

REGO-INTER-EWING-1

Phase Ib study of the combination of regorafenib with conventional chemotherapy for the treatment of newly diagnosed patients with multimetastatic Ewing sarcoma

Gustave Roussy

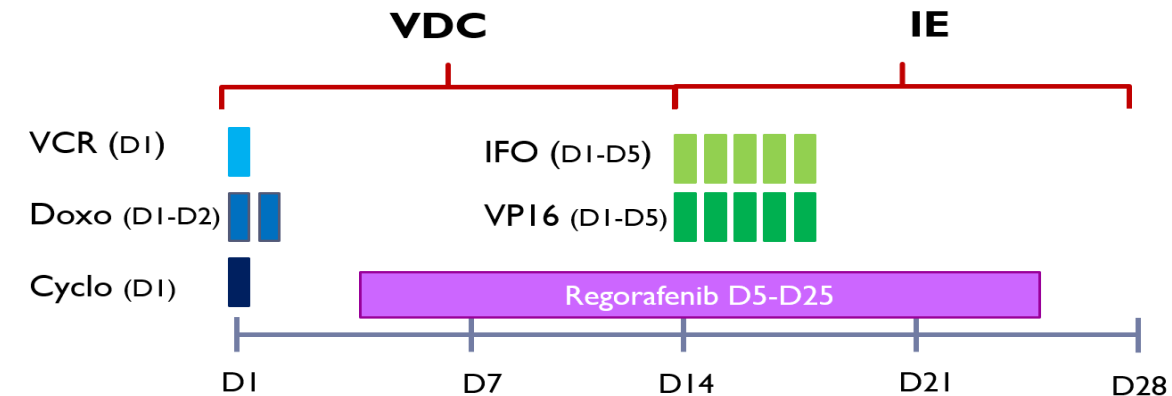
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Centres participants

- 15 centres en Europe (France, Italy, UK, Spain, Netherlands)
- 4 centres in France: IGR, Lyon, Lille, Bordeaux à confirmer.

Molécules, schéma de traitement

- Traitement standard sarcome d'Ewing métastatique (hors poumon/pleura): VDC/IE (concomitant avec regorafenib) + traitement local + BuMel



VCR: 2 mg/m²/d (max 2 mg) D1
Doxo: 37.5 mg/m²/d D1-D2
Cyclo: 1200 mg/m²/d D1

IFO: 1800 mg/m²/d D1-D5
VPI6: 100 mg/m²/d D1-D5

DLI: 82 mg/m² (100% single-agent RP2D) 21 days on/7 days off

DL0: 66 mg/m² (80% single-agent RP2D) 21 days on/7 days off

DL-1: 50 mg/m² (60% single-agent RP2D) 21 days on/7 days off

Indication : Newly diagnosed patients with multimetastatic Ewing sarcoma (other than lung/pleura)

Principaux critères d'inclusion

- Metastatic Ewing sarcoma (other than pleura/lung)
- >2 years and < 50 years
- No previous chemotherapy

Endpoint et stat succinctes

- Hypothèse stat : phase Ib (TITE-CRM)
- Endpoint 1aire : MTD/RP2D
- Endpoints 2aire : OS/PRS
- Nombre de patients nécessaires : 24 patients

Etat d'avancement

Etat du recrutement

- Financement FKC call 2021
- Regorafenib (BAYER IIS)
- Début Q2 2022

- Selon résultats: phase III randomisé (INTER-EWING-1, R1: VDC/IE ± regorafenib)

Problème/ Amendement à venir

