REGOMAIN

A randomized, placebo-controlled, double-blinded, multicentre, comparative phase II study of the efficacy of regorafenib as maintenance treatment in patients with high grade bone sarcomas (HGBS) at diagnosis or relapse and without complete remission after standard treatment

Nom du Centre porteur : Centre Léon Bérard

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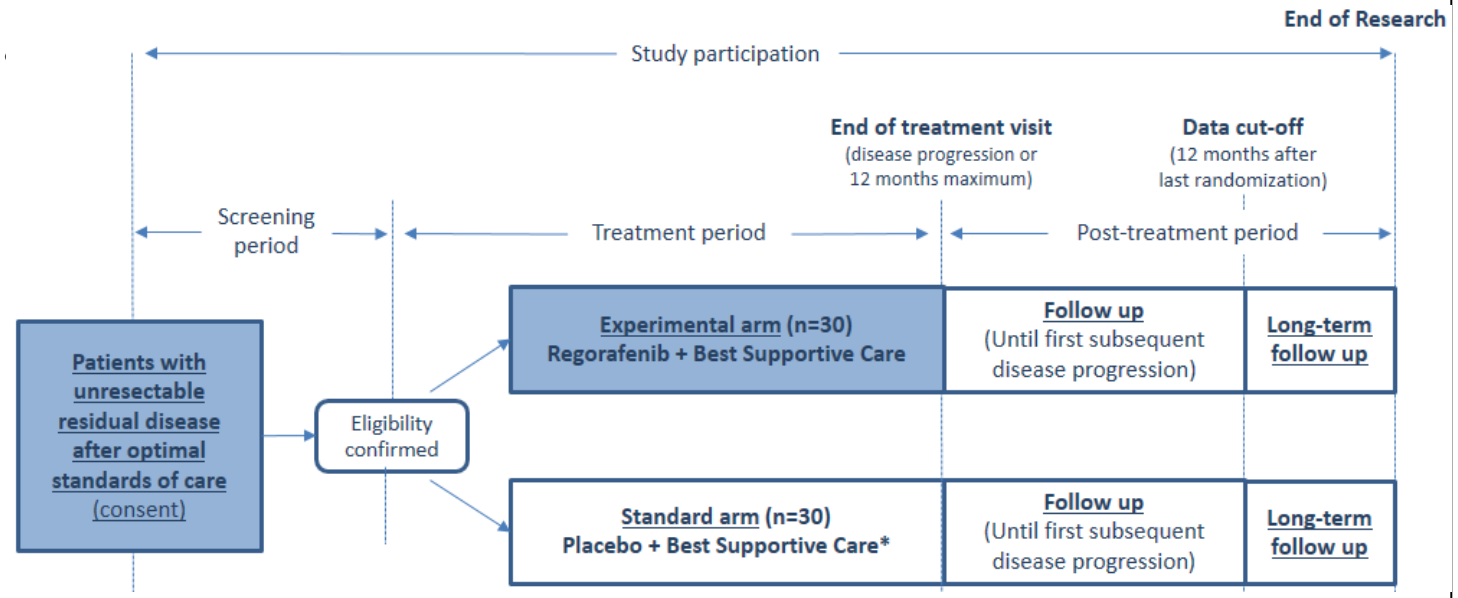
Centres participants

- **Centre Léon Bérard, Lyon**
- Hôp. Jean Minjoz, Besançon
- **Institut de Cancérologie Lucien Neuwirth, Saint Priest en Jarez**
- CHU la Timone, Marseille
- **Institut Bergonié, Bordeaux**
- Centre Oscar Lambret, Lille (en signature)
- **Institut de Cancérologie de l'Ouest, Saint-Herblain**
- **IUCT, Toulouse**
- APHP, Hôp. Cochin
- Institut de Cancérologie de Montpellier
- Institut de Cancérologie Strasbourg Europe
- CHRU Strasbourg
- Centre G.-F. Leclerc, Dijon
- Institut Curie, Paris (à déclarer)

Molécules, schéma de traitement

- **Randomization 1:1 to receive either REGORAFENIB or PLACEBO** during 12 months, as maintenance therapy, in patients with residual disease after standard treatments
- Stratification : residual disease at diagnosis or at relapse after standard multimodal treatment
- REGORAFENIB : 120 mg /d, 3 weeks on/1 week off during 12 months OR



Indication : Situation avancée non opérable, 4e ligne et plus après traitements standard (imatinib, sunitinib, regorafenib)

Principaux critères d'inclusion

- Histologically confirmed diagnosis of **Osteosarcoma** (conventional-intramedullary/central High grade, small cell, telangiectatic or high-grade surface OS),
- **Bone sarcoma** other than Ewing sarcoma, chondrosarcoma, chordoma)
- Availability of FFPE block
- **Measurable residual disease** not amenable to resection after multimodal treatment principles either at diagnosis (after surgery and pre and/or post-surgery chemotherapy) or at first relapse (chemotherapy)
- Non-progressive (RECIST 1.1) at study entry,
- Age ≥ 16 years,
- ECOG PS <= 2 (Karnofsky ≥ 70% for < 18yrs)

Endpoint et stat succintes

Primary end-point : Progression-Free Survival (PFS)

Secondary end-points : Objective Response Rate (ORR), Disease Control Rate (DCR), Time to Treatment Failure (TTF), Overall Survival (OS), Quality of Life (EORTC QLQ-C30), tolerance profile (NCI-CTC AE version 5).

PFS at 4 months 30% (H0), α = 5% (*2-sided*),

HR= 0.42, H1 = 60%

A total of 52 events would have 87% power to show a significant improved PFS

52 events required to perform analysis,

➔ **60 patients to be randomized : 30 per arm**

Etat d'avancement

Etat du recrutement

- Nombre de patients inclus : 3
- Nombre de patients restant à inclure : 60
- Fermeture prévue le : 36 mois de recrutement

Problème/ Amendement à venir

- **Ouverture effective de l'ensemble des centres (relances en cours)**
- **Amendement :**
  - **Inclusion des patients de au moins 12 ans (actuellement âge de au moins 16 ans)**
  - **Ajout de sous-types histologiques (CS, Ewing et autres sarcomes osseux hors chordomes)**

  > TC Bayer à venir

  ➢ **Soumission Dec. 2021 / Activation Feb. 2022**