



September 3, 2024

Dear GIST Community,

We are pleased to announce that our Global Phase 3 PEAK study for adults living with Advanced, Unresectable or Metastatic GIST has completed enrollment. This is an important step toward the potential approval of bezuclastinib, an investigational candidate for the treatment of second line GIST in combination with sunitinib. You can access the press release by clicking on the link [here](#).

We would like to extend our deepest gratitude to the individuals participating in this study, their families and caregivers and the entire GIST community. Without you, this work would not be possible. Because of the commitment and dedication of this community, we are one step closer to understanding the potential of the investigational compound bezuclastinib in combination with sunitinib for the treatment of GIST. We would also like to thank the GIST patient advocacy groups, including the Life Raft Group, Sarcoma Patient Advocacy Global Network (SPAGN) and many others who have been instrumental in helping raise awareness about the PEAK study within their communities.

We understand that you may have some questions about bezuclastinib, Cogent and the future of the program upon hearing this news. The purpose of this letter is to help address some of those questions. Please see details below.

We are immensely proud of this progress and are excited about the potential for bezuclastinib to address unmet needs in GIST. We know that the community is urgently awaiting additional treatment options and is eager to learn more about the future of our program. We are committed to providing updates to the community as information becomes available, and we will continue to do so through patient advocacy groups, and through our website and social media channels.

How Can I Stay Informed About Updates from Cogent?

Sign up for updates about Cogent's GIST program at www.GISTpathways.com.



We are honored to work with the GIST community and grateful for your support.

Sincerely,
The Cogent Patient Advocacy & Engagement Team

Frequently Asked Questions:

1. Is bezuclastinib approved anywhere in the world?
 - No. Bezuclastinib is an investigational medicine and is not approved anywhere in the world for use in any disease or indication.
2. What is the current status of the PEAK study?
 - The PEAK study is still ongoing. On September 3, 2024, Cogent announced that enrollment had been completed with 413 patients enrolled. We expect to report top-line results from the PEAK trial by the end of 2025. You can sign up to receive email alerts on our website and follow Cogent Biosciences on LinkedIn and @CogentBio on X (Twitter) for updates. You can also sign up to receive more information about Cogent's clinical program in GIST by going to gistpathways.com.
3. What does enrollment completion mean?
 - Enrollment completion means that PEAK has reached the total number of planned participants with GIST that were required in the Phase 3 portion of the study. No additional patients will be enrolled in the randomized Phase 3 part of the PEAK study.
4. When do you anticipate a data readout from PEAK?
 - We expect to report top-line results from the Phase 3 portion of the PEAK trial by the end of 2025. You can sign up to receive email alerts on our website and follow Cogent Biosciences on LinkedIn and @CogentBio on X (Twitter) for updates. You can also sign up to receive more information about Cogent's clinical program in GIST by going to gistpathways.com.



5. Can you share any more information about ongoing bezuclastinib trials for GIST?
 - While PEAK is closed for enrollment, there is an ongoing clinical trial for later line GIST supported through SARC. Please visit clinicaltrials.gov (NCT 06208748) or speak with your physician for more information.

6. I am a patient who needs access to the bezuclastinib + sunitinib combination, is it available? What is the process to request access?
 - We are unable to provide access to bezuclastinib outside of our clinical program at this time. As we engage with regulatory agencies and understand the data requirements to support registration, we will continue to evaluate the opportunity to provide access to bezuclastinib outside of registrational clinical trials. We recognize the urgency of the request and will provide additional information if changes arise regarding access. If your physician determines that the combination of bezuclastinib + sunitinib is the best option for your care and treatment of GIST, they may reach out to Cogent to request access by contacting trialinfo@cogentbio.com.

7. What is the timing for FDA review and approval?
 - The process to get a drug approved in the US is long and challenging. We are pleased to have enrolled the PEAK trial ahead of schedule and are thankful for all the patients and families who have participated. We are working rapidly on how to best provide access as soon as possible.

8. What are your plans for commercialization and seeking approval in the US and outside of the US?
 - The process to get a drug approved is long and challenging. We are pleased to have enrolled the PEAK trial ahead of schedule and are thankful for all the patients and families/caregivers who have participated. We are working rapidly on how to best provide access as soon as possible.
 - We hope to share more about the potential for bezuclastinib to become commercially available in GIST when we present top-line results in 2025.

9. If bezuclastinib is approved by the FDA, who will be eligible to receive it?
 - If approved, the initial GIST indication for bezuclastinib is in patients with second line GIST. Please connect with your healthcare provider to see if you could become eligible.
 - We hope to share more about the potential for bezuclastinib to become commercially available for GIST when we present top-line results in 2025.