Cogent Biosciences Announces FDA Breakthrough Therapy Designation for Bezuclastinib

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- *Detailed results from bezuclastinib's positive SUMMIT trial evaluating bezuclastinib in patients with NonAdvanced Systemic Mastocytosis planned for presentation at upcoming scientific conference this year*

- *NDA submission for bezuclastinib planned by YE 2025*

WALTHAM, Mass. and BOULDER, Colo., Oct. 20, 2025 (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 granted Breakthrough Therapy Designation for bezuclastinib in NonAdvanced Systemic Mastocytosis (NonAdvSM) patients previously treated with avapritinib as well as in patients with Smoldering Systemic Mastocytosis; populations with no currently approved standard of care.

"We are excited to announce Breakthrough Therapy Designