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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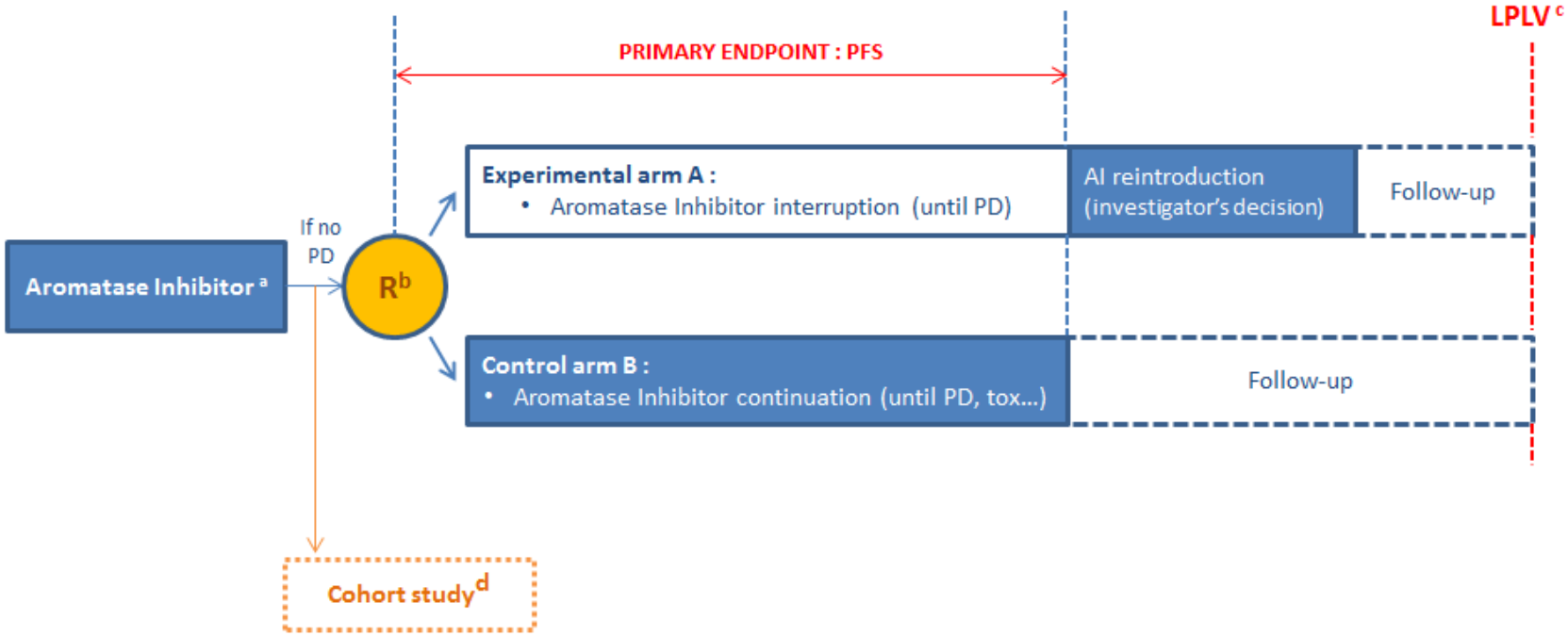
Centres participants

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

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* ≥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 inluded 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

