



March 16, 2026

To the Systemic Mastocytosis Community:

We are pleased to share that the U.S. Food and Drug Administration (FDA) has accepted our New Drug Application (NDA) for bezuclastinib, Cogent's investigational therapy in patients with NonAdvanced Systemic Mastocytosis (NonAdvSM) and assigned a Prescription Drug User Fee Act (PDUFA) target action date of **December 30, 2026**. Cogent plans to file the NDA submission for bezuclastinib in patients with Advanced Systemic Mastocytosis (AdvSM) during the first half of 2026.

We invite you to read our full press release here and encourage you to reach out to your healthcare provider if you have questions about the Summit trial or bezuclastinib: <https://investors.cogentbio.com/news-releases/news-release-details/cogent-biosciences-announces-fda-acceptance-new-drug-application>.

We would like to extend our heartfelt gratitude to the people living with Systemic Mastocytosis, along with their families and loved ones, for their participation in the Summit clinical trial. This achievement reflects the strength and commitment of everyone who has contributed and continues to contribute to the Summit program. We also want to thank the broader community and the dedicated Mast Cell Disease Patient Advocacy Groups for their ongoing support, education, and commitment to raising awareness about 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 here: www.cogentbio.com/eap.

Cogent will continue to provide information to the systemic mastocytosis community as it becomes available. If you would like to sign up to receive additional information about Cogent's programs and resources, you may do so at www.SMpathways.com.

Sincerely,
The Cogent Patient Advocacy & Engagement Team