# BGB-A317-301 - (dernière mise à jour : 24/10/2019)

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## Informations générales

**Titre de l'étude** : Étude multicentrique de phase III, randomisée, en ouvert, visant à comparer l'efficacité et la sécurité d'emploi du BGB-A317 par rapport au sorafénib dans le traitement de première intention chez des patients atteints d'un carcinome hépatocellulaire non résécable

**Traitement** : Métastasique ou localement avancé

**Type d'étude** : Ciblage moléculaire / Innovation thérapeutique

**Phase** : III **Stade** : Localisé à Métastatique **Ligne(s)** : 1

**Schéma** : This is a Phase 3, randomized, open-label, multicenter, global study designed to compare the efficacy and safety of BGB-A317 versus sorafenib as a first-line systemic treatment in patients with unresectable hepatocellular carcinoma.

2 treatment arms:
- Experimental: Arm A: BGB-A317
- Active Comparator: Arm B: Sorafenib

## Spécialités / Localisations

**Spécialité n°1** : Organes digestifs

**CIM10 - Localisation n°1** : **C22** - Tumeur maligne du foie et des voies biliaires intrahépatiques

## Critères

**Critères d'inclusion** : 1. Histologically confirmed diagnosis of HCC

2. Barcelona Clinic Liver Cancer (BCLC) Stage B or C disease not amenable to or progressing after loco-regional therapy and not amenable to a curative treatment approach

3. No prior systemic therapy for HCC (with the exception of HCC patients enrolled in the safety run-in substudy [Japan only])

4. Measurable disease

5. Child-Pugh score A

6. Easter Cooperative Oncology Group (ECOG) Performance Status <= 1

7. Adequate organ function

**Critères de non-inclusion** : 1. Known fibrolamellar HCC, sarcomatoid HCC, or mixed cholangiocarcinoma and HCC histology

2. Tumor thrombus involving main trunk of portal vein or inferior vena cava

3. Loco-regional therapy to the liver within 28 days before randomization

4. Clinical evidence of portal hypertension with bleeding esophageal or gastric varices at Screening, or within 6 months before randomization

5. Bleeding or thrombotic disorder or any prescribed anticoagulant requiring therapeutic international normalized ratio monitoring (eg, warfarin or similar agents) at Screening, or within 6 months before randomization/enrollment

6. Presence at Screening of active immune deficiency or autoimmune disease and/or prior history of any immune deficiency or autoimmune disease that may relapse

7. Patient with any condition requiring systemic treatment with either corticosteroids (> 10 mg daily of prednisone or equivalent) or other immunosuppressive medication within 14 days before randomization

8. History of interstitial lung disease or non-infectious pneumonitis, unless induced by radiation therapy

9. QT interval corrected for heart rate (QTc) (corrected by Fridericia's method) > 450 msec at Screening

## 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 Universitaire de Lille

**Adresse** : 2 Avenue Oscar Lambret 59000 LILLE

**Investigateur** : Professeur Philippe MATHURIN

**TEC / ARC / IDE** : Madame Daphnée SORET - *Mail :* Daphnee.SORET@CHRU-LILLE.FR - *Tél :* 03 20 44 59 62 - Poste 30671

**Ouverture de l'essai** : CLOS

## Liens utiles

**ClinicalTrials** : https://clinicaltrials.gov/ct2/show/NCT03412773