



# Promotion Centre Léon Bérard

Portfolio études onco sarcomes - Juin 2021

# RAR-IMMUNE

Etude randomisée, comparative, prospective, multicentrique, de l'efficacité de nivolumab + ipilimumab + pazopanib versus pazopanib seul chez des patients porteurs de sarcomes rares des tissus mous avancés ou métastatiques.

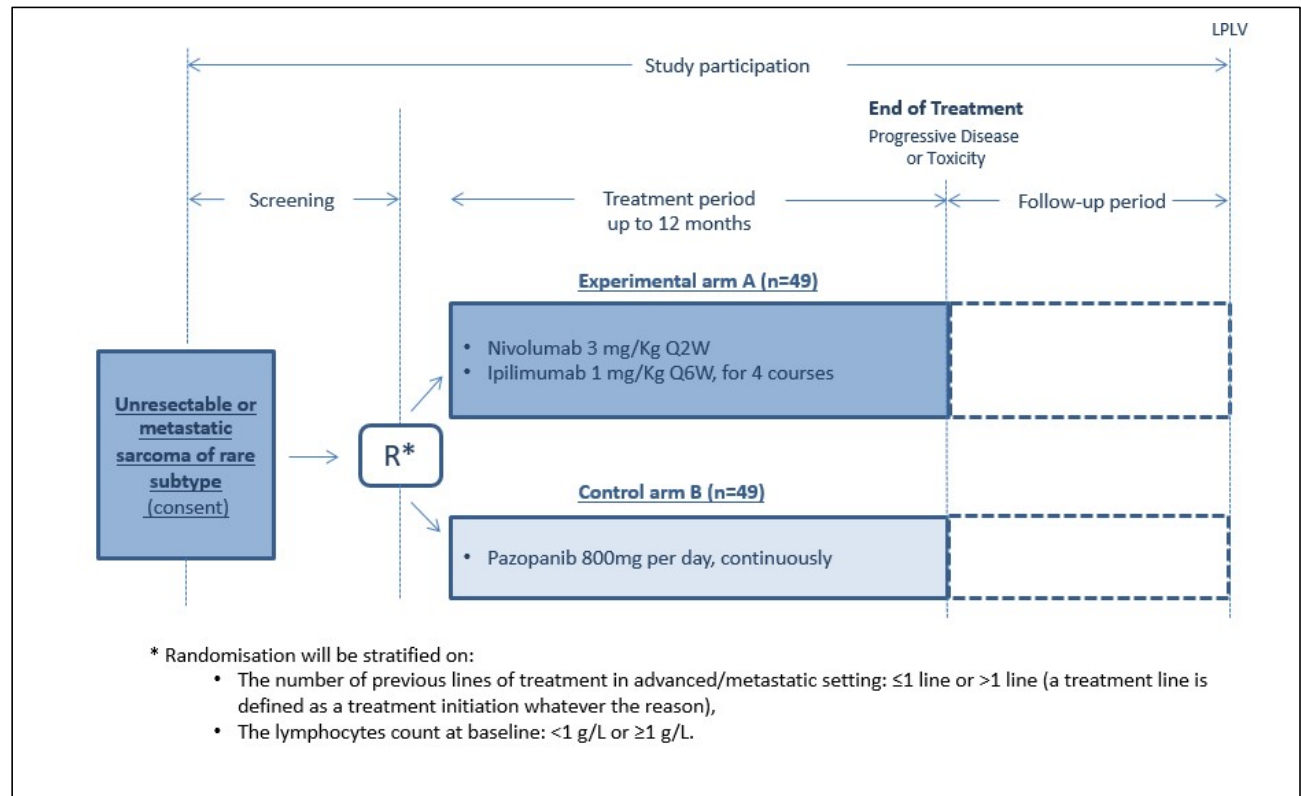
Centre Léon Bérard

Mehdi Brahmi, [mehdi.brahmi@lyon.unicancer.fr](mailto:mehdi.brahmi@lyon.unicancer.fr)

## Centres participants

- Activés
  - CLB, IB, CAL
- En attente d'activation
  - GR, COL, AP-HM, ICM, IPC, Curie, IUCT, CGFL, CEM, ICO, ICLN, CHU Tours, CHB
- En attente réglementaire
  - Cochin

## Molécules, schéma de traitement



## Indication : situation et ligne

### Principaux critères d'inclusion

Angiosarcoma	EMC
ASPS	SFT
CCSA	EHE
DSRCT	IMT
SEF	Epithelioid sarcoma
PEComa	Fibrosarcoma
Intimal Sarcoma	SMARCA-4 deficient sarcomas
MPNST	Chordoma

- Metastatic / advanced disease
- Previously treated with anthracycline-based regimen except for whom standard therapy does not exist or is not considered appropriate by the Investigator: inclusion in first line is allowed
  - Randomisation will be stratified according to the number of previous treatment lines)

### Endpoint et stat succinctes

- Hypothèse stat :
  - Study calibrated to detect HR of 0.5 with an overall type I error rate of 0.05 (two-sided) and 90% power, assuming a median PFS of :
    - 9.0 months in the immunotherapy arm
    - 4.5 months in the control arm
- Endpoint 1aire : PFS
- Endpoints 2aire :
  - Best Overall Response (BOR), the Objective Response Rate (ORR) and the duration of response (DOR);
  - The Time to Treatment Failure (TTF);
  - The Overall Survival (OS);
  - The Quality of Life (QoL);
  - The profile of tolerance.
- Nombre de patients nécessaires : 98

## *Etat d'avancement*

### **Etat du recrutement**

- Nombre de patients inclus : 7
- Nombre de patients restant à inclure : 91
- Fermeture prévue : 2024

### **Problème/ Amendement à venir**

- **Ajout autres sous types histo**
  - **Chondro méenchymateux tissus mous**
  - **Sarcome fibromyxoïde bas grade**
  - **Sarcomes de Kaposi**