The **INSIGHT** Study

Deciphera Pharmaceuticals, LLC, is conducting the Phase 3 **INSIGHT** study to test a new investigational use of the drug ripretinib in a subset of patients living with gastrointestinal stromal tumors (GIST).

What is the purpose of this study?

The study is being done to learn more about the safety of ripretinib and how well it works against GIST, as compared to sunitinib (the standard second-line treatment), in patients with a specific gene mutation and whose cancer has progressed while receiving imatinib.

What drug is being studied?

Ripretinib is an oral medication designed to treat GIST that may be growing because of changes in specific genes. Ripretinib is approved by the United States Food and Drug Administration for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitor medicines, including imatinib (fourth-line treatment). In this study, ripretinib is an investigational drug, which means that it has not been approved by regulatory agencies for this specific use in second-line treatment.

What mutations can patients have for this study?

Prior to enrollment, you will receive circulating tumor DNA (ctDNA) testing at no cost to confirm your GIST gene mutation type for participation. This process requires a blood draw to determine the mutation.

Patients must have a KIT exon 11 and a KIT exon 17 and/or KIT exon 18 mutation for inclusion in this study. Patients cannot have a KIT exon 9, KIT exon 13, or KIT exon 14 mutation for this study.

Who can participate in this study?

Approximately 54 people will participate in the clinical study worldwide. You may be eligible to join the study if you:

- Are at least 18 years old
- Have been diagnosed with GIST and have a specific gene mutation
- Have cancer that progressed after receiving prior treatment with imatinib only
- Are willing and able to comply with study procedures and restrictions

You will be pre-screened to determine your eligibility by GIST mutation. After your mutation is confirmed, there are further requirements that must be met for eligibility. The study doctor will review these additional criteria with you to determine if you qualify for participation in the study after the confirmation of mutation.

What will happen if I join the study?

If you qualify and choose to take part in the **INSIGHT** study, you will be assigned by chance to receive either ripretinib or sunitinib. This process is called randomization. You will have a 2-in-3 chance of receiving ripretinib and a 1-in-3 chance of receiving sunitinib. Because this is an open-label study, you and the study team will know what treatment you receive.

If you are randomly assigned to ripretinib, you will receive ripretinib at 150 mg (three 50 mg tablets) once daily by mouth every day, for repeating 42-day cycles.

If you are randomly assigned to sunitinib, you will receive 50 mg (four 12.5 mg capsules) once daily by mouth for 28 days on, followed by 14 days off (or per your doctor's instructions), for repeating 42-day cycles. If you are receiving sunitinib and your cancer progresses, you will have the opportunity to cross-over to receive ripretinib treatment.

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Your actual time in the study will depend on factors such as how your body responds to treatment and what you and the study doctor think is best for your health and well-being. Participation is always completely voluntary.

Travel reimbursement is provided. During the study, the sponsor will pay the expenses for ripretinib and sunitinib.

How can I find more information about this study?

Please discuss further with your physician.

Click here to find the contact and location information for sites participating in **INSIGHT**. If you need help navigating clinical trials, please reach out to The Life Raft Group team at liferaft@liferaftgroup.org.