ATEZOGIST

A prospective, randomized, multicenter, comparative study of the efficacy of imatinib resumption combined with atezolizumab versus imatinib resumption alone in patients with unresectable advanced gastrointestinal stromal tumors (GIST) after failure of standard treatments

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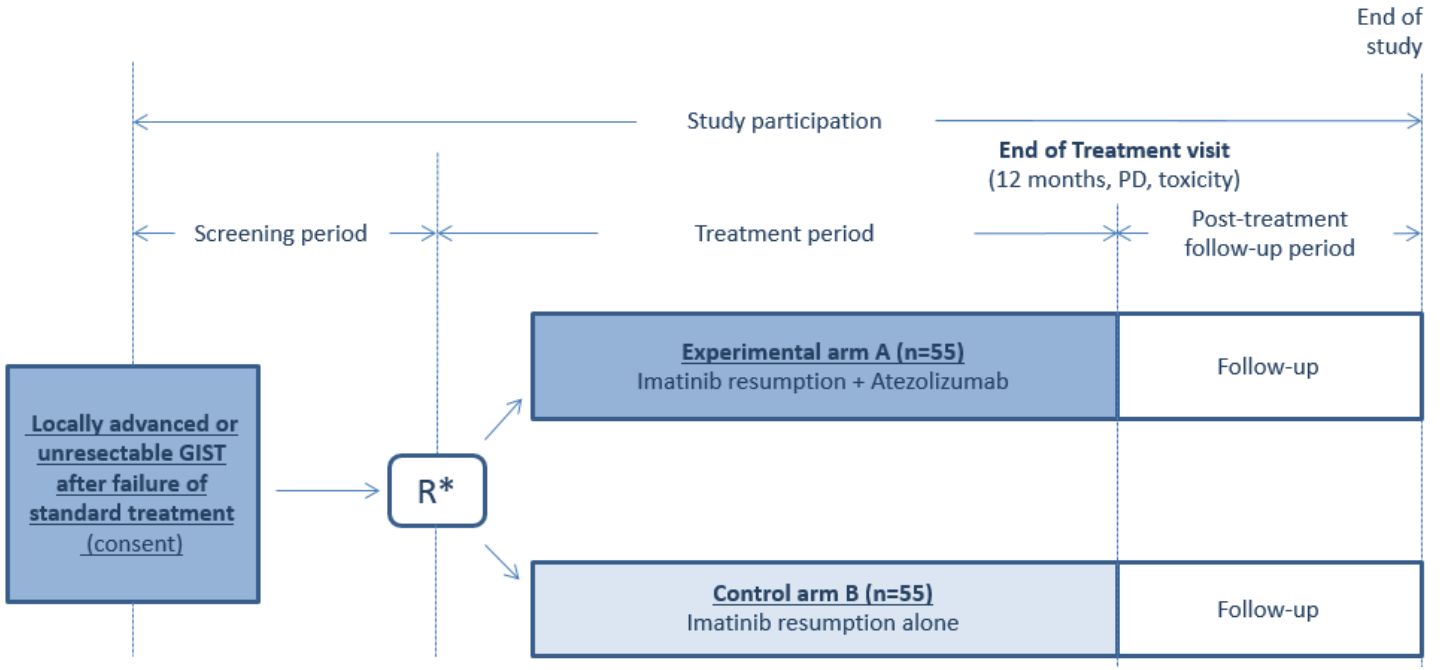
Molécules, schéma de traitement

- Imatinib *per os* 400 mg daily continuously (not supplied)
- Atezolizumab *i.v.* fixed dose of 1 200 mg every 3 weeks until PD or a maximum duration of 12 months (supplied by Roche)
- Stratification criteria : Kit exon 11 (wild-type or mutant)



Indication : Situation avancée non opérable, 4e ligne et plus après traitements standard (imatinib, sunitinib, regorafenib)

Principaux critères d'inclusion

- Male or female ≥ 18 years
- Histologically confirmed diagnosis of GIST (RRePS)
- Locally advanced or metastatic disease confirmed as measurable according to the RECIST V1.1
- Previously failed to at least imatinib, sunitinib and then regorafenib. Failure is defined for Imatinib as progressive disease, and for sunitinib and regorafenib as progressive disease and/or intolerance
- Performance Status of the ECOG of 0 or 1
- No prior rechallenge of imatinib after sunitinib as second line;
- Absence of D842V mutation in Exon 18 of PDGFRA;
- No prior treatment with CD137 agonists or immune checkpoint blockade therapies, including anti-cytotoxic T lymphocyte-associated protein 4 , anti-TIGIT, anti PD-1,and anti PD-L1 therapeutic antibodies;

Endpoint et stat succintes

- Hypothèse stat : 6-month PFS (exp. : 30% versus standard : 10% ; HR=0.523)
- Endpoint 1aire : Progression-Free Survival
- Endpoints 2aire : Best Response Rate (BRR), Objective Response Rate (ORR), Time to Treatment Failure (TTF), Overall Survival (OS), Quality of Life, Tolerability
- Nombre de patients nécessaires : 100 évènements, soit une taille d'échantillon de 110 patients (55 par bras)

Etat d'avancement

Etat du recrutement

- Nombre de patients inclus : 0
- Nombre de patients restant à inclure : 110
- Fermeture prévue le : 36 mois de recrutement

Problème/ Amendement à venir

- **Autorisations obtenues en novembre 2021**
- **Conventions envoyées (revues +/- commissions internes en cours)**
- **Mises en place prévues à partir de janvier 21**
- **Proposition possible de façon séquentielle avec LENVAGIST**