

# First-in-human Study of IDRX-42 in Participants With Metastatic and/or Unresectable Gastrointestinal Stromal Tumors

NCT05489237

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Status	RECRUITING
Phase	Phase 1
Sponsor	IDRx Inc. - A GSK Company
Enrollment	278 participants

## Key Eligibility Criteria

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### Inclusion (14)

- Phase 1
- Male or female participants ≥18 years of age
- Histologically or cytologically confirmed metastatic and/or surgically unresectable GIST
- Documented progression on imatinib (Phase 1)
- Documented pathogenic mutation in KIT OR any PDGFRA mutation other than exon 18 mutations, determined through local testing
- ... and 9 more (see full listing online)

### Exclusion (5)

- Any prior exposure to the following investigational agents NB003 or THE-630 or bezuclastinib plus sunitinib combination (except for participants treated in Cohort 4 of Phase 1b).
- GIST with no documented mutation in both KIT and PDGFRA genes.
- Primary brain malignancy or known untreated or active central nervous system metastases.
- Has an active uncontrolled infection, including, but not limited to, the requirement for intravenous antibiotics.
- Has significant, uncontrolled, or active cardiovascular disease.

## Locations (30 total)

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GSK Investigational Site, Miami, Florida, United States  
GSK Investigational Site, Boston, Massachusetts, United States  
GSK Investigational Site, St Louis, Missouri, United States  
... and 27 more locations