Essai Clinique

Généré le 26 avr. 2025 à partir de

Titre	A Randomized, Double-blind, Multicenter, Phase 3 Study to Evaluate Efficacy and Safety of Belumosudil in Combination With Corticosteroids Versus Placebo in Combination With Corticosteroids in Participants at Least 12 Years of Age With Newly Diagnosed Chronic Graft Versus Host Disease.
Protocole ID	ROCKnrol-1
ClinicalTrials.gov ID	NCT06143891
Type(s) de cancer	Hémato/Greffe
Phase	Phase III
Type étude	Clinique
Médicament	Belumosudil en association avec des corticosteroids versus placebo en association avec des corticosteroids
Institution	CIUSSS DE L'EST-DE-L'ILE-DE-MONTREAL PAV. MAISONNEUVE/PAV. MARCEL-LAMOUREUX 5415 boul. de l'Assomption, Montréal, QC, H1T2M4
Ville	
Investigateur principal	Dr Jean Roy
Coordonnateur	Michel-Olivier Gratton 514-252-3400 poste 2397
Statut	Actif en recrutement
Date d'activation	15-12-2023
But étude	This is a parallel, Phase 3, two-arm study for the treatment of newly diagnosed moderate or severe chronic GVHD. The study duration for a participant includes up to 4 weeks for screening; a treatment period until clinically meaningful cGVHD progression (defined as progression requiring addition of new systemic treatment for cGVHD), relapse/recurrence of the underlying disease, participant starts new systemic treatment for cGVHD or experiences an unacceptable toxicity, at the request of the participants or the investigators, or until the end of study is reached, whichever comes first; at least 30 days follow-up of adverse events (AEs) after the last dose until resolution or stabilization, if applicable; and long-term follow-up until death or study close-out, whichever comes first.
Critères d'éligibilité	• Patients must be at least 12 years of age inclusive, at the time of signing the informed consent • Participants who have undergone allogenic HCT with newly diagnosed moderate to severe cGVHD according to NIH consensus diagnosis and staging criteria (2014) • Participants who require systemic treatment with corticosteroids for cGVHD • Participants who have not received any prior systemic treatment for cGVHD (including ECP) • If participants are receiving other immunosuppressive agents for the prophylaxis or treatment of acute GVHD, the dose should be under the threshold pre-defined in protocol • Body weight ≥ 40kg • Contraceptive use by men and women should be consistent with local regulations regarding the methods of contraception for those participating in clinical studies. • Participants or their legally authorized representative must be capable of giving signed informed consent

Critères d'exclusion	Medical conditions • Histological relapse of the underlying disease after most recent allogeneic HCT • Post-transplant lymphoproliferative disease within 4 weeks prior to randomization • Female participants who are pregnant or breastfeeding • Unable to tolerate a prednisone equivalent dose of corticosteroids ≥ 1 mg/kg/day Prior/concomitant therapy • Participant has had previous exposure to belumosudil. • Received any previous systemic treatment for cGVHD with the following exception: Corticosteroids for cGVHD received within 7 days prior to the planned administration of IMP only if in the interest of participant. Prior/concurrent clinical study experience • Received any investigational agents, or any investigational device or procedure, or prohibited therapy for this study within 28 days or 5 elimination half-lives prior to randomization, whichever is longer Diagnostic assessments • Karnofsky (if aged ≥16 years)/Lansky (if aged <16 years) Performance Score of < 60 • Platelets <50 x 109/L. Platelet transfusion is not allowed within 3 days before the screening hematological test • Absolute neutrophil count (ANC) <1.0 x 109/L. The use of granulocyte-colony stimulating factor (G-CSF) is not allowed to reach this level during screening • Estimated Glomerular Filtration Rate (eGFR) <30 mL/min/1.73 m2 using the MDRD-4 variable formula (if aged ≥18 years) or using the Bedside Schwartz formula (if aged <18 years) • Aspartate aminotransferase (AST) and/or alanine aminotransferase (ALT) >3 x ULN without liver cGVHD (or >5 × ULN if due to cGVHD with liver cGVHD) • Total bilirubin >1.5 × (ULN) (>3 × ULN if Gilbert syndrome) • Participant has forced expiratory volume in 1 second (FEV1) of predicted ≤39% or has lung score of 3 according to NIH consensus diagnostic and staging criteria (2014) • History or other evidence of severe illness or any other conditions that would make the participant, in the opinion of the Investigator, unsuitable for the study (such as malabsorption syndromes, poorly controlled psychiatric disease or coronary artery disease) • Known history of human immunodeficiency virus (HIV) • Active viral disease including hepatitis B virus (HBV) or hepatitis C virus (HCV) • Active uncontrolled cytomegalovirus (CMV) and Epstein-Barr virus (EBV) infection. Infections are considered controlled if appropriate therapy has been instituted and, at the time of screening, no signs of infection worsening are present according to Investigator's judgement • Diagnosed or treated for another malignancy other than the underlying disease allogeneic HCT was indicated for, within 3 years prior to randomization with the exception of complete resection of basal cell carcinoma or squamous cell carcinoma of the skin, an in-situ malignancy, or low risk prostate cancer after curative therapy • Unable to swallow tablets • Participant not suitable for participation, whatever the reason, as judged by the Investigator, including medical or clinical conditions, or participants potentially at risk of noncompliance to study procedures