



# Promotion Centre Léon Bérard

Portfolio études onco sarcomes - Juin 2021



## BFR ESS 01

*A randomized comparative, prospective, multicenter phase II study evaluating the clinical impact of interruption versus maintenance of aromatase inhibitors in patients with locally advanced or metastatic Low Grade Endometrial Stromal Sarcoma (LGESS).*

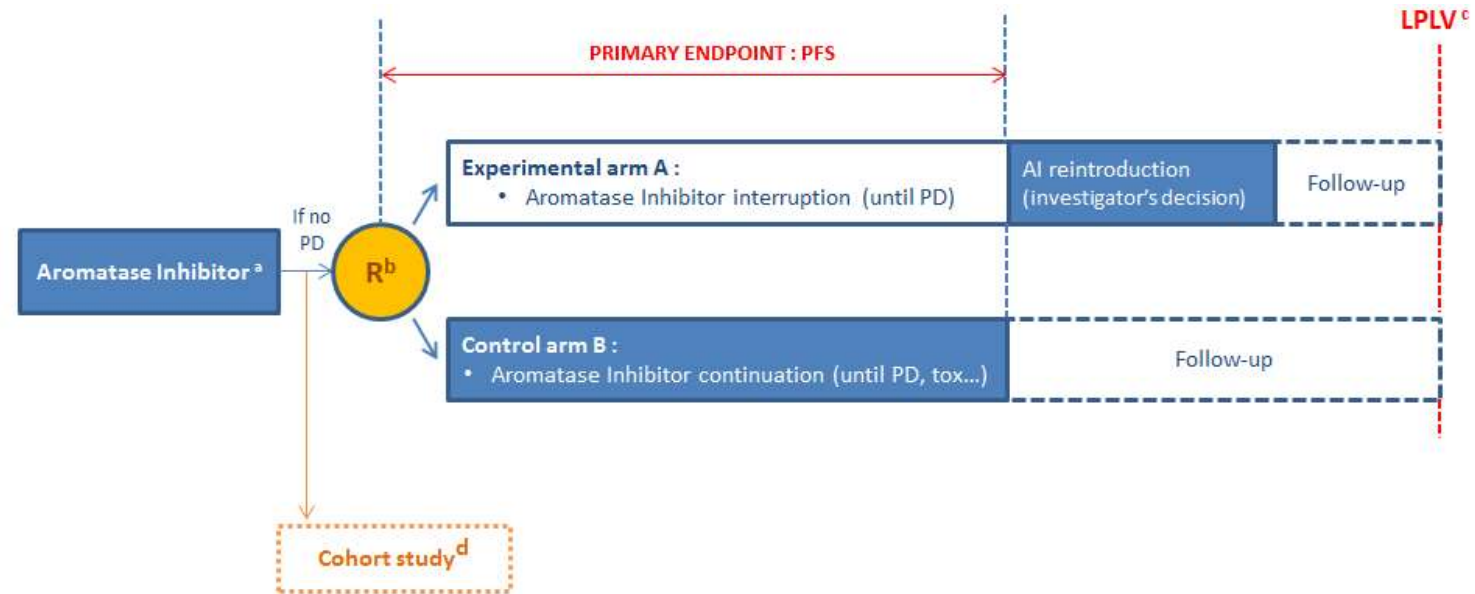
Promue par le Centre Léon Bérard

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## Centres participants

- Centre Léon Bérard
- CHU Besançon
- Institut Bergonié
- Centre F. Baclesse
- Centre Jean Perrin
- APHM
- ICM
- APHP-Cochin
- APHP-Pitié Salpêtrière
- CHU Limoges
- Institut Curie
- Institut Jean Godinot
- ICO Saint-Herblain
- CHU Tours
- IPC
- Centre Henri Becquerel
- ICLN

## Molécules, schéma de traitement



a: AI duration (last line) = 2 years for patients with no measurable disease or at least 3 years for patients with measurable disease.

b: Randomization stratified according to :

- the line of AI treatment (first vs  $\geq 2$ )
- the status of disease at the last AI introduction (presence vs absence of measurable disease as per RECIST 1.1)

c: Last Patient Last visit (LPLV) will be defined as the 36-month follow-up visit of the last included patient

d: For patient not included in the clinical study, they could be registered in the cohort study,

## Indication : situation et ligne

### Principaux critères d'inclusion

- Histologically confirmed diagnosis of low grade ESS
- Locally advanced or metastatic disease at diagnosis or patient experiencing a tumor effraction during hysterectomy
- Treatment with Aromatase Inhibitors initiated either :
  - for 24 months (in patients with no residual disease or non-measurable disease)
  - for at least 36 months (in patients with measurable disease)
- Disease must be controlled (objective response or stable disease) by aromatase inhibitors at the time of the randomization.
- No prior history of malignancies other than study disease unless the patient has been free of the disease for least 3 years.
- No using other approved or investigational antineoplastic agents

### Endpoint et stat succinctes

- Hypothèse stat : Bayesia approach
- Endpoint 1aire : Time from randomization to date of 1rst documented radiological progression (RECIST 1.1) or death due to any cause.
- Endpoints 2aire :
  - Overall Survival
  - Quality of Life and Safety
  - In the discontinuation arm: ORR, duration of response and PFS after AI reintroduction
  - To identify predictive factors of prolonged response to HT or late resistance
  - A Sociabehaviorial section
- Number of patients: 40 ( 20 per arm)

# Etat d'avancement

## Etat du recrutement

CENTERS	Inclusions in <b>RANDOMIZED study</b>	Inclusions in <b>COHORTE study</b>
Centre Léon Bérard	9	5
ICO St Herblain	1	1
ICLN (Saint-Etienne)	1	0
AP-HP - Hôpital Cochin (PARIS 14)	0	1
CHRU BESANCON	1	0
Centre Henri Becquerel	1	0
CHU Limoges	1	0
Centre Jean Perrin	1	1
Institut Curie	0	1
Institut Paoli Calmettes	2	0
AP-HP – Pitié Salpêtrière	1	0
<b>TOTAL</b>	<b>18 / 40</b>	<b>9</b>

- Nombre de patients restant à inclure : 22
- Fermeture prévue le : January 2023

