Clinical trial information

Registration Item	Details of registration Item	Contents
Title of the study	Title of the study	A Phase 1, Single Site, Open-label, Uncontrolled Study of FF-21101In / FF-21101Y in Patients with Solid Tumors that Relapsed or Metastasized after Standard Therapy
	Primary sponsor	FUJIFILM Toyama Chemical Co. Ltd
	Study Type	interventional (drug)
	Summary	This study will evaluate estimated radiation dose of FF-21101In and FF-21101Y after single administration of FF-21101In, and safety, tolerability, pharmacokinetics and efficacy of FF-21101Y in patients with ovarian carcinoma, biliary tract carcinoma, or head and neck squamous cell carcinoma that relapsed or metastasized after standard therapy.
Details of study	Interventional drug name	FF-21101In
	Target illness	Solid Tumors that Relapsed or Metastasized after Standard Therapy
	Classification name (code) of the investigational drug	430 Radiopharmaceutical
	Administration route	Intravenous administration
	Interventional drug name	FF-21101Y
	Target illness	Solid Tumors that Relapsed or Metastasized after Standard Therapy
	Classification name (code) of the investigational drug	430 Radiopharmaceutical
	Administration route	Intravenous administration
	Control drug name(code/td)	-
	Classification name (code) of the investigational drug	-
	Administration route	-
	Objectives of the study	Treatment
	Study phase	Phase I
	Study design	Open-label, Uncontrolled, Single Site Study

	Criteria	Inclusion (1) Patients conforming to any of 1) to 3) below 1) Has ovarian carcinoma to which all of a) to c) below. a) Has any of histopathologically confirmed epithelial ovarian, fallopian tube, or primary peritoneal carcinoma. b) The possibility of ovarian borderline malignancy has been ruled out. c) Has platinum resistance with which relapse occurred in less than 6 months after completion of chemotherapy that included platinum. 2) Has biliary tract carcinoma to which all of a) to c) below. a) Has any of intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, gallbladder carcinoma, or papillary carcinoma confirmed on CT, MRCP, or other testing. b) Surgically unresectable. c) Deemed unresponsive to or intolerant of regimens that included gemcitabine. 3) Has head and neck squamous cell carcinoma to which all of a) to c) below. a) Has histopathologically confirmed head and neck squamous cell carcinoma. b) The primary site is the maxillary sinus, oral cavity, epipharynx, oropharynx, hypopharynx, or larynx. c) Experienced relapse or metastasis after chemotherapy that included platinum or after treatment with nivolumab. (2) Had no more than 4 previous chemotherapy regimens. (3) Has at least one measurable lesion by CT or MRI according to RECIST v.1.1 (long axis ≥ 10 mm for tumors; short axis ≥ 15 mm for lymph node lesions). (4) Expected survival of ≥ 6 months. Exclusion (1) Had chemotherapy (including antibody therapy), surgery, or external radiation therapy within 4 weeks prior to FF-21101In administration. (2) Administered other investigational products within 12 weeks prior to FF-21101In administration. (3) Previously received internal radiation therapy. (4) Has a history of severe hypersensitivity to components of FF-21101In / FF-21101Y (5) Previously received external radiation therapy to any organ up to minimal tolerable dose ($TD_{5/5}$, radiation dose that could cause no more than a 5% severe complication rate within 5 years of treatment).
	Outcome	Safety, pharmacokinetics and Tolerability
	Study status	On going
	Duration of the study	-
	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