Clinical trial information

Registration Item	Details of registration Item	Contents
Title of the study	Title of the study	A phase II clinical study of F-1614 in patients with pheochromocytoma (including paraganglioma)
	Primary sponsor	FUJIFILM RI Pharma Co., Ltd.
	Study Type	interventional (drug)
	Summary	The purpose of this study is to assess the efficacy and safety of F-1614 internal radiation therapy.
Details of study	Interventional drug name	F-1614: 3-iodobenzylguanidine (I-131)
	Target illness	Pheochromocytoma
	Classification name (code) of the investigational drug	430 (radioactive medicines)
	Dosage and administration	F-1614 will be administered at a dose of 7.4 GBq by intravenous infusion. In case 7.4 GBq can not be administered due to radiation limit, at least 5.55 GBq should be administered.
	Objectives of the study	Treatment
	Study phase	Phase II
	Study design	Single arm, open-label, multicenter
	Target sample size	13
	Criteria	Inclusion Criteria - Age：20 years old or more - Sex：Both - Comfirmed unresectable/metastatic/recurrent pheochromocytoma, paraganglioma, malignant pheochromocytoma, or malignant paraganglioma. - Presence of at least one measurable disease as defined by RECIST (ver.1.1). - Accumulation of ^{123}I-MIBG to at least one target lesion documented by CT/MRI scans at screening. - For at least one of the following urinary catecholamines, the laboratory data is more than 3 times the upper limit of the normal range at screening: adrenaline, noradrenaline, metanephrine, or normetanephrine. - Patients must have sufficient organ functions meeting the following criteria at screening: 1) Bone marrow function: WBC >= 3,000/mm^3 without G-CSF use, Hb >= 9.0 g/dL without transfusion, and PLT >= 100,000/mm^3 without transfusion 2) Renal function: eGFR >= 30 mL/min/1.73 m^2 3) Liver function: AST < 100 IU/L, ALT < 100 IU/L,

		LDH < 400 IU/L 4) Heart function: New York Heart Association (NYHA) Functional Classification <= I 5) Metabolic function: HbA1c < 8.0% (NGSP) 6) Respiratory function: SpO_2 >= 96% - ECOG Performance Status 0 or 1. - Expected survival of at least 6 months. - Patients who can take self-care while isolated in the radioisotope therapy ward. - Japanese patients aged >= 20 years at the time of informed consent. Exclusion Criteria - Previous MIBG therapy. - History of any surgery, CVD therapy, (chemo)embolization to hepatic metastases, medication to bone metastases, or external radiation within 8 weeks before enrollment. - History of uncontrollable adrenergic storm. - History of fatal arrhythmia or asystole. - Pregnant, within 28 days after giving birth, or breast-feeding patients (excluding breast-feeding patients who can agree to stop breast-feeding for 6 months after the administration of the study drug). - Patients who cannot agree to use contraceptive methods until 6 months after the administration of the study drug. - Presence or suspicious history of allergy to potassium iodine. - Participation in any other clinical study within 3 months before informed consent. - Patients assessed by the principal investigator or the subinvestigator as not appropriate as a subject of this study for any other reason.
	Outcome	Efficacy and safety
	Institutions	Kanazawa University Hospital, Gunma University Hospital, Hokkaido University Hospital, Kagoshima University Hospital
	Study status	Ongoing
	Duration of the study	2017-11-1 ～ 2019-12-31
	Region	Japan
Contact information	Organization	FUJIFILM RI Pharma Co., Ltd.
	Division	Development Dept.
	Contact	03-5250-2634