Essai Clinique

Généré le 19 avr. 2024 à partir de

Titre	A Randomized, Open-label, Phase I/II Open Platform Study Evaluating Safety and Efficacy of Novel Ruxolitinib Combinations in Myelofibrosis Patients
Protocole ID	ADORE
ClinicalTrials.gov ID	NCT04097821
Type(s) de cancer	NMP : Vaquez , Thrombocythémie essentielle, Métaplasie myéloide
Phase	Phase I-II
Type étude	Clinique
Médicament	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	The purpose of this study is to investigate the safety, pharmacokinetics and preliminary efficacy of combinations treatment of ruxolitinib with 5 novel compounds: siremadlin, crizanlizumab, sabatolimab, LTT462 and NIS793 in myelofibrosis (MF) subjects.
Critères d'éligibilité	• Subjects have diagnosis of primary myelofibrosis (PMF) according to the 2016 World Health Organization (WHO) criteria, or diagnosis of post-essential thrombocythemia (ET) (PET-MF) or post-polycythemia vera (PV) myelofibrosis (PPV-MF) according to the International Working Group for Myelofibrosis Research and Treatment (IWG-MRT) 2007 criteria • Palpable spleen of at least 5 cm from the left costal margin (LCM) to the point of greatest splenic protrusion or enlarged spleen volume of at least 450 cm3 per MRI or CT scan at baseline (a MRI/CT scan up to 8 weeks prior to first dose of study treatment can be accepted). • Have been treated with ruxolitinib for at least 24 weeks prior to first dose of study treatment • Are stable (no dose adjustments) on the prescribed ruxolitinib dose (between 5 and 25 mg twice a day (BID)) for ≥ 8 weeks prior to first dose of study treatment
Critères d'exclusion	• Not able to understand and to comply with study instructions and requirements. • Received any investigational agent for the treatment of MF (except ruxolitinib) within 30 days of first dose of study treatment or within 5 half-lives of the study treatment, whichever is greater • Peripheral blood blasts count of > 10%. • Received a monoclonal antibody (Ab) or immunoglobulin-based agent within 1 year of screening, or has documented severe hypersensitivity reactions/immunogenicity (IG) to a prior biologic • Splenic irradiation within 6 months prior to the first dose of study drug • Received blood platelet transfusion within 28 days prior to first dose of study treatment. Other protocol-defined Inclusion/Exclusion criteria may apply.