REGOSTA

A Randomized Phase II, placebo-controlled, multicenter study evaluating the efficacy and safety of regorafenib as maintenance post first-line treatment in patients with bone sarcomas

Centre porteur: Centre Léon Bérard

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Centres participants

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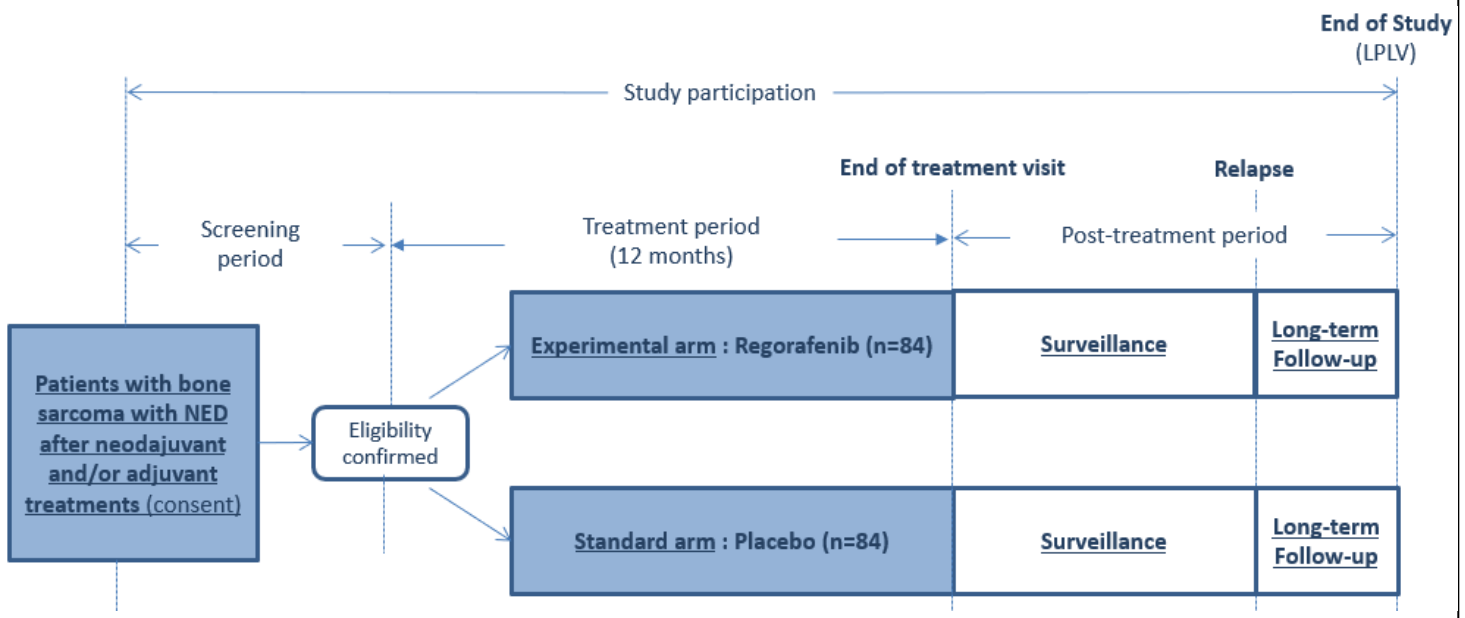
- Gustave Roussy, Villejuif
- APHP, Hôp. Cochin
- Institut de Cancérologie de Montpellier
- Institut de Cancérologie Strasbourg Europe
- CHRU Strasbourg
- CHU Poitiers (convention envoyée)

Molécules, schéma de traitement

- **Randomization 1:1 to receive either REGORAFENIB or PLACEBO** during 12 months, as maintenance therapy, after completed neadjuvant and adjuvant chemotherapy
- Stratification on Risk factor : High Risk vs Low Risk



Indication : en situation de maladie (localisée/métastatique) invisible - non mesurable, après la fin de la chimiothérapie adjuvante

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
- **CONFIRMED Complete remission of NO EVIDENCE of disease** (after complete resection of mets for met disease)
- Prior treatment for **localized or metastatic** disease for OS or other Bone Sarcoma should include the following : Neoadjuvant chemotherapy (with histological response),Local procedure and (complete surgical resection or radiotherapy if tumor unresectable), Adjuvant chemotherapy
    - Age ≥ 16 years**,
- ECOG PS <= 2 (Karnofsky ≥ 70% for < 18yrs)

Endpoints , Statistics

Primary end-point : RFS

Secondary end-points : Time to Treatment Failure (TTF),

Overall Survival,Quality of Life (EORTC QLQ-C30), tolerance profile (NCI-CTC AE version 5),Compliance to study treatment

RFS at 3yrs at 55% (H0), α = 5% (*2-sided*),

HR= 0.50, H1 = 74.6%

A total of 66 events would have 80% power to show a significant improved RFS

66 events required to perform analysis,

➔ in total total 168 patients to beincluded : 84 in arm A/ 84 in am B

Etat d'avancement

Etat du recrutement

- Nombre de patients inclus : 11
- Nombre de patients à inclure : 168
- Fermeture prévue le : 11.02.2023 (First patient + 36 months)

Problème/ Amendement à venir

- **Recrutement**
- **Amendement :**
  - **Inclusion des patients de au moins 12 ans (actuellement âge de au moins 16 ans)**
  - **Ajout de sous-types histologiques (Chondros)**

  > TC Bayer à venir

  > Soumission Dec. 2021 / Activation Feb. 2022