News Release

PDRadiopharma
A PeptiDream Company

May 20, 2025
PDRadiopharma Inc.

PDRadiopharma Submits Partial Change Application for Additional Indication of Raiatt MIBG-I131 for Neuroblastoma

**This release is an English translation of "「ライアット MIBG-I 131 静注」神経芽腫に対する効能・効果追加に関する一部変更承認申請のお知らせ", with a priority given to Japanese for content and interpretation. The indication is specifically for Japan only and not for other countries.*

TOKYO, JAPAN – May 20, 2025 - PDRadiopharma Inc. (President: Masato Murakami, Headquarters: Chuo-ku, Tokyo, Japan) today announced the submission of a partial change application in Japan for Raiatt MIBG-I 131 Injection (generic name: 3-Iodobenzylguanidine(^{131}I)) to add a new indication for the treatment of "MIBG-avid neuroblastoma".

Neuroblastoma is a malignant tumor originating from the sympathetic-adrenal lineage of neural crest cells and occurs primarily in children. Neuroblastoma exhibits a wide range of malignancy depending on factors such as the patient's age at onset, disease stage, and the tumor's biological characteristics. In high-risk cases, relapse is common even after a favorable initial response to chemotherapy. Despite the use of intensive treatments, including high-dose chemotherapy and stem cell transplantation, the five-year progression-free survival rate remains at approximately 30%. There is a significant need for treatment options that act via mechanisms distinct from those of existing therapies.

Raiatt MIBG-I 131 Injection was approved in Japan in September 2021 as a therapeutic radiopharmaceutical indicated for the treatment of "MIBG-avid, unresectable pheochromocytoma and paraganglioma." Subsequent studies demonstrating its potential efficacy in neuroblastoma, formal request for an indication expansion were submitted by the Japanese Society of Nuclear Medicine and the Japanese Society of Pediatric Hematology/Oncology.

In response to requests from patients and academic societies, at the 62nd Meeting of the Evaluation Committee on Unapproved or Off-Label Drugs with High Medical Needs held on March 14, 2025, the use of this product for neuroblastoma was deemed to qualify for a public knowledge-based application. This was followed by the Second Committee on Drugs of the Pharmaceutical Affairs Council on April 21, which confirmed that there were no objections to proceeding with the application under this framework. Accordingly, PDRadiopharma submitted the partial change application on this day.*

PDRadiopharma remains committed to delivering innovative treatment options to patients as quickly as possible. Through the development of novel radiopharmaceuticals, we aim to address high unmet medical needs and contribute to building a society where all patients can access effective and reliable therapies with confidence.

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* Approval application supported by a grant from the Pharmaceutical Development Support Center (a general incorporated association).

About Raiatt MIBG-I 131 Injection

This drug is a pharmaceutical product in which radioactive iodine (^{131}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 β-rays emitted from the ^{131}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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