Essai Clinique

Généré le 29 mars 2024 à partir de

Titre	Étude de phase 3 multicentrique, ouverte et à répartition aléatoire comparant le ponatinib par rapport à l'imatinib, administré en association à une chimiothérapie d'intensité réduite, chez des patients ayant un nouveau diagnostic de leucémie aiguë lymphoblastique à chromosome Philadelphie positif (LAL Ph+)
Protocole ID	Ponatinib-3001
ClinicalTrials.gov ID	NCT03589326
Type(s) de cancer	Leucémie lymphoide aiguë (LLA)
Phase	Phase III
Type étude	Traitement
Médicament	Ponatinib vs Imatinib
Institution	CISSS DE LA MONTEREGIE-CENTRE HOPITAL CHARLES-LE MOYNE 3120 boulevard Taschereau, Greenfield Park, QC, J4V2H1
Ville	Greenfield Park
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Statut	Fermé
But étude	The purpose of this study is to compare the efficacy of ponatinib versus imatinib, administered as first-line therapy in combination with reduced-intensity chemotherapy, in participants with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), as measured by the minimal residual disease (MRD)-negative complete remission (CR) at the end of induction.
Critères d'éligibilité	• Newly diagnosed Philadelphia chromosome-positive (Ph+) or BCR-ABL1-positive ALL, as defined by the 2017 national comprehensive cancer network (NCCN) guidelines. • Molecular assessment of BCR-ABL1 must demonstrate the presence of a p190 (that is e1a2) or p210 (ie, e13a2 or e14a2 [also known as b2a2 or b3a2]) transcript type. • Eastern Cooperative Oncology Group (ECOG) performance status of <=2.
Critères d'exclusion	• With a history or current diagnosis of chronic phase, accelerated phase, or blast phase chronic myeloid leukemia (CML). • Prior/current treatment with any systemic anticancer therapy (including but not limited to any tyrosine kinase inhibitor [TKI]) and/or radiotherapy for cancer, with the exception of an optional prephase therapy, which should be discussed with the sponsor's medical monitor/designee. • Currently taking drugs that are known to have a risk of causing prolonged QTc or torsades de pointes (TdP) (unless these can be changed to acceptable alternatives or discontinued). • Taking any medications or herbal supplements that are known to be strong inhibitors or strong inducers of cytochrome P450 (CYP)3A4 within at least 14 days before the first dose of study drug. • Active serious infection requiring antibiotics within 14 days before the first dose of study drug. • Major surgery within 28 days before randomization (minor surgical procedures such as catheter placement or BM biopsy are not exclusionary criteria). • Ongoing or active systemic infection, known seropositive human immunodeficiency virus (HIV), known active hepatitis B or C infection. • History of acute pancreatitis within 1 year of study screening or history of chronic pancreatitis. • Uncontrolled hypertriglyceridemia (triglycerides >450 mg/dL). • Diagnosed and treated for another malignancy within 5 years before randomization or previously diagnosed with another malignancy and have any evidence of residual disease.

Participants with nonmelanoma skin cancer or carcinoma in situ of any type are excluded if they have not undergone complete resection.

- History or presence of clinically relevant CNS pathology such as epilepsy, childhood or adult seizure, paresis, aphasia, stroke, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or psychosis.
- Clinical manifestations of CNS or extramedullary involvement with ALL.
- Autoimmune disease with potential CNS involvement.
- Known significant neuropathy of Grade >=2 severity.
- Clinically significant, uncontrolled, or active cardiovascular, cerebrovascular, or peripheral vascular disease, or history of or active venous thrombotic/embolic event.
- Had a significant bleeding disorder unrelated to ALL.