Essai Clinique

Généré le 24 avr. 2024 à partir de

Titre	Étude de phase I sur l'administration de [225Ac]-FPI-1434 par injection chez des patients atteints de tumeurs solides avancées
Protocole ID	FPX-01-01
ClinicalTrials.gov ID	NCT03746431
Type(s) de cancer	Tumeurs solides
Phase	Phase I
Stade	Maladie avancée ou métastatique
Type étude	Traitement
Médicament	[225Ac]-FPI-1434
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL L'HOTEL-DIEU DE QUEBEC ET CRCEO 11 Côte du Palais, Québec, QC, G1R 2J6
Ville	Québec
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Statut	Fermé
But étude	This is a first-in-human Phase 1, non-randomized, multi-center, open-label clinical trial designed to investigate the safety, tolerability, pharmacokinetics of [111In]-FPI-1547 Injection and [225Ac]-FPI-1434 Injection and to establish the maximum tolerated dose of a single [225Ac]-FPI-1434 Injection in patients with solid tumours with demonstrated tumour uptake of [111In]-FPI-1547.
Critères d'éligibilité	• Age ≥18 years old. • Pathologically documented, definitively diagnosed, advanced solid tumour that is refractory to all standard treatment, for which no standard treatment is available, or it is contraindicated, or the patient refuses standard therapy. • At least 1 measurable lesion (≥ 20 mm in largest diameter [≥ 20 mm in shortest diameter if lymph node]). • Eastern Cooperative Oncology Group (ECOG) Performance status of 0 or 1. • Life expectancy of greater than 3 months as judged by the treating physician. • Available tumour tissue (either archival or fresh biopsy) for IGF-1R immunohistochemistry. Submission of the tissue is not required prior to enrolment. • Adequate bone marrow reserves without the use of hematopoietic growth factors, red cell or platelet transfusion as evidenced by: • Absolute neutrophil count ≥ 1,500/ mm^3 (≥ 1.5 x 10^9/L) • Platelet count ≥ 100,000/ mm^3 (≥ 100 x 10^9/L) • Hemoglobin ≥ 9 g/dL (≥ 90 g/L) • Adequate renal function as evidenced by a creatinine clearance ≥ 60 mL/min using the Cockcroft-Gault Equation. Actual body weight should be used for calculating creatinine clearance using the Cockcroft-Gault Equation. • Adequate hepatic function as evidenced by: • Serum total bilirubin ≤ 1.5x upper limit of normal (ULN), unless patient has Gilbert's disease • Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) ≤ 2.5 x ULN (≤ 5 x ULN in patients with known liver metastasis) • Other laboratory results, vital signs and ECG are judged by the Investigator to be acceptable for enrolment into the study.

	• Females of childbearing potential must have a negative pregnancy test results during the general and imaging screening periods. • Females of childbearing potential and all men must agree to use at least two highly effective forms of contraception one of which must be a barrier method, or agree to remain abstinent, for the duration of study participation and 3 months after completion of the study. • Ability to understand and the willingness to sign a written informed consent document. • In the judgement of the Investigator, the patient is expected to be compliant and have a high probability of completing the study.
Critères d'exclusion	• Received a systemic therapeutic radiopharmaceutical within 6 months prior to enrolment into this study. • Contraindications to or inability to perform the required imaging procedures in this study (e.g. inability to lay flat for the image acquisitions, etc.) • Uncontrolled brain metastasis, including but not limited to need for treatment with steroids, surgery or radiation therapy. • Anticancer therapy (including investigations agents) or external beam radiation therapy within 14 days of the dosing of [111In]-FPI-1547 (6 weeks for mitomycin-C). Ongoing androgen deprivation therapy for prostate cancer, thyroid stimulating hormone suppression for differentiated thyroid cancer, somatostatin analogues for neuroendocrine tumours are NOT considered exclusion criteria. • Prior organ transplantation, including stem cell transplantation. • Any prior treatment with nitrosoureas and actinomycin-D. • Clinical relevant proteinuria (e.g. urinary dipstick analysis for proteins is 3+ [300 mg/dL or 4+ [1,000 mg/dL], or daily urinary excretion > 500 mg/dL). • Known or suspect allergies or contraindications to the Investigational Products or any component of the investigational drug formulation. • Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, diabetes (random blood sugar during screening ≥250 mg/dL [≥ 13.9 mmol/L]), or psychiatric illness/social situations that would limit compliance with study requirements. • Received > 20 Gy prior radiation to large areas of the bone marrow (e.g. external radiation therapy to whole pelvis)