Marketing Authorization Granted for Lutathera® Injection in Japan

- The first approval in Japan for peptide receptor radionuclide treatment drug, providing a new therapeutic option for neuroendocrine tumors

TOKYO, June 23, 2021—FUJIFILM Toyama Chemical Co., Ltd. (Head Office: Chuo-ku, Tokyo; President: Junji Okada; hereinafter "FUJIFILM Toyama Chemical") today received marketing authorization in Japan for Lutathera® Injection (INN: lutetium (^{177}Lu) oxodotreotide) (hereinafter "Lutathera") for the treatment of somatostatin receptor-positive neuroendocrine tumors[*1].

Lutathera is a peptide receptor radionuclide therapy (PRRT), a type of radioligand therapy (RLT)[*2], and was approved as the first PRRT drug in Japan.

Neuroendocrine tumors originate in neuroendocrine cells that secrete hormones and peptides. Tumors frequently develop in a variety of organs throughout the body, in particular, the pancreas, gastrointestinal tract, and lungs. Because of its limited options for drug therapy, the disease is considered to have high unmet medical needs. PRRT is widely used in many countries, as there is a need for additional effective treatment options for patients with neuroendocrine tumors..

In 2015, FUJIFILM Toyama Chemical concluded a licensing agreement with Advanced Accelerator Applications International S.A. (hereinafter "AAA"), a Novartis company, for the domestic development and marketing of Lutathera®[*3]. FUJIFILM Toyama Chemical has confirmed the drug's efficacy and safety in Japanese patients through a phase I clinical study and a phase I/II clinical study, and filed an application for marketing authorization approval in 2020.

Lutathera is a therapeutic radiopharmaceutical product in which a somatostatin analog is radiolabeled with lutetium-177. It binds to somatostatin receptors that are highly expressed in neuroendocrine tumors, and directly targets cancer cells with radiation released from lutetium-177.

FUJIFILM Toyama Chemical will work to make PRRT accessible to patients in Japan by offering Lutathera. Along with Lutathera, the company also obtained domestic marketing authorization for LysaKare® Injection (hereinafter "LysaKare")[*4], an amino acid infusion solution used in combination with Lutathera for reduction of renal (kidney) radiation exposure during therapy with Lutathera. Both products are planned to be launched shortly in Japan.

By adding a therapeutic radiopharmaceutical product, Lutathera, to OctreoScan® Injection Kit[*5] (for the preparation of indium (^{111}In) pentetreotide injection fluid), a diagnostic radiopharmaceutical agent for neuroendocrine tumors already marketed, FUJIFILM Toyama Chemical will expand its offerings of comprehensive solutions for patients with neuroendocrine tumors , from diagnosis to treatment.

FUJIFILM Toyama Chemical will continue to contribute to enhancing medicine even further by delivering high value-added drugs.

*1 Neuroendocrine tumors that express somatostatin receptors. Somatostatin is a peptide hormone comprised of 14 amino acids that are produced in the hypothalamus, the pituitary gland, as well as the delta cells in the pancreatic islets of Langerhans. It has actions that inhibit the secretion of growth hormones, insulin, etc. Because somatostatin receptors are highly expressed in neuroendocrine tumors, they are considered an effective target of neuroendocrine tumor treatment.

*2 A type of therapy in which ligands, or targeting molecules that specifically bind to receptors expressed by a tumor are labeled with radioactive substances, and administered to patients to irradiate the target foci from inside the body. PRRT targets peptide receptors that are expressed in a tumor.

*3 A therapeutic drug for neuroendocrine tumors, developed by AAA. It is currently approved in countries and regions around the world including 32 European countries, as well as the U.S., Canada, Israel, South Korea, Singapore, Hong Kong, and Taiwan.

*4 FUJIFILM Toyama Chemical obtained licensing rights for the domestic development and marketing of LysaKare® in 2017 from AAA, and had worked to develop the drug. AAA has developed the drug and is engaged in its overseas development. At present, LysaKare® is approved in countries and regions around the world including 31 European countries, as well as Singapore and Hong Kong.

*5 A radiopharmaceutical product in which a somatostatin analog is radiolabeled with indium-111. It is used for the diagnostic imaging of neuroendocrine tumors. It targets somatostatin receptors, similarly to Lutathera.

【Product overview】

Brand name	Lutathera® Injection	LysaKare® Injection
INN	lutetium (^{177}Lu) oxodotreotide	L-lysine hydrochloride / L-arginine hydrochloride
Date approved	June 23, 2021	June 23, 2021
Indication	Somatostatin receptor-positive neuroendocrine tumors	Reduction of renal radiation exposure by lutetium (^{177}Lu) oxodotreotide