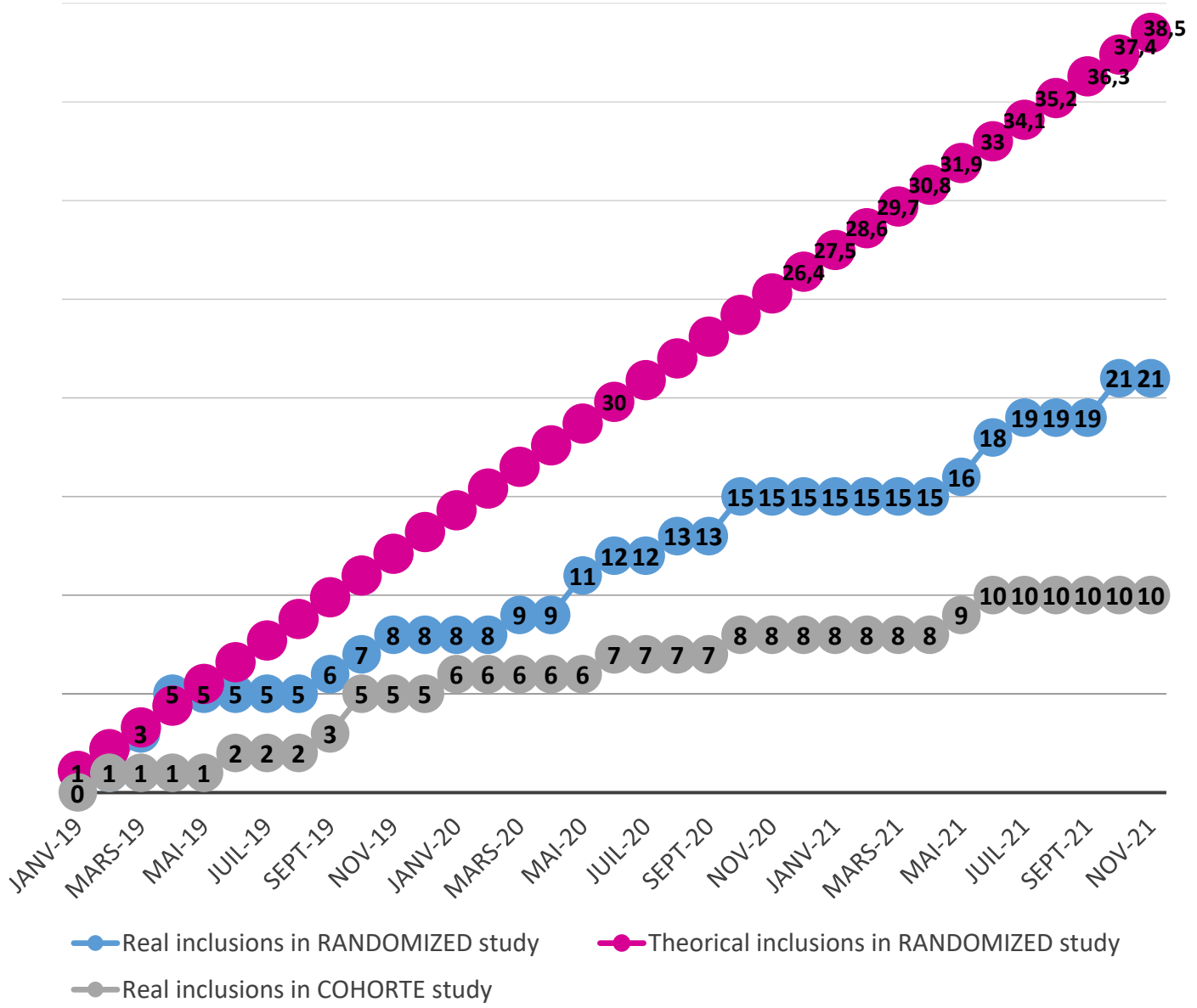
Endpoint et stat succintes

- 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 Sociabehavorial section
- Number of patients: 40 (20 per arm)

Etat d'avancement

Etat du recrutement

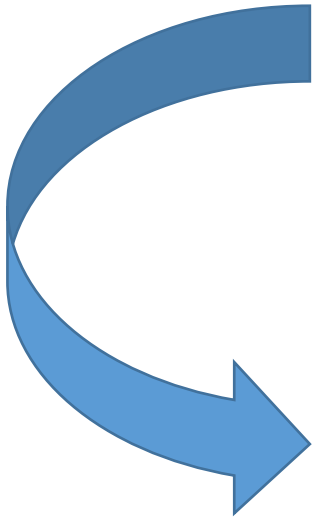
CENTERS	Inclusions in RANDOMIZED study	Inclusions in COHORTE study
Centre Léon Bérard	10	5
ICO St Herblain	1	1
ICLN (Saint-Etienne)	1	0
AP-HP - Hôpital Cochin (PARIS 14)	0	1
CHRU BESANCON	1	0
Centre Henri Becquerel	1	0
CHU Limoges	1	0
Centre Jean Perrin	1	1
Institut Curie	0	1
Institut Paoli Calmettes	2	1
Hôpital la Timone	1	0
CHU Tours	1	0
AP-HP – Pitié Salpétrière	1	0
TOTAL	**21**	10



- Nombre de patients restant à inclure : 19
- <u>Fermeture prévue le :</u> January 2023

1ère analyse intermédiaire (modèle bayésien)

- Date de randomisation de la 20ème patiente: 05 Octobre 2021
- 6 mois follow-up: Avril 2022



Analyse intermédiaire: mai 2022