



April 2, 2026

Dear GIST Community,

On April 1st 2026, Cogent Biosciences announced the completion of the submission of its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for bezuclastinib in patients with Gastrointestinal Stromal Tumor (GIST) who have received prior treatment with imatinib. Based on the positive results from the Peak clinical trial, the bezuclastinib NDA was submitted under the FDA's Real-Time Oncology Review (RTOR) program, which is intended to enable a more streamlined review process. Bezuclastinib was also granted Breakthrough Therapy Designation as a treatment for GIST earlier this year.

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 like to extend our deepest thanks to the individuals who participated in the Peak study, along with their loved ones and caregivers, without whom this milestone would not have been possible. We also extend our appreciation to the GIST Patient Advocacy Groups for their continued support, education, and commitment to raising awareness of clinical trials and expanded access programs.

We understand there may be questions about access to bezuclastinib during this time. Treatment decisions should be made in consultation with a qualified healthcare provider based on individual patient needs and available care options. Cogent has established an Expanded Access Program (EAP) for bezuclastinib for certain eligible patients. Expanded access involves a physician request, and access is not guaranteed.

You can also reference our letter to the community regarding our Expanded Access Program here: www.cogentbio.com/eap.

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