



# Promotion Centre Léon Bérard

Portfolio études onco sarcomes - Juin 2021

# GSK-SS-NYESO-1

Impact de l'expression de NYESO-1 et HLA sur les outcomes cliniques  
des patients atteints de synovialosarcomes métastatiques

Etude non-interventionnelle

Nom du Centre porteur: CLB

Nom et mail du médecin responsable qui peut être contacter:

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## Centres participants

- APHM, Marseille
- CFB, Caen
- CJP, Clermont
- CLB, Lyon
- COL, Lille
- Curie, Paris
- HTRO, Tours
- IB, Bordeaux
- ICM, Montpellier
- ICL, Nancy
- ICO, Nantes
- IGR, Villejuif
- IUCT, Toulouse
  
- **Questionnaire es faisabilité envoyé fin 2019**

## Molécules, schéma de traitement

- Non-applicable

**Indication** : metastatic synovial sarcoma

## Principaux critères d'inclusion

I1. Adult, male or female, patients with a histologically confirmed diagnosis of metastatic synovial sarcoma diagnosed since 2000.

I2. Patients previously registered in the French sarcoma Database

I3. Availability of a representative FFPE archival tumor sample from primary tumor, with the corresponding pathological report. Tumor sample must be sufficient for testing and meet the following quality/quantity control (QC) criteria confirmed by a central pathological review:

- at least 20% (ideally 30%) of tumor cells and
- a sample size surface area > 5mm<sup>2</sup> and depth >90µm.

## Endpoint et stat succinctes

- Hypothèse stat : prevalence of NY-ESO-1 expression and HLA type, and their impact on clinical outcomes in metastatic SS.

- Endpoint 1aire :

To assess the level of expression† of NY-ESO-1 (CTAG1B) and HLA-A\*02:01, HLA-A\*02:05, or HLA-A\*02:06 subtypes in adults metastatic SS patients using tumor samples.

To describe and compare clinical outcomes (OS, PFS, ORR, and TTP) among patients who express NY-ESO-1 and relevant HLA-A\*02 subtype against those who do not (independently, and together) in SS patients, and specific SS patient sub-groups by metastatic status and lines of treatment using multivariate regression analysis.

- Endpoints 2aire :

To evaluate if the degrees of expression of NY-ESO-1, and HLA-A\*02:01, HLA-A\*02:05, or HLA-A\*02:06 subtypes are predictive or prognostically associated with treatment outcomes (OS, PFS, ORR, TTP) overall and in specific SS patient sub-groups by metastatic status and lines of treatment.

To identify and describe the prevalence of biomarkers beyond NY-ESO-1 through an exploratory non-supervised study of RNA seq data.

- Nombre de patients nécessaires : 150

## *Etat d'avancement*

### **Etat du recrutement**

- Nombre de patients inclus : 143
- Nombre de patients restant à inclure : 0
- Fermeture prévue le : 30 Juin 2021

### **Problème/ Amendement à venir**

- **Amendement pour réutilisation des échantillons (2 lame IHC supplémentaires) pour une seconde étude financée par Adaptimmune**