Cogent Biosciences Announces Submission of New Drug Application for Bezuclastinib in NonAdvanced Systemic Mastocytosis

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WALTHAM, Mass. and BOULDER, Colo., Dec. 30, 2025 (GLOBE NEWSWIRE) -- Cogent Biosciences, Inc. (Nasdaq: COGT), a biotechnology company focused on developing precision therapies for genetically defined diseases, today announced it has submitted its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for bezuclastinib in NonAdvanced Systemic Mastocytosis (NonAdvSM). The submission is based on positive clinical data from the SUMMIT pivotal trial and follows the Breakthrough Therapy Designation for bezuclastinib in patients with SSM and patients with NonAdvSM who have received prior avapritinib.

“This NDA is the first of three planned submissions for bezuclastinib based on positive clinical data from three pivotal trials completed in 2025 for patients with systemic mastocytosis and GIST. Building on the exceptional results from the SUMMIT trial, this filing moves us closer to delivering an important disease-modifying therapy to patients with NonAdvSM,” said Andrew Robbins, Cogent’s President and Chief Executive Officer. “We extend our deep appreciation to the patients, families, clinicians, collaborators, and our Cogent team, who all helped make this possible.”

As reported first in July 2025, and more recently at the ASH annual meeting, the SUMMIT trial of bezuclastinib in patients with NonAdvSM achieved statistical significance across all primary and key secondary endpoints.

Bezuclastinib demonstrated clear clinical benefit across all symptom domains, including significant improvements across 11 individual patient reported symptoms as well as the most severe symptom at baseline. Reductions in objective measures of disease, including serum tryptase, correlated with improvements in symptom severity, representing the first time this relationship has been demonstrated in patients with NonAdvSM.

Updated data from the SUMMIT trial through 48 weeks showcased a clear and continued deepening of symptomatic improvement over time, supporting the potential for sustained clinical benefit with longer duration of therapy. Across the SUMMIT trial, bezuclastinib demonstrated a favorable safety and tolerability profile, supporting its potential for chronic use in patients with NonAdvSM.

Bezuclastinib was granted Breakthrough Therapy Designation by the FDA in October 2025, reflecting the agency’s recognition of its potential to address a significant unmet medical need.

NDA submissions for bezuclastinib in Gastrointestinal Stromal Tumors (GIST) and Advanced Systemic Mastocytosis (AdvSM) are on-track for the first half of 2026 based on the strength of clinical results from the PEAK and APEX clinical trials as reported in Q4 2025.

About Cogent Biosciences, Inc.
Cogent Biosciences is a biotechnology company focused on developing precision therapies for genetically defined diseases. The most advanced clinical program, bezuclastinib, is a selective tyrosine kinase inhibitor that is designed to potently inhibit the KIT D816V mutation as well as other mutations in KIT exon 17. KIT D816V is responsible for driving systemic mastocytosis, a serious disease caused by unchecked proliferation of mast cells. Exon 17 mutations are also found in patients with advanced gastrointestinal stromal tumors (GIST), a type of cancer with strong dependence on oncogenic KIT signaling. The company also has an ongoing Phase 1 study of its novel internally discovered FGFR2/3 inhibitor. In addition, the Cogent Research Team is developing a portfolio of novel targeted therapies to help patients fighting serious, genetically driven diseases targeting mutations in ErbB2, PI3Ka, KRAS and JAK2. Cogent Biosciences is based in Waltham, MA and Boulder, CO. Visit our website for more information at **www.cogentbio.com**. Follow Cogent Biosciences on social media: **X** (formerly known as Twitter) and **LinkedIn**. Information that may be important to investors will be routinely posted on our website and **X**.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding: the company’s plan to deliver an important disease-modifying therapy to patients with NonAdvSM; the potential for bezuclastinib to deliver sustained clinical benefit with longer duration of therapy for patients with NonAdvSM; the potential for bezuclastinib’s chronic use in patients with NonAdvSM; the potential for bezuclastinib to address a significant unmet medical need and the company’s plans to submit two more NDAs for bezuclastinib in GIST and AdvSM in the first half of 2026. The use of words such as, but not limited to, "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "target," "will," or "would" and similar words expressions are intended to identify forward-looking statements. Forward-looking statements are neither historical facts nor

assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our clinical results, the rate of enrollment in our clinical trials and other future conditions. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements. We may not actually achieve the forecasts or milestones disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Such forward-looking statements are subject to a number of material risks and uncertainties including but not limited to those set forth under the caption "Risk Factors" in Cogent's most recent Quarterly Report on Form 10-Q filed with the SEC. Any forward-looking statement speaks only as of the date on which it was made. Neither we, nor our affiliates, advisors or representatives, undertake any obligation to publicly update or revise any forward-looking statement, whether as result of new information, future events or otherwise, except as required by law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date hereof.

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