FOR IMMEDIATE RELEASE April 5, 2022

Curium Announces FDA Approval of a Generic Version of DaTscan™ (Ioflupane I 123 Injection) in the U.S.

(St. Louis, MO – April 5, 2022) - Curium announced today that its generic version of DaTscan (Ioflupane I 123 Injection) was approved on March 30, 2022, by the U.S. Food and Drug Administration (FDA). Ioflupane I 123 Injection is a single-photon emission computed tomography (SPECT) brain imaging agent used to assist in the evaluation of adult patients with suspected Parkinsonian Syndromes. Curium has begun accepting customer orders for fulfillment beginning Monday, April 11.

“The number of patients being diagnosed with Parkinsonian Syndromes is, unfortunately, growing. Approximately 1% of the population over the age of 65 are affected and that population is increasing. The addition of Curium’s generic Ioflupane I 123 Injection to the market will offer appropriate patients an opportunity to be scanned Monday through Thursday early in the morning.” said Michael Patterson, Curium’s North American CEO. “Providing hospitals and imaging centers the opportunity to scan patients on a day or at a time not currently available offers flexibility when scheduling this important study.”

“Ioflupane I 123 Injection is an important tool many neurologists and movement disorder specialists use when diagnosing adult patients with suspected Parkinsonian Syndromes,” said Ed Porter, North American Vice President of Medical and Compliance. “Over the past two years Curium has introduced several new products, both branded and generic, which help physicians diagnose patients. We are thrilled to add Ioflupane I 123 Injection to that growing list of medicines to help patients move life forward.”

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.

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