Essai Clinique

Généré le 28 avr. 2024 à partir de

Titre	A Phase 1/2 Study of CPI-0610, a Small Molecule Inhibitor of BET Proteins: Phase 1 (in Patients With Hematological Malignancies) and Phase 2 (Dose Expansion of CPI-0610 With and Without Ruxolitinib in Patients With Myelofibrosis)
Protocole ID	CPI-0610-02
ClinicalTrials.gov ID	NCT02158858
Type(s) de cancer	Syndrome myélodysplasique
Phase	Phase II
Stade	Myélofibrose
Type étude	Traitement
Médicament	CPI-0610 avec Ruxolitinib vs CPI-0610 seul
Institution	CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
Ville	Montréal
Investigateur principal	Dre Shireen Sirhan
Coordonnateur	Chadi Zakaria 514-340-8222 poste 28326
Statut	Fermé
But étude	Phase 1 Part (Complete): Open-label, sequential dose escalation study of CPI-0610 in patients with previously treated Acute Leukemia, Myelodysplastic Syndrome, Myelodysplastic/Myeloproliferative Neoplasms, and Myelofibrosis.Phase 2 Part: Open-label study of CPI-0610 with and without Ruxolitinib in patients with Myelofibrosis.CPI-0610 is a small molecule inhibitor of bromodomain and extra-terminal (BET) proteins.
Critères d'éligibilité	• Adult (aged ≥ 18 years) • Phase 2 part: Patients with confirmed diagnosis of MF who meet all of the following criteria: • Dynamic International Prognostic Scoring System (DIPSS; see Appendix 3) risk category of intermediate-1 or higher. • ANC ≥ 1 x 10^9/L without the assistance of granulocyte growth factors • Peripheral blood blast count <10% • ECOG performance status ≤ 2. • Adequate hematological, renal, hepatic, and coagulation laboratory assessments • Patients must give written informed consent to participate in this study before the performance of any study-related procedure. • For Arm 1 and 2 the following criteria should be considered: • Palpable spleen ≥ 5 cm that is below the costal margin on physical examination OR RBC transfusion dependent (defined as an average of ≥2 units of RBC transfusions per month over the 12 weeks prior to enrollment) • At least 2 symptoms measurable (score ≥ 1) using the Myelofibrosis Symptom Assessment Form Version 4.0 (MFSAF v4.0) • Platelet count ≥ 75 x 10^9/L without the assistance of thrombopoietic factors or transfusions for at least 14 days • Monotherapy Arm (Arm 1): Previously treated with a JAK inhibitor and be intolerant, resistant, refractory or lost response to the JAK inhibitor • Combination Arm (Arm 2): Must have received single agent ruxolitinib and be on a stable dose for a minimum 8 weeks

	• For Arm 3 (JAK inhibitors naïve) the following criteria should be considered: • Platelet count ≥ 100 x 10^9/L without the assistance of thrombopoietic factors or transfusions • Palpable spleen ≥ 5 cm that is below the costal margin on physical examination • Anemic, defined as a hemoglobin < 10g/dL • At least 2 symptoms measurable (score ≥ 3) or a total score of ≥ 10 using the MFSAF v4.0 • No prior treatment with JAKi allowed
Critères d'exclusion	• Current known active or chronic infection with human immunodeficiency virus (HIV), Hepatitis B or Hepatitis C. • Impaired cardiac function or clinically significant cardiac diseases • Patients with Child-Pugh Class B or C • Impairment of gastrointestinal (GI) function or GI disease that could significantly alter the absorption of CPI-0610 and/or ruxolitinib, including any unresolved nausea, vomiting, or diarrhea that is CTCAE grade >1 • Prior treatment with a BET inhibitor. • Pregnant or lactating women • Any other concurrent severe and/or uncontrolled concomitant medical condition that could compromise participation in the study • Patients unwilling or unable to comply with this study protocol.