BGB-3111-212 - BGB-3111-212 (dernière mise à jour : 27/01/2020)

http://archimaid.fr/index.php?action=show&id=951

Informations générales

Titre de l'étude : Etude de Phase 2 randomisée, ouverte comparant BGB-3111 + l'Obinutuzumab VS Obinutuzumab en monothérapie (ratio 2:1) dans les Lymphomes folliculaires en rechutes ou réfractaires (ROSEWOOD)

Traitement :

Type d'étude : Hors ciblage moléculaire

Phase : II **Stade** : NA **Ligne(s)** :

Schéma : This 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.

Study arms:
- Experimental: Arm A
Approximately 140 subjects to receive BGB-3111 and obinutuzumab
Interventions:
- Experimental: Arm B
Approximately 70 subjects to receive obinutuzumab

Current primary outcome:
Objective response rate (ORR) [Time Frame: up to 3 years]

Current secondary outcomes:
- Progression free survival (PFS) [Time Frame: up to 3 years]
- Duration of response (DOR) [Time Frame: up to 3 years]
- Time to response (TTR) [Time Frame: up to 3 years]
- Incidence, timing, severity of treatment-emergent AEs [Time Frame: up to 3 years]
- Safety and Tolerability

Spécialités / Localisations

Spécialité n°1 : Tissus lymphoïde, hématopoïétique et apparentés

CIM10 - Localisation n°1 : **C82** - Lymphome folliculaire

Critères

Critères d'inclusion : - 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 de non-inclusion :
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.

Informations promoteur

Nom du promoteur : Beigene

Type de promoteur : Industriel

Adresse : - 00000 HORS FRANCE

Coordonnateur : - *Mail :* - *Tél :*

Informations centre investigateur n°1

Nom du centre : Centre hospitalier de Dunkerque

Adresse : 130, avenue Louis Herbeaux 59140 DUNKERQUE

Investigateur : Docteur Jean-Michel PIGNON

TEC / ARC / IDE : Virginie EL AZOUZI - PAQUEZ - *Mail :* Virginie.Paquez@ch-dunkerque.fr - *Tél :* 03 28 28 59 00 poste 6485

Ouverture de l'essai : OUVERT

Liens utiles

ClinicalTrials (anglais) : https://clinicaltrials.gov/ct2/show/NCT03332017?term=BeiGene+BGB-3111-212&rank=1