Clinical trial information

Registration Item	Details of registration Item	Contents
Title of the study	Title of the study	A phase I clinical study of F-1515 in combination with F-1520 in patients with somatostatin receptor positive, progressive pancreatic, gastrointestinal, or pulmonary neuroendocrine tumors
	Primary sponsor	FUJIFILM Toyama Chemical Co., Ltd.
	Study Type	interventional (drug)
	Summary	The purpose of this study is to evaluate the safety, tolerability, pharmacokinetics, dosimetry, 1 cm dose equivalent rate and efficacy of F-1515 in combination with F-1520 infusion in patients with pancreatic, gastrointestinal, or pulmonary neuroendocrine tumors (NET).
Details of study	Interventional drug name	F-1515/F-1520
	Target illness	Pancreatic, gastrointestinal, or pulmonary neuroendocrine tumors
	Classification name (code) of the investigational drug	430 (radioactive medicines)/799 (other agents for not mainly purpose of therapeutic,n.e.c.)
	Administration route	Intravenous infusion
	Objectives of the study	Treatment
	Study phase	Phase I
	Study design	Open-label, uncontrolled, single-center
	Target sample size	6
	Criteria	Inclusion Criteria - Age：20 years old or more - Sex：Both - Histopathological diagnosis of NET of the pancreas, gastrointestinal tract, or lung. - Patients must have metastatic or locally advanced disease not amenable to curative resection. - Tumor progression confirmed within 12 months before enrollment. - Presence of at least one measurable disease as defined by RECIST. - Accumulation of ^{111}In-pentetreotide in all target lesions exceeding the accumulation in the normal liver documented by whole-body planar imaging. Exclusion Criteria

		- History of systemic treatment with any antineoplastic agents (excluding somatostatin analogs) within 8 weeks before enrollment. - History of any surgery, radiofrequency ablation, (chemo)embolization, or radioembolization within 12 weeks before enrollment. - History of peptide receptor radionuclide therapy (PRRT) even once. - History of external radiation therapy covering >= 25% bone marrow. - Patients currently receiving treatment with somatostatin analog who are expected to have difficulty in temporarily discontinuing the treatment for a defined period before each dose of F-1515.
	Outcome	Primary Outcome - Safety, tolerability, pharmacokinetics and dosimetry of F-1515 administered as a single dose in combination with F-1520 infusion. Secondary Outcome − Safety and efficacy of F-1515 administered to the maximum dose (4 doses) in combination with F-1520 infusion. − 1 cm dose equivalent rate of F-1515 administered as a single dose in combination with F-1520 infusion.
	Study status	Completed
	Duration of the study	2017-4-1 ～ 2019-9-30
	Region	Japan
Contact information	Organization	FUJIFILM Toyama Chemical Co., Ltd.
	Division	Development Coordination Department
	Contact	Form for Inquiry https://www.fujifilm.co.jp/form/fftc/ja/general/input.php?id=FFTCClinicalEn