update Ioflupane I 123 Injection important risk information to include the new safety information at the time of labeling implementation. Ioflupane I 123 Injection is a SPECT brain imaging agent used to assist in the evaluation of adult patients with suspected Parkinsonian syndromes.

Approximately one in five patients with dementia suffers from DLB, making it the second most common form of degenerative dementia after Alzheimer's Disease[1]. 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[2]. The expected new indication enables clinicians to use Ioflupane I 123 Injection 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[3].

Ed Porter, North American Vice President of Regulatory and Medical at Curium commented: "Ioflupane I 123 Injection continues to be an important tool when evaluating the complex set of diseases considered Parkinsonian syndromes. Curium has years of experience in this disease state as our Ioflupane I 123 Injection product in Europe launched with this indication. We intend to leverage that experience in the US to continue our efforts on making an everyday impact on patients and their families."

DaTscan™ is a registered trademark of GE Healthcare Limited.

References:

[1] 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

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

[3] Zweig and Galvin Alzheimer's Research & Therapy 2014, 6.21; https://alzres.biomedcentral.com/articles/10.1186/alzrt251

About Ioflupane I 123 Injection

INDICATIONS AND USAGE

Ioflupane I 123 Injection is a radiopharmaceutical indicated for striatal dopamine transporter visualization using

single photon emission computed tomography (SPECT) brain imaging to assist in the evaluation of adult patients with suspected Parkinsonian syndromes (PS). In these patients, Ioflupane I 123 Injection may be used to help differentiate essential tremor from tremor due to PS (idiopathic Parkinson's disease, multiple system atrophy and progressive supranuclear palsy). Ioflupane I 123 Injection is an adjunct to other diagnostic evaluations.

Ioflupane I 123 Injection was not designed to distinguish among PD, MSA, and PSP. The effectiveness of Ioflupane I 123 Injection as a screening or confirmatory test and for monitoring disease progression or response to therapy has not been established.

IMPORTANT RISK INFORMATION

Contraindications

- Ioflupane I 123 Injection 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 Ioflupane I 123 Injection administration
- **Thyroid Accumulation**: The Ioflupane I 123 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 Ioflupane I 123 Injection; 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 Ioflupane I 123 Injection image. The impact of dopamine agonists and antagonists on Ioflupane I 123 Injection 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 Ioflupane I 123 Injection in a pregnant woman. All radiopharmaceuticals have potential to cause fetal harm. There are no available data on Ioflupane I 123 Injection use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. Advise pregnant women of the potential risks of fetal exposure to radiation with the administration of Ioflupane I 123 Injection
- **Lactation**: Iodine 123 (I 123), the radionuclide in Ioflupane I 123 Injection, 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 Ioflupane I 123 Injection administration to minimize radiation exposure to a breastfeeding infant
- **Pediatric Use**: The safety and efficacy of Ioflupane I 123 Injection 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 Ioflupane I 123 Injection imaging has not been established. The kidney excretes Ioflupane I 123 Injection; patients with severe renal impairment may have increased radiation exposure and altered Ioflupane I 123 Injection 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

- Ioflupane I 123 Injection emits radiation and must be handled with safety measures to minimize radiation exposure to clinical personnel and patients

Please see full Prescribing Information by clicking here or visit https://www.curiumpharma.com/loflupane-PI.pdf

About Curium

Curium is the world's largest nuclear medicine company. We develop, manufacture and distribute world-class radiopharmaceutical products to help patients around the globe. Our proven heritage combined with a pioneering approach are the hallmarks to deliver innovation, excellence and unparalleled service.

With manufacturing facilities across Europe and the United States, Curium delivers SPECT, PET and therapeutic radiopharmaceutical solutions for life-threatening diseases to over 14 million patients annually. The name 'Curium' honors the legacy of pioneering radioactive materials researchers Marie and Pierre Curie, after whom the radioactive element curium was named and emphasizes our focus on nuclear medicine. To learn more, visit curiumpharma.com.

For more information about this press release, please contact Ross Bethell ross.bethell@curiumpharma.com or +44.7827.833.176.