

September 19, 2025

PDRadiopharma Inc.

## **PDRadiopharma Receives Approval for Expanded Indication of Raiatt MIBG-I131 for Neuroblastoma**

*\*This release is an English translation of “「ライアット MIBG-I 131 静注」神経芽腫への効能・効果適応追加に関する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 – September 19, 2025 - PDRadiopharma Inc. (President: Masato Murakami, Headquarters: Chuo-ku, Tokyo, Japan) today announced that it has received approval in Japan for a partial change (indication expansion) of Raiatt MIBG-I 131 Injection (generic name: 3-Iodobenzylguanidine ( $^{131}\text{I}$ )), adding a new indication for the treatment of “MIBG-avid neuroblastoma”.

### **Approved Indication**

- **"MIBG-avid, unresectable pheochromocytoma and paraganglioma"**
- **"MIBG-avid neuroblastoma" (newly approved indication)**

The newly approved indication, “MIBG-avid neuroblastoma,” is a malignant tumor originating from the sympathetic nervous system and adrenal medullary cells, primarily affecting children. It is associated with a high rate of recurrence, and there is an urgent need for new therapies with novel mechanisms of action.

Raiatt MIBG-I 131 Injection was approved in Japan in September 2021 for the treatment of "MIBG-avid, unresectable pheochromocytoma and paraganglioma". Subsequently, studies demonstrating its efficacy in neuroblastoma, and based on requests from the Japanese Society of Nuclear Medicine and the Japanese Society of Pediatric Hematology/Oncology, the product was reviewed by the *Evaluation Committee on Unapproved or Off-Label Drugs with High Medical Needs*.

At its 62nd meeting on March 14, 2025, the committee determined that the product was qualified for a public knowledge application. The Second Committee on Drugs of the Pharmaceutical Affairs Council confirmed that such an application would be acceptable on April 21, and PDRadiopharma submitted the application for approval of the additional indication on May 20. Approval was subsequently granted.

Furthermore, in accordance with the notification issued by the Ministry of Health, Labour and Welfare titled “*Handling of Pharmaceuticals That Have Completed Preliminary Evaluation for Public Knowledge-based Applications*,” the product was already covered under Japan’s National Health Insurance as of April 21, 2025. With this new regulatory approval under the Pharmaceuticals and Medical Devices Act (PMDA), PDRadiopharma will continue to provide appropriate information and ensure stable supply for use in the treatment of neuroblastoma.

PDRadiopharma remains committed to expanding supply capacity and strengthening stable supply systems, with the goal of delivering this treatment to patients as quickly as possible. Through the development of innovative radiopharmaceuticals, we aim to address high unmet medical needs and contribute to building a society where patients can access effective and reliable therapies with confidence.

### **About Raiatt MIBG-I 131 Injection**

This drug is a pharmaceutical product in which radioactive iodine ( $^{131}\text{I}$ ) is attached to 3-iodobenzylguanidine (MIBG), a substance similar to the adrenal medullary hormone norepinephrine. It is specifically taken up by tumors through a mechanism similar to that of norepinephrine, and the  $\beta$ -rays emitted from the  $^{131}\text{I}$  cause damage to the tumor cells, thereby exerting therapeutic effects.

### **About PDRadiopharma**

PDRadiopharma, a wholly-owned subsidiary of PeptiDream from 2022, has been providing high-quality radiopharmaceuticals through the research and development, manufacturing, regulatory and sales as a forerunner in the field of radiopharmaceuticals, since it started its business in 1968. Currently PDRadiopharma offers 22 radiodiagnostic products (spanning both SPECT and PET products) and 8 radiotherapeutic products (3 product categories) in Japan. Additionally, PDRadiopharma and PeptiDream are developing a broad pipeline of radiotherapeutics and radiodiagnostics for both the Japan and global markets. For more information about PDRadiopharma, please visit <https://www.pdradiopharma.com/>

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