

An International, Phase 3, Randomized, Multicenter, Open label Study of Ripretinib vs Sunitinib in Patients with Advanced Gastrointestinal Stromal Tumor (GIST) with KIT Exon 11 and Co occurring KIT Exons 17 and/or 18 Mutations Who Were Previously Treated with Imatinib (INSIGHT)

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: 18 years and over

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- diagnosis of GIST with co-occurring KIT exons 11+17/18 mutations confirmed by ctDNA sample - disease progression on imatinib treatment, confirmed by scan - ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours - participants of reproductive potential must agree to follow contraception requirements - contact study staff for additional inclusion criteria

Exclusion Criteria:

- known active central nervous system metastases - heart disease, myocardial infarction within 6 months of starting the study, active ischemia or any other uncontrolled cardiac condition such as angina, significant cardiac arrhythmia requiring therapy, uncontrolled hypertension, or congestive heart failure - Gastrointestinal abnormalities such as inability to take oral medication, malabsorption syndromes, requirement for intravenous alimentation - additional exclusions apply malabsorption syndromes requirement for intravenous alimentation

Conditions & Interventions

Conditions:

Rare Diseases, Cancer

Keywords:

Clinics and Surgery Center (CSC), Advanced Gastrointestinal Stromal Tumor, GIST, Stomach Cancer

More Information

Description: This study is being done to learn how well ripretinib works against cancer as compared to sunitinib in patients with a specific GIST-gene mutation who have received imatinib. We will also learn more about the safety of ripretinib and look at how ripretinib may affect your body. The choice of whether you will be given ripretinib or sunitinib will be assigned by a computer, by chance, like the flip of a coin. You will have a 2 out of 3 chances of receiving ripretinib. You will know if you are receiving ripretinib or sunitinib.

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Phase: PHASE3

IRB Number: SITE00001953

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