Essai Clinique

Généré le 23 avr. 2024 à partir de

Titre	Une étude ouverte multicentrique de phase 1/2 du DCC-3014 pour évaluer l'innocuité, l'efficacité, la pharmacocinétique et la pharmacodynamique chez les patients atteints d'une tumeur avancée ou d'une tumeur ténosynoviale à cellules géantes
Protocole ID	DCC-3014-01-001
ClinicalTrials.gov ID	NCT03069469
Type(s) de cancer	Tumeurs solides
Phase	Phase I-II
Stade	Maladie avancée ou métastatique
Type étude	Clinique
Médicament	DCC-3014
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
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Statut	Fermé
But étude	This is a multicenter, open-label Phase 1/2 study of DCC-3014 in patients with malignant solid tumors and tenosynovial giant cell tumor (TGCT). There will be 2 distinct parts in this study: Dose Escalation (Phase 1) and Expansion (Phase 2). Phase 1 will enroll both malignant solid tumor and TGCT patients. Phase 2 will comprise two cohorts (Cohort A and Cohort B) and will only enroll TGCT patients.
Critères d'éligibilité	Dose Escalation Phase: 1. Patients ≥18 years of age 2. Patients must have: 1. advanced malignant solid tumors; or 2. symptomatic TGCT for which surgical resection is not an option (tumor biopsy to confirm diagnosis required if no histology/pathology available at screening) 3. Malignant solid tumor patients only: Able to provide a tumor tissue sample 4. Must have 1 measurable lesion according to RECIST Version 1.1 5. Malignant solid tumor patients only: Must have ECOG performance status of 0-1 6. Adequate organ and bone marrow function 7. If a female of childbearing potential, must have a negative pregnancy test prior to enrollment and agree to follow the contraception requirements. 8. Must provide signed consent to participate in the study and is willing to comply with study-specific procedures. Expansion Phase (Cohorts A and B) 1. Patients ≥18 years of age 2. Patients must have symptomatic TGCT for which surgical resection is not an option (tumor biopsy to confirm diagnosis required if no histology/pathology available at screening)a) Expansion Cohort B: patients must have prior systemic treatment with anti-CSF1 or anti-CSF1R therapy, with the exception of imatinib or nilotinib 3. Adequate organ and bone marrow function 4. Must have at least 1 measurable lesion according to RECIST Version 1.1

	5. If a female of childbearing potential, must have a negative pregnancy test prior to enrollment and agree to follow the contraception requirements. 6. Must provide signed consent to participate in the study and is willing to comply with study-specific procedures.
Critères d'exclusion	Dose Escalation Phase: 1. Received anticancer therapy or therapy for TGCT, including investigational therapy, within 2 weeks or 28 days for therapies with half-life (t1/2) longer than 3 days prior to the administration of study drug. 2. Unresolved toxicity (Grade >1 or baseline) from previous anticancer therapy or TGCT therapy, excluding alopecia. 3. Known active CNS metastases. 4. History or presence of clinically relevant cardiovascular abnormalities. 5. Systemic arterial or venous thrombotic or embolic events. 6. QT interval corrected by Fridericia's formula (QTcF) >450 ms in males or >470 ms in females or history of long QT syndrome. 7. Left ventricular ejection fraction (LVEF) <50%. 8. Concurrent treatment with proton-pump inhibitor(s). 9. Major surgery within 2 weeks of the first dose of study drug. 10. Malabsorption syndrome or other illness that could affect oral absorption. 11. Known human immunodeficiency virus, active hepatitis B, active hepatitis C, or active mycobacterium tuberculosis infection. 12. If female, the patient is pregnant or lactating. 13. Known allergy or hypersensitivity to any component of the study drug. 14. Any other clinically significant comorbidities. Expansion Phase (Cohorts A and B) 1. Expansion Cohort A: received systemic therapy targeting CSF1 or CSF1R; previous therapy with imatinib and nilotinib is allowed. 2. Expansion Cohort B: discontinued systemic therapy targeting anti-CSF1 or anti-CSF1R due to drug-induced liver injury. 3. Treatment with therapy for TGCT, including investigational therapy, within 2 weeks or 28 days for therapies with a t1/2 longer than 3 days prior to the administration of the study drug. 4. Known metastatic TGCT or other active cancer that requires concurrent treatment. 5. QT interval corrected by Fridericia's formula (QTcF) >450 ms in males or >470 ms in females or history of long QT syndrome. 6. Left ventricular ejection fraction (LVEF) <55%. 7. Concurrent treatment with proton-pump inhibitor(s). 8. Major surgery within 2 weeks of the first dose of study drug. 9. Any clinically significant comorbidities 10. Malabsorption syndrome or other illness that could affect oral absorption. 11. Known human immunodeficiency virus (HIV), active or chronic hepatitis B, active or chronic hepatitis C, or active mycobacterium tuberculosis infection. 12. If female, the patient is pregnant or lactating. 13. Known allergy or hypersensitivity to any component of the study drug. 14. Contraindication for MRI 15. Active liver or biliary disease, including evidence of fatty liver, nonalcoholic steatohepatitis (NASH), or cirrhosis