

December 22, 2023



PDRadiopharma Inc.

Approval of Partial Change to the Indication of MyoMIBG[®]-I 123 Injection for Cardiac Scintigraphy for Patients with Parkinson's Disease and Dementia with Lewy Bodies

**This release is an English translation of “「ミオ MIBG[®]-I 123 注射液」パーキンソン病及びレビー小体型認知症患者を対象とした心シンチグラフィに係る一部変更承認取得のお知らせ”, with a priority given to Japanese for content and interpretation. The indication is specifically for Japan only and not for other countries.*

TOKYO, JAPAN – December 22, 2023 - PDRadiopharma Inc. (President: Susumu Tanahashi, Headquarters: Chuo-ku, Tokyo, Japan) today announced that it has received approval for a partial change (indication expansion) of MyoMIBG[®]-I 123 Injection (generic name: 3-iodobenzylguanidine (¹²³I) injection) for an additional indication of "cardiac scintigraphy for the diagnosis of Parkinson's disease and dementia with Lewy bodies".

MyoMIBG[®]-I 123 Injection is used to diagnose various diseases by imaging radiation emitted from a noradrenaline*¹ analog, 3-iodobenzylguanidine (¹²³I) using a gamma camera.*² After intravenous administration, the agent is taken up by sympathetic nerve endings in the heart to visualize cardiac sympathetic function. Cardiac sympathetic nerve degeneration and desensitization occur early in patients with Parkinson's disease and dementia with Lewy bodies, and cardiac scintigraphy is an established method to diagnose these conditions. MyoMIBG[®]-I 123 Injection was first approved for diagnosis of cardiac diseases by cardiac scintigraphy in 1992, and expanded its indications for diagnosis of neuroblastoma by tumor scintigraphy in 2009 and for diagnosis of pheochromocytoma by tumor scintigraphy in 2011.

Cardiac scintigraphy of MyoMIBG[®]-I 123 Injection for patients with Parkinson's disease and dementia with Lewy bodies is covered by insurance even if the drug is used off-label, in accordance with the notice "Handling of Drugs in Insurance Treatment" (Notice of the Director-General of the Health Insurance Bureau, Ministry of Health and Welfare No. 51 dated September 3, 1980), and has been widely used in clinical practice. Cardiac scintigraphy has also been established as one of the diagnostic standards for Parkinson's disease and dementia with Lewy bodies in domestic and international guidelines. In light of these circumstances, we filed an application to receive official approval for this important indication.

As expert in radiopharmaceuticals, PDRadiopharma aims to continuously contribute to the improvement

of people's health and medical care.

*1 noradrenaline: A neurotransmitter hormone secreted from the adrenal medulla involved in the transmission of sympathetic nerve information. Citation from Ministry of Health, Labour and Welfare e-Health Net (<https://www.e-healthnet.mhlw.go.jp/information/dictionary/heart/yk-047.html>)]

*2 gamma camera: A device that images gamma rays emitted by radiopharmaceuticals administered into the body.

About PDRadiopharma

PDRadiopharma has been providing high-quality radiopharmaceuticals since it started its business in 1968. Our vision is to shine the lives through innovative diagnostics and therapeutics using radiopharmaceuticals. Currently, we domestically market 22 SPECT diagnostics, 2 PET diagnostics, and 8 therapeutic drugs (3 product categories). For more information, please visit <https://www.pdradiopharma.com/>

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