Essai Clinique

Généré le 18 mai 2024 à partir de

Titre	An Open-label, Phase I Dose Escalation Followed by Dose Expansion Trial in Patients With Advanced Solid Tumours to Investigate Safety, Pharmacokinetics, and Efficacy and to Select the Dose for Further Development of BI 770371 in Combination With Ezabenlimab
Protocole ID	1501-0001
ClinicalTrials.gov ID	NCT05327946
Type(s) de cancer	Tumeurs solides
Phase	Phase I
Stade	Maladie avancée ou métastatique
Type étude	Clinique
Médicament	BI 770371 en association avec Ezabenlimab
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
Investigateur principal	Dre Rahima Jamal
Coordonnateur	Adeline Hamon 514-890-8000 poste 30737
Statut	Actif en recrutement
But étude	This study is open to adults with advanced cancer (solid tumours). People for whom previous treatment was not successful and for whom no other treatment options exist can join the study. The purpose of this study is to find the highest dose of BI 770371 that people with advanced cancer can tolerate when taken alone or together with a medicine called ezabenlimab. BI 770371 and ezabenlimab are antibodies that may help the immune system fight cancer (checkpoint inhibitors). In this study, BI 770371 is given to people for the first time.Participants get BI 770371 alone or together with ezabenlimab as an infusion every 3 weeks. It is planned that participants can stay in the study for up to 2 years, if they benefit from treatment and can tolerate it. During this time, they visit the study site regularly. The doctors collect information on any health problems of the participants. The doctors also regularly monitor the size of the tumour.
Critères d'éligibilité	• Signed and dated written informed consent form (ICF) in accordance with International Council for Harmonisation-Good Clinical Practice (ICH-GCP) and local legislation prior to admission to the trial • Patients ≥18 years of age and over the legal age of consent as required by local legislation at the time of signature of the ICF • Presence of at least one measurable lesion according to Response Evaluation Criteria In Solid Tumours (RECIST) v1.1 • Eastern Cooperative Oncology Group (ECOG) Score: 0 to 1 • Life expectancy ≥3 months at the start of treatment in the opinion of the Investigator. • Patients with a confirmed diagnosis of advanced, unresectable, and/or metastatic solid tumours (any type) • Patients who have failed conventional treatment or for whom no therapy of proven efficacy exists or who are not eligible for established treatment options (including anti-Programmed Cell Death 1 (PD-1) or anti-Programmed Death-Ligand 1 (PD-L1) therapies, if relevant). Patients must have exhausted available treatment options known to prolong survival for their disease • All toxicities related to previous anti-cancer therapies have resolved ≤ Common Terminology Criteria for Adverse Events (CTCAE) Grade 1 prior to trial treatment administration (except for alopecia, peripheral neuropathy and endocrinopathies considered irreversible [like hypothyroidism], and amenorrhea/menstrual disorders which can be any grade) Further

	inclusion criteria apply

Critères d'exclusion	• Major surgery (major according to the Investigator's assessment) performed within 12 weeks prior to randomisation or planned within 12 months after screening, e.g. hip replacement
	• Presence of active invasive cancers other than the one treated in this trial within 5 years prior to screening, with the exception of appropriately treated basal-cell carcinoma of the skin, in situ carcinoma of the uterine cervix, or other local tumours considered cured by local treatment
	• Untreated brain metastasis(es) that may be considered active. Patients with previously treated brain metastases may participate provided they are stable (i.e., without evidence of Progressive Disease (PD) by imaging for at least 4 weeks prior to the first dose of trial treatment, and any neurologic symptoms have returned to baseline), and there is no evidence of new or enlarging brain metastases
	• Radiotherapy within 4 weeks prior to randomisation except as follows:
	  • Palliative radiotherapy to regions other than the chest is allowed if completed at least 2 weeks prior to randomisation
	  • Single dose palliative radiotherapy for symptomatic metastasis within 2 weeks prior to randomisation may be allowed but must be discussed with the Sponsor
	• Patients who must or wish to continue the intake of restricted medications or any drug considered likely to interfere with the safe conduct of the trial
	• History of pneumonitis within the last 5 years or Interstitial lung disease
	• Known history of allergy to any trial drug, or any excipients of the trial drug(s)
	• History of severe hypersensitivity reactions and/or severe infusion related reactions (Grade ≥ 3 National Cancer Institute (NCI) CTCAE v5.0) to other Monoclonal Antibodies (mAbs) Further exclusion criteria apply