# Essai Clinique

Généré le 29 mars 2024 à partir de

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| 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 + Chimiothérapie d'intensité réduite |
| Institution | CIUSSS DE L'EST-DE-L'ILE-DE-MONTREAL<br>PAV. MAISONNEUVE/PAV. MARCEL-LAMOUREUX<br>5415 boul. de l'Assomption, Montréal, QC, H1T2M4 |
| Ville | |
| Investigateur principal | Dre Julie Bergeron |
| Coordonnateur | Julie Trinh Lu<br>514-252-3400 poste 3336 |
| Statut | Fermé |
| But étude | Déterminer si le ponatinib sera plus efficace que l'imatinib chez les patients atteints de leucémie aiguë lymphoblastique à chromosome Philadelphie positif (LAL Ph+). |
| Critères d'éligibilité | • Male or female patients aged 18 years or older.<br>• Newly diagnosed Ph+ or BCR-ABL1-positive ALL, as defined by the 2017 NCCN guidelines.<br>• Molecular assessment of BCR-ABL1 must demonstrate the presence of a p190 (ie, e1a2) or p210 (ie, e13a2 or e14a2 [also known as b2a2 or b3a2]) transcript type.<br>• Eastern Cooperative Oncology Group (ECOG) performance status of ≤2.<br>• Clinical laboratory values as follows, within 30 days before randomization: a) Total serum bilirubin ≤1.5× the upper limit of normal (ULN). b) Alanine aminotransferase or aspartate aminotransferase (AST) ≤2.5× the ULN. c) Serum creatinine ≤1.5× the ULN and estimated creatinine clearance (CrCl) ≥40 mL/minute (Cockcroft-Gault formula). d) Serum lipase and amylase <1.5× the ULN.<br>• Normal QT interval corrected per Fridericia method (QTcF) on screening electrocardiogram (ECG), defined as QTcF of ≤450 ms in males or ≤470 ms in females.<br>• Female patients who: a) Are postmenopausal for at least 1 year before the screening visit, OR b) Are surgically sterile, OR c) If they are of childbearing potential, agree to practice 1 highly effective method of contraception and 1 additional effective (barrier) method at the same time, from the time of signing the informed consent through 1 month after the last dose of study drug, OR d) Agree to practice true abstinence, when this is in line with the preferred and usual lifestyle of the subject. (Periodic abstinence [eg, calendar, ovulation, symptothermal, postovulation methods], withdrawal, spermicides only, and lactational amenorrhea are not acceptable methods of contraception. Female and male condoms should not be used together.)<br>• Male patients, even if surgically sterilized (ie, status postvasectomy), who: a) Agree to practice effective barrier contraception during the entire study treatment period and through 120 days after the last dose of study drug, OR b) Agree to practice true abstinence, when this is in line with the preferred and usual lifestyle of the subject. (Periodic abstinence [eg, calendar, ovulation, symptothermal, postovulation methods], withdrawal, spermicides only, and lactational amenorrhea are not acceptable methods of contraception. Female and male condoms should not be used together.) |

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| | • Voluntary written consent must be given before performance of any study-related procedure not part of standard medical care, with the understanding that consent may be withdrawn by the patient at any time without prejudice to future medical care.<br>• Willingness and ability to comply with scheduled visits and study procedures. |
| Critères d'exclusion | • Patients with a history or current diagnosis of chronic phase, accelerated phase, or blast phase CML.<br>• Prior/current treatment with any systemic anticancer therapy (including but not limited to any TKI) and/or radiotherapy for ALL, with the exception of an optional prephase therapy, which should be discussed with the sponsor’s medical monitor/designee.<br>• Treatment with any investigational products within 30 days before randomization or 6 half-lives of the agent, whichever is longer.<br>• 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) (Appendix E).<br>• 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 (Appendix F).<br>• Active serious infection requiring antibiotics within 14 days before the first dose of study drug.<br>• Major surgery within 28 days before randomization (minor surgical procedures such as catheter placement or BM biopsy are not exclusionary criteria).<br>• Ongoing or active systemic infection, known seropositive HIV, known active hepatitis B or C infection.<br>• History of acute pancreatitis within 1 year of study screening or history of chronic pancreatitis.<br>• Uncontrolled hypertriglyceridemia (triglycerides >450 mg/dL).<br>• Diagnosed and treated for another malignancy within 5 years before randomization or previously diagnosed with another malignancy and have any evidence of residual |