Essai Clinique

Généré le 05 mai 2024 à partir de

Titre	A Phase 2a, Randomized, Open-Label Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ISIS 702843 Administered to Patients With Phlebotomy Dependent Polycythemia Vera (PD-PV)
Protocole ID	ISIS 702843-CS4
ClinicalTrials.gov ID	NCT05143957
Type(s) de cancer	NMP : Vaquez , Thrombocythémie essentielle, Métaplasie myéloide
Phase	Phase II
Type étude	Clinique
Médicament	IONIS-TMPRSS6-LRx
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL H SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dr Jonathan How
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Statut	Actif en recrutement
Date d'activation	25-08-2022
But étude	The main purpose of this study is to evaluate the efficacy of IONIS-TMPRSS6-LRx in reducing the frequency of phlebotomy and in improving quality of life assessments in participants with polycythemia vera.
Critères d'éligibilité	• Meet modified World Health Organization (WHO) 2016 diagnostic criteria for polycythemia vera (PV) at the time of clinical diagnosis • Participant must be phlebotomy dependent. • If the participant is currently on cytoreductive therapy or has been previously treated with cytoreductive therapy, the participant's cytoreductive therapy must either be discontinued at least 3 months prior to Screening, OR participant must be on a stable dose for at least 3 months prior to Screening.
Critères d'exclusion	• Meets criteria for post-polycythemia vera myelofibrosis (PPV-MF) as defined by the International Working Group- Myeloproliferative Neoplasms Research and Treatment (IWG-MRT) • Moderate to severe splenic pain or spleen-related organ obstruction • Active or chronic bleeding within 1 month of Screening, significant concurrent/recent coagulopathy, history of immune thrombocytopenic purpura (ITP) • Known primary or secondary immunodeficiency • Active infection with human immunodeficiency virus (HIV), hepatitis C, or hepatitis B. • Active infection requiring systemic antiviral or antimicrobial therapy or active novel coronavirus disease (Covid-19) infection • Malignancy within 5 years, except for basal or squamous cell carcinoma of the skin or carcinoma in situ of the cervix or non-metastatic prostate cancer that has been successfully treated • Surgery requiring general anesthesia within 1 month prior to Screening