Essai Clinique

Généré le 05 mai 2024 à partir de

Titre	A Randomized, Open-Label, Phase 1-2 Study of ASTX727 Low Dose (ASTX727 LD) Extended Schedule in Subjects With Lower Risk (IPSS Low or Intermediate-1) Myelodysplastic Syndromes (MDS)
Protocole ID	ASTX727-03
ClinicalTrials.gov ID	NCT03502668
Type(s) de cancer	Syndrome myélodysplasique
Phase	Phase I-II
Type étude	Clinique
Médicament	ASTX727
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
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Statut	Fermé
Date d'activation	25-07-2022
But étude	Multicenter, open-label study of various ASTX727 LD doses and schedules to assess safety, pharmacodynamics, pharmacokinetics, and hematologic response in subjects with International Prognostic Scoring System (IPSS) risk category of low-risk or Intermediate-1 MDS. This study will be conducted in two phases. In phase 1 subjects will be randomized into 3 cohorts in a 28-day cycles. Phase 2, 80 new subjects will be randomized in a 1:1 ratio into 2 doses/schedules.

Critères d'éligibilité	• Able to understand and comply with the study procedures, understand the risks involved in the study, and provide written informed consent before the first study-specific procedure.
	• Men or women ≥18 years with IPSS low risk or Int-1 MDS (all subjects). Subjects must have had at least 1 of the following disease-related criteria during the 8 weeks before randomization:
	  • Red blood cell (RBC) transfusion dependence of 2 or more units of RBC transfusions (RBC transfusion administered for hemoglobin (Hb) levels ≤9.0 g/dL are counted).
	  • Hb of <9.0 g/dL in at least 2 blood counts prior to randomization or in 1 blood count if RBC transfusion was received.
	  • Absolute Neutrophil Count (ANC) of <0.5 × 10^9/L in at least 2 blood counts prior to randomization.
	  • Platelet counts of <50 × 10^9/L in at least 2 blood counts prior to randomization.
	• Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2.
	• Adequate organ function.
	• Women of child-bearing potential (according to recommendations of the Clinical Trial Facilitation Group [CTFG]) must not be pregnant or breastfeeding and must have a negative pregnancy test at screening.
	• Women of child-bearing potential must agree to use contraceptive measures of birth control for 6 months after completing treatment; men must use contraceptive measures and agree not to father a child for at least 3 months after completing treatment.

Critères d'exclusion	• Treatment with any investigational drug or therapy within 2 weeks before study treatment. • Treatments for MDS must be concluded 1 month prior to study treatment. • Prior treatment with azacitidine, decitabine, or guadecitabine. • Diagnosis of chronic myelomonocytic leukemia (CMML). • Poor medical risk because of other conditions such as uncontrolled systemic diseases or active uncontrolled infections. • Prior malignancy, except for adequately treated basal cell or squamous cell skin cancer, in situ cervical cancer, prostate cancer or breast cancer under control with hormone therapy, or other cancer from which the subject has been disease free for at least 1 year. • Known active infection with human immunodeficiency virus or hepatitis viruses.