



November 10, 2025

Dear GIST Community,

We are pleased to share that Cogent Biosciences has announced positive top-line results from the Global Phase 3 PEAK study for adults living with Advanced, Unresectable or Metastatic GIST. The PEAK study was designed to evaluate the efficacy and safety of CGT9486, also known as bezuclastinib, an investigational candidate for the treatment of second-line GIST, in combination with sunitinib.

The full press release can be found [here](#). We've included a summary of the top-line results reported on Monday, November 10th, 2025, below:

- 16.5 months median progression free survival (mPFS) for patients taking bezuclastinib plus sunitinib compared to 9.2 months mPFS for sunitinib monotherapy
- 46% Objective Response Rate (ORR) reported for bezuclastinib combination compared to 26% ORR for sunitinib monotherapy
- Safety profile of bezuclastinib combination was well tolerated with no unique risks observed with the combination when compared to the known safety profile of sunitinib
- First positive Phase 3 trial in second-line GIST patients in over 20 years
- We anticipate submitting a New Drug Application (NDA) to the Food & Drug Administration (FDA) for review in the first half of 2026

We would like to extend our heartfelt gratitude to the people living with GIST, along with their families and loved ones, whose participation makes this clinical trial possible. This achievement reflects the strength and commitment of everyone who has contributed and continues to contribute to the PEAK program.

We also want to thank the broader GIST community and the dedicated GIST Patient Advocacy Groups for their ongoing support, education, and commitment to raising



awareness about clinical trials, including the PEAK study.

We understand that there may be questions around the next steps for this program and that the GIST community urgently awaits additional treatment options. We encourage you to speak with your healthcare provider about your treatment options and will continue to provide information to the GIST Community as it becomes available.

If you would like to sign up to receive additional information about Cogent's GIST program, you may do so at www.GISTpathways.com.

Sincerely,

The Cogent Patient Advocacy & Engagement Team