Essai Clinique

Généré le 18 avr. 2024 à partir de

Titre	An International, Phase 2, Open-Label, Randomized Study of BGB-3111 Combined With Obinutuzumab Compared With Obinutuzumab Monotherapy in Relapsed/ Refractory Follicular Lymphoma
Protocole ID	BGB-3111-212 (ROSEWOOD)
ClinicalTrials.gov ID	NCT03332017
Type(s) de cancer	Lymphome non-hodgkinien (LNH)
Phase	Phase II
Stade	Lymphome folliculaire/zone marginale
Type étude	Traitement
Médicament	BGB-3111 avec Obinutuzumab vs Obinutuzumab seul
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 the study is to evaluate the efficacy, safety and tolerability and of BGB-3111plus obinutuzumab versus obinutuzumab alone in subjects with relapsed/refractory non-Hodgkin follicular lymphomaThis is an open-label, randomized active control study of BGB-3111 plus obinutuzumab versus obinutuzumab alone in subjects with relapsed or refractory follicular lymphoma. Randomization is 2:1 and subjects will be stratified by the number of prior lines of therapy (2 - 3 vs > 3) and rituximab-refractory status. The study will evaluate the efficacy, as measured by overall response rate by independent review, safety and tolerability. Pharmacokinetic profile of BGB-3111 and obinutuzumab combination therapy will also be evaluated.
Critères d'éligibilité	• Histologically confirmed diagnosis of B-cell follicular lymphoma based on the WHO 2008 classification of tumors of hematopoietic and lymphoid tissue. • ≥2 prior systemic treatments for follicular lymphoma. • Previously received an anti-CD20 antibody and an appropriate alkylator-based combination therapy. • Disease progression within 12 months after completion of most recent therapy or refractory disease. • Presence of measurable disease. • Availability of archival tissue confirming diagnosis. • ECOG performance status of 0,1 or 2. • Life expectancy ≥6 months. • Adequate bone marrow function. • Adequate renal and hepatic function. • Females of childbearing potential and non-sterile males must agree to use highly effective methods of birth control throughout the course of study and at least up to 90 days after last dosing, or 18 months after the last dose of obinutuzumab, whichever is longer. • Male subjects are eligible if vasectomized or if they agree to the use of barrier contraception in combination with other methods during the study treatment period and for ≥ 90 days after the last dose of BGB-3111.

	• Ability to provide the written informed consent and can understand and comply with the requirements of the study.
Critères d'exclusion	• Prior exposure to a BTK inhibitor. • Known central nervous system involvement by leukemia or lymphoma. • No evidence of transformation from follicular lymphoma to other aggressive histology. • No allogeneic hematopoietic stem cell transplantation within 12 months of enrollment • Prior malignancy within the past 5 years, except for basal or squamous cell skin cancer, superficial bladder cancer, carcinoma in situ of the cervix of breast, or localized Gleason score 6 prostate • Clinically significant cardiovascular disease. • Major surgery or significant injury ≤ 4 weeks prior to start of study treatment. • Active fungal, bacterial or viral infection requiring systemic treatment. • History of severe bleeding disorder. • History of stroke or intracranial hemorrhage within 6 months before first study drug. • Severe or debilitating pulmonary disease. • Known human immunodeficiency virus (HIV) or active hepatitis B or C. • Unable to swallow capsules or significant gastrointestinal disease that would interfere with drug absorption. • Requires ongoing treatment with a strong CYP3A inhibitor or inducer • Pregnant or nursing females. • Vaccination with live vaccine within 35 days prior to first dose. • Ongoing drug or alcohol addiction. • Hypersensitivity to BGB-3111, known ingredients of BGB-3111 or obinutuzumab. • Participation in another therapeutic trial.