What are clinical research studies?

Clinical research studies help scientists and doctors explore whether a medical strategy, drug, or device is safe and effective for people. Before a new drug can be approved by regulatory agencies for commerical use, it must go through several phases of clinical research. There are typically 4 phases:

Phase 1: Researchers test a possible new drug on a small group of participants to assess the drug's safety and dosage.

Phase 2: Researchers give the drug to a larger group of people to continue studying the drug's safety and efficacy.

Phase 3: Researchers give the drug to even more people to confirm whether it works and to learn more about its safety. The drug is often compared to existing treatments or a placebo.

Phase 4: Sometimes researchers continue studying the drug after it has received government approval for public use.

Peak is a **Phase 3** study. Participation in clinical research studies is your choice. We appreciate and thank you for considering the Peak study.

For more information about the Peak study, visit cogentclinicaltrials.com/peak, clinicaltrials.gov/ct2/show/NCT05208047, or email peakinfo@cogentbio.com.

V3 | 12JUN2023 | CGT9486-21-301

Has your gastrointestinal stromal tumor (GIST) not responded to therapy?

If YES, you may be able to join the Peak study.

Peak GIST

What is GIST?

A gastrointestinal stromal tumor (GIST) is a rare cancer that affects the gastrointestinal (GI) tract. In most cases, GISTs arise in the stomach or small intestine, but they can form anywhere along the digestive tract. GISTs are most often driven by genetic mutations in the KIT tyrosine kinase receptor gene. In addition to surgery, GISTs are often treated with tyrosine kinase inhibitors that target KIT/PDGFRα mutations, such as imatinib and sunitinib.

What is the Peak study?

The Peak study is a Phase 3 clinical research study (also called clinical trial) evaluating a study drug (bezuclastinib, also known as CGT9486) in combination with sunitinib in people with locally advanced, unresectable, or metastatic GIST who have previously received imatinib (standard of care medication).

What therapy will be evaluated in the Peak study?

The Peak study is evaluating the investigational study drug, bezuclastinib (CGT9486), in combination with sunitinib. Sunitinib is an approved therapy for GIST often used after people have received imatinib. Sunitinib works against some but not all types of mutations that can occur in the KIT gene. Bezuclastinib is a tyrosine kinase inhibitor that is designed to selectively and potently target a specific range of KIT mutations, including some mutations that sunitinib does not work against. Using bezuclastinib and sunitinib together may have the potential to provide complementary coverage across several mutations in the KIT gene.

Investigational means the study drug has not been approved by regulatory agencies or other healthcare authorities around the world for commercial use and can only be used in research studies.

Who can join the study?

You may qualify if you meet the following requirements*:

- 18 years of age or older
- Have histologically confirmed locally advanced, metastatic, and/or unresectable GIST with 1 measurable lesion
  - *Metastatic = cancer cells spread from the location of origin to other parts of the body*
  - *Unresectable = unable to be surgically removed*
- Have received prior therapy with imatinib
- Do not have a PDGFR mutation or succinate dehydrogenase (SDH) deficiency causing your GIST
- Are not pregnant or breastfeeding

*Additional requirements will apply, including previous therapies you have received and certain health conditions.

What can study participants expect?

For those who qualify, participation includes:

Screening period: Used to determine eligibility

Dosing period: Dosing will be every day based on the assigned cohort (group)

You will be assigned at random to one of the following cohorts and corresponding study therapies:

- Cohort A: sunitinib alone
- Cohort B: bezuclastinib + sunitinib

Participants randomized to receive sunitinib alone whose disease progresses during the study may be able to cross over to receive the combination of bezuclastinib + sunitinib.

Health assessments: Occur approximately monthly during study participation

Follow-up period: Study clinic visit 30 days after the last dose, possible regular imaging tests, and a phone call every 3 to 6 months