Essai Clinique

Généré le 07 mai 2024 à partir de

Titre	Étude de phase III, à double insu et à répartition aléatoire, contrôlée par témoin actif, comparant le CPI-0610 et le ruxolitinib au placebo et au ruxolitinib chez des patients atteints de MF n'ayant jamais été traités par un inhibiteur des Janus kinases (iJAK).
Protocole ID	MANIFEST-2
ClinicalTrials.gov ID	NCT04603495
Type(s) de cancer	NMP : Vaquez , Thrombocythémie essentielle, Métaplasie myéloide
Phase	Phase III
Type étude	Clinique
Médicament	CPI-0610 et Ruxolitinib versus placebo et Ruxolitinib
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	Dre Natasha Szuber
Coordonnateur	Michaël Harnois 514-252-3400 poste 6288
Statut	Fermé
But étude	A Phase 3, randomized, blinded study comparing CPI-0610 and ruxolitinib with placebo and ruxolitinib in myelofibrosis (MF) patients that have not been exposed previously to Janus kinase inhibitors (JAKi). CPI-0610 is a small molecule inhibitor of bromodomain and extra-terminal (BET) proteins. Evidence suggests that inhibition of both BET and JAK pathways can result in synergistic reduction of disease and overall improvement in the prognosis of MF.
Critères d'éligibilité	• Aged ≥ 18 years • Confirmed diagnosis of myelofibrosis (primary, post-polycythemia vera, or post essential thrombocythemia) • Adequate hematologic, renal, and hepatic function • Have at least 2 symptoms with an average score ≥ 3 or an average total score of ≥ 10 over the 7-day period prior to randomization using the MFSAF v4.0 • Prognostic risk-factor score of Intermediate-1 or higher per Dynamic International Prognostic Scoring System (DIPSS) scoring system • Spleen volume of ≥ 450 cm^3 • Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2
Critères d'exclusion	• Splenectomy or splenic irradiation in the previous 6 months • Chronic or active conditions and/or concomitant medication use that would prohibit treatment • Had prior treatment with any JAKi or BET inhibitor for treatment of a myeloproliferative neoplasm