

A Study of IDRX-42 (GSK6042981) Versus (vs) Sunitinib in Participants With Gastrointestinal Stromal Tumors After Imatinib Therapy

NCT07218926

Status	RECRUITING
Phase	Phase 3
Sponsor	GlaxoSmithKline
Enrollment	450 participants

Key Eligibility Criteria

Inclusion (3)

- Participants with histologically or cytologically confirmed GIST that is metastatic and/or surgically unresectable.
- Documented disease progression on or intolerance to imatinib administered for first-line treatment of unresectable/metastatic disease.
- Tumor tissue must be available to be submitted to the central laboratory for retrospective biomarker analysis. The sample may be from archival tissue or a new biopsy. Tissue samples are not required to be submitted centrally prior to randomization.

Exclusion (3)

- Known untreated or active central nervous system metastases.
- Participants with a known allergy or hypersensitivity to any component of IDRX-42 (GSK6042981) or sunitinib. Participants with a history of Stevens-Johnson syndrome on a prior Tyrosine kinase inhibitor (TKI) are excluded.
- Has a malignancy (except disease under study) that has progressed or required active treatment within the past 24 months except for basal cell or squamous cell carcinomas of the skin or in-situ carcinomas [e.g., breast, cervix, bladder] that have been resected with no evidence of metastatic disease.

Locations (84 total)

GSK Investigational Site, Phoenix, Arizona, United States
GSK Investigational Site, Jacksonville, Florida, United States
GSK Investigational Site, Orlando, Florida, United States
... and 81 more locations