Essai Clinique

Généré le 27 avr. 2024 à partir de

Titre	A Phase 3b, Multicenter, Open-label, PCI-32765 (Ibrutinib) Long-term Extension Study
Protocole ID	PCI-32765CAN3001
ClinicalTrials.gov ID	NCT01804686
Type(s) de cancer	Leucémie lymphoïde chronique (LLC)
Phase	Phase III
Type étude	Traitement
Médicament	Ibrutinib
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
Ville	Montréal
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Statut	Fermé
But étude	The purpose of this study is to collect long-term safety and efficacy data for participants treated with PCI-32765 (Ibrutinib) and to provide ongoing access to PCI-32765 for participants who are currently enrolled in PCI-32765 studies that have been completed according to the parent protocol, are actively receiving treatment with PCI-32765, and who continue to benefit from PCI-32765 treatment.
Critères d'éligibilité	• Participants must be currently participating in a PCI-32765 clinical study considered completed and have received at least 6 months of treatment with PCI-32765. • At study entry, participants must be actively receiving treatment with single-agent PCI-32765 or participants must have participated in a PCI-32765 randomized clinical study in which they initially received comparator treatment and now cross-over to ibrutinib. Note: A minimum of 6 months requirement for prior PCI-32765 treatment will not be mandatory in this case and participants with less than 6 months will be required to have more frequent initial safety assessments • Agrees to protocol-defined use of effective contraception • Negative blood or urine pregnancy test at screening
Critères d'exclusion	• Requires anticoagulation with warfarin or equivalent vitamin K antagonists • Requires treatment with strong cytochrome P450 (CYP)3A4/5 inhibitors, unless previously approved by sponsor • Any condition or situation which, in the opinion of the investigator, may put the participant at significant risk, may confound the study results, or may interfere significantly with volunteer's participation in the study