



May 29, 2026

Dear GIST Community,

We are pleased to inform you that yesterday, May 28th 2026, Cogent announced that the U.S. Food and Drug Administration (FDA) has accepted its New Drug Application (NDA) for bezuclastinib in combination with sunitinib for patients with Gastrointestinal Stromal Tumors (GIST) who have received prior treatment with imatinib. The FDA has granted the application Priority Review and assigned a Prescription Drug User Fee Act (PDUFA) target action date of November 30, 2026. In addition, the FDA communicated that it does not currently plan to convene an advisory committee and has not identified any potential review issues at this time.

You may read our full press release by clicking the link [here](#). We encourage you to reach out to your healthcare provider if you have questions about the Peak study or bezuclastinib.

We would once again like to express our deepest gratitude to the participants in the Peak study, as well as their families and caregivers, whose contributions made this important milestone possible. We are also sincerely grateful to the GIST patient advocacy groups for their ongoing support, education, and dedication to increasing awareness of clinical trials and expanded access programs.

We understand there may be questions about access to bezuclastinib during this period. We encourage you to speak with your healthcare provider about your treatment options. You can also reference our letter to the community regarding our Expanded Access Program/Compassionate Use Program [HERE](#).

Cogent 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