Cogent Biosciences Announces FDA Acceptance of New Drug Application for Bezuclastinib in Patients with NonAdvanced Systemic Mastocytosis (NonAdvSM)

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NDA based on positive clinical results from the SUMMIT pivotal trial in which bezuclastinib demonstrated clear clinical benefit across all symptom domains

WALTHAM, Mass. and BOULDER, Colo., March 16, 2026 (GLOBE NEWSWIRE) -- Cogent Biosciences, Inc. (Nasdaq: COGT), a biotechnology company focused on developing precision therapies for genetically defined diseases, today announced that the U.S. Food and Drug Administration (FDA) has accepted its New Drug Application (NDA) for bezuclastinib in patients with NonAdvanced Systemic Mastocytosis (NonAdvSM) and assigned a Prescription Drug User Fee Act (PDUFA) target action date of December 30, 2026. In addition, the FDA communicated that at this time, there is no plan to hold an advisory committee, nor have they identified any potential review issues.

Clinical results from the pivotal SUMMIT trial with bezuclastinib in NonAdvSM patients demonstrated clinically meaningful and highly statistically significant improvements across the primary and all key secondary endpoints. 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. In addition, results also showed the benefit of bezuclastinib in populations with high unmet need and bezuclastinib's impact on bone mineral density as well as evidence of disease modification. Across the SUMMIT trial, bezuclastinib demonstrated a favorable safety and tolerability profile, supporting its potential for chronic use in patients with NonAdvSM.

Completion of the NDA submission for bezuclastinib in patients with Gastrointestinal Stromal Tumors (GIST) who have received prior treatment with imatinib remains on track for April 2026. The GIST submission was initiated under Real-Time Oncology Review (RTOR), and bezuclastinib received Breakthrough Therapy Designation in this indication. The NDA submission for bezuclastinib in patients with Advanced Systemic Mastocytosis (AdvSM) remains on track for the first half of 2026.

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. 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, PI3Kα, 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 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 company's expectation that it will complete its NDA submission for bezuclastinib in patients with GIST in April 2026; and the company's expectation that it will submit its NDA for bezuclastinib in patients with 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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