

Clinical trial information

Registration Item	Details of registration Item	Contents
Title of the study	Title of the study	A phase I/II clinical study of F-1515 in combination with F-1520 in patients with somatostatin receptor positive, progressive midgut carcinoids and other neuroendocrine tumors
	Primary sponsor	FUJIFILM RI Pharma Co., Ltd.
	Study Type	interventional (drug)
	Summary	The pharmacokinetics and dosimetry of F-1515 administered as a single dose in combination with F-1520 infusion will be evaluated in patients with midgut carcinoid. Also, the efficacy and safety of peptide receptor radionuclide therapy (PRRT) with F-1515 in combination with F-1520 infusion will be evaluated in patients with midgut carcinoid, and pancreatic, gastrointestinal or pulmonary neuroendocrine tumors (NET) including midgut carcinoid.
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 • II
	Study design	Open-label, uncontrolled, multi-center
	Target sample size	15
	Criteria	<p>Inclusion Criteria</p> <ul style="list-style-type: none"> - Age : 20 years old or more - Sex : Both - Histopathological diagnosis of midgut carcinoid, or NET of pancreas, gastrointestinal tract (excluding midgut carcinoid) 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 ¹¹¹In-pentetreotide in all target lesions exceeding the accumulation in the normal liver documented by whole-body planar imaging.

		<p>Exclusion Criteria</p> <ul style="list-style-type: none"> - 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 \geq 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	<p>Primary Outcome</p> <ul style="list-style-type: none"> - Pharmacokinetics and dosimetry of F-1515 administered as a single dose in combination with F-1520 infusion in patients with midgut carcinoid. - Objective response rate (ORR) of F-1515 in combination with F-1520 infusion. <p>Secondary Outcome</p> <ul style="list-style-type: none"> - Clinical benefit rate (CBR), progression free survival (PFS), quality of life (QoL) of F-1515 in combination with F-1520 infusion. - Safety of F-1515 in combination with F-1520 infusion.
	Institutions	Tokyo Medical and Dental University, Medical Hospital; Yokohama City University Hospital.
	Study status	Ongoing
	Duration of the study	2017-12-1 ~ 2020-3-31
	Region	Japan
Contact information	Organization	FUJIFILM RI Pharma Co., Ltd.
	Division	Development Dept.
	Contact	03-5250-2634