GIST-TEN

Randomized, prospective multicentre, open label, phase II study evaluating the interest of imatinib (GLIVEC) treatment maintenance or interruption after at least 10 years of treatment in patients with locally advanced/metastatic Gastrointestinal Stromal Tumors (GISTs)

Promoteur : Centre Léon Bérard

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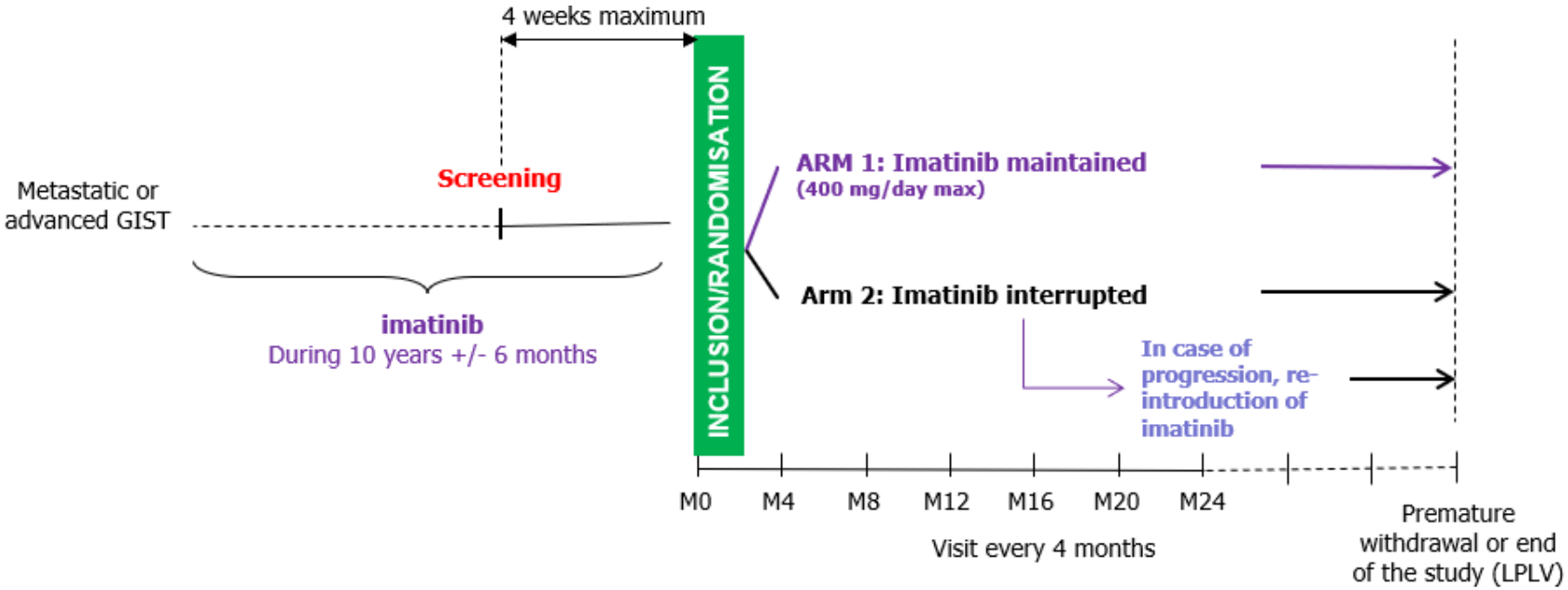
Centres participants

- Centre Léon Bérard, Lyon
- Institut Bergonié, Bordeaux
- Institut Paoli Calmettes, Marseille
- Institut de Cancérologie de l'Ouest, Saint Herblain
- Gustave Roussy, Villejuif
- CHU Robert Debré, Reims
- Institut de Cancérologie Lucien Neuwirth, Saint Priest en Jarez
- Centre Eugène Marquis, Rennes
- Institut Universitaire du Cancer de Toulouse
- CHU Besançon

Molécules, schéma de traitement



- In **ARM A**: in case of 1st relapse, imatinib will be reintroduced at 400 mg per day and further increased at 800 mg per day in case of 2nd relapse after re-introduction
- In **ARM B**: imatinib is administrated 300 or 400 mg per day. In case of progressive disease imatinib will be increased up to 800mg per day.
- The randomization will be stratified on the disease status at inclusion (Complete response vs Partial response/stable disease).

Indication : patients with an advanced/metastatic GIST controlled after 10 years of imatinib treatment.

Principaux critères d'inclusion

- Patients ≥ 18 years of age
- Histologically documented diagnosis of malignant advanced/metastatic GIST with c-kit (CD117) expression
- ECOG Performance status (PS) 0, 1, 2
- Under imatinib treatment (at 300 or 400mg/day) maintained for 10 years or over with no more than 12 months in total or 3 consecutive months of interruption during the treatment period
- Controlled disease (without any progression under imatinib)

Endpoint et stat succintes

- Hypothèse stat : Bayesian approach
- Endpoint 1aire : Progression-free rate at 6 months (PFR-6m)
- Endpoints 2aire :
  - Progression-free survival (PFS)
  - Overall survival (OS)
  - Safety
  - Quality of life (QoL)

  In the interruption arm only: to determine in the subgroup of patients who progressed:
  - Progression-free survival (PFS2)
  - Objective response rate (ORR)
  - Duration of response (DOR) after imatinib reintroduction
- Nombre de patients necessaires : maximum sample size of 25 patients per arm (**total of 50 patients**)

Etat d'avancement

Etat du recrutement

- Nombre de patients inclus : 0 / 50
- Nombre de patients restant à inclure : 50
- Fermeture prévue le : FPI + 36 mois

36 mois de recrutement / 24 mois de suivi

Problème/ Amendement à venir

- **Soumission réglementaire initiale effectuée**
- **Envoi des conventions inter-établissement en cours**
- **2 centres ouverts: CLB et Institut Bergonié**
- **En attente ouverture: CHU Besançon et Gustave Roussy**
- **Si des centres sont intéressés par cette étude, merci d'envoyer un mail au coordonnateur.**