Cogent Biosciences Announces SUMMIT Continues to Showcase Powerful Symptomatic Improvement in NonAdvanced Systemic Mastocytosis Patients

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65% mean improvement in Total Symptom Score (TSS) at 48 weeks, including 88% of patients achieving at least a 50% reduction in TSS

Top-line results from Summit Part 2 registration-directed trial on track for July 2025

WALTHAM, Mass. and BOULDER, Colo., Feb. 27, 2025 (GLOBE NEWSWIRE) -- Cogent Biosciences, Inc. (Nasdaq: COGT), a biotechnology company focused on developing precision therapies for genetically defined diseases, today announced expanded clinical results from the Open Label Extension (OLE) portion of SUMMIT, a clinical trial evaluating bezuclastinib in patients with nonadvanced systemic mastocytosis (NonAdvSM). The data presented at the 2025 American Academy of Allergy Asthma & Immunology/World Allergy Organization (AAAAI/WAO) Joint Congress taking place February 28-March 3, 2025 in San Diego, CA will focus on the patients who received 100 mg bezuclastinib for at least 48 weeks.

"The expanded SUMMIT data presented at AAAAI 2025 reinforce our belief that bezuclastinib can rapidly and meaningfully improve a wide variety of symptoms that impact the daily lives of patients with nonadvanced systemic mastocytosis," said Andrew Robbins, Cogent's President and Chief Executive Officer. "This poster underscores the significance of our findings and builds upon the data we shared at ASH last year. Top-line results from SUMMIT Part 2 are on track for July 2025, as we aim to make bezuclastinib available to all NonAdvSM patients as quickly as possible."

Patient Demographics
SUMMIT is a registration-directed, randomized, double-blind, placebo-controlled, global, multicenter, clinical trial of bezuclastinib in patients with NonAdvSM. After the initial 12-week period in SUMMIT Part 1, all patients were given the opportunity to receive bezuclastinib in the SUMMIT OLE. The clinical results presented at AAAAI 2025 focus on the patients from the OLE who have received treatment with the recommended Phase 2 dose of 100 mg bezuclastinib for at least 48 weeks. The median age of patients at study entry was 52 years (ranging from 36-76 years).

Patient Reported Outcomes (PRO) Data
SUMMIT patients were evaluated for signs of clinical activity over 48 weeks using multiple PRO measures, including the Mastocytosis Symptom Severity Daily Diary (MS2D2) and the Mastocytosis Quality-of-Life (MC-QoL) scale. Updated clinical data presented today show:

- 65% mean improvement in Total Symptom Score (TSS) at 48 weeks
- 88% of patients demonstrated >50% reduction from baseline in MS2D2 Total Symptom Score (TSS) with 94% of patients exceeded 30% TSS reduction from baseline at 48 weeks
- 63% reduction from baseline in MS2D2 most severe symptom at 48 weeks
- The impact to patients' quality of life improved to mild as early as week four and sustained improvement through 48 weeks as measured by MC-QoL Total Score

Safety Data
As of the data cutoff, August 29, 2024, the median duration of bezuclastinib treatment was 56 weeks for patients in the active arm and 40 weeks for placebo patients who crossed over to the OLE. The majority of treatment emergent adverse events were low grade and reversible with no treatment-related bleeding or cognitive impairment events reported. The most common treatment related adverse events were hair discoloration and transaminase elevations. All patients experiencing elevated transaminases were asymptomatic and reversible: five patients resolved without any dose modifications and remained on study; two patients resolved with dose reduction and remained on study, one of whom re-escalated to original dose; and two patients resolved following discontinuation. All safety data were previously reported at ASH 2024.

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 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, PI3Kα and KRAS. 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 expectation to present top-line results from SUMMIT Part 2 in July 2025; the therapeutic potential of bezuclastinib to rapidly and meaningfully improve a wide variety of symptoms that impact the daily lives of patients with NonAdvSM**;** and the company's goal of making bezuclastinib available to all NonAdvSM patients as quickly as possible. 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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