Launch of Therapeutic Radiopharmaceutical Product, Lutathera® Injection targeting neuroendocrine tumors in Japan

TOKYO, August 31, 2021—FUJIFILM Toyama Chemical Co., Ltd. (Head Office: Chuo-ku, Tokyo; President: Junji Okada; hereinafter "FUJIFILM Toyama Chemical") will launch, on September 29, 2021, Lutathera®*1 Injection (INN: lutetium (^{177}Lu) oxodotreotide) (hereinafter "Lutathera") in Japan, for the treatment of somatostatin receptor-positive neuroendocrine tumors*2. Lutathera is the first approved Peptide Receptor Radionuclide Therapy (PRRT), a type of radioligand therapy*3, 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.

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

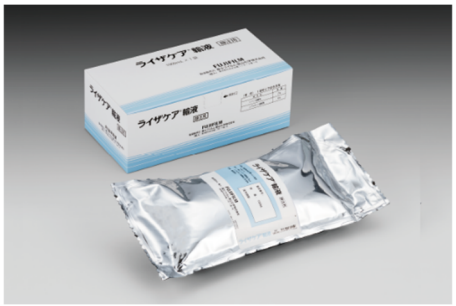
Prior to the launch of Lutathera, FUJIFILM Toyama Chemical begins to accept orders for the product as of September 6, 2021. By adding therapeutic radiopharmaceutical product Lutathera, to OctreoScan® Injection Kit*4 (for the preparation of indium pentetreotide [^{111}In] injection fluid), a diagnostic radiopharmaceutical product for neuroendocrine tumors already marketed, FUJIFILM Toyama Chemical will expand its offerings of comprehensive solutions for patients with neuroendocrine tumors, from diagnosis to treatment.

Along with Lutathera, the company will launch LysaKare®*5 Injection (hereinafter "LysaKare") , an amino acid infusion solution used in combination with Lutathera for reduction of renal (kidney) radiation exposure during therapy with Lutathera.

To realize PRRT in Japan, 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*6. After confirmation of the product's efficacy and safety in Japanese patients through clinical studies and filing of marketing authorization approval application in 2020, FUJIFILM Toyama Chemical received marketing authorization on June 23, 2021.

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

【Product overview】

Brand name	Lutathera® Injection	LysaKare® Injection
INN	lutetium (^{177}Lu) oxodotreotide	L-lysine hydrochloride / L-arginine hydrochloride
Indication	Somatostatin receptor-positive neuroendocrine tumors	Reduction of renal radiation exposure from lutetium (^{177}Lu) oxodotreotide
Date approved	June 23, 2021	
NHI price listing date	August 12, 2021	
Order start date	September 6, 2021	
First delivery date	September 29,2021	
NHI drug price	JPY 2,648,153/ Vial	JPY 1,180/ Bag
Manufacturer	FUJIFILM Toyama Chemical Co., Ltd.	
Product photograph		

*1 Lutathera is a registered trademark of Advanced Accelerator Applications, a Novartis company.

*2 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.

*3 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. It includes PRRT, which targets peptide receptors that are expressed in tumors.

*4 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.

*5 LysaKare is a registered trademark of AAA. FUJIFILM Toyama Chemical obtained licensing rights for the domestic development and marketing of LysaKare in 2017 from AAA, and has worked to expand development of the drug to Japan. At present, LysaKare is approved in countries and regions around the world including the UK and 30 other European countries, as well as in South Korea, Singapore and Hong Kong.

*6 A therapeutic drug for neuroendocrine tumors, developed by AAA. It is currently approved in countries and regions around the world including the UK, Switzerland and 30 other European countries, as well as in the U.S., Canada, Israel, South Korea, Singapore, Hong Kong, and Taiwan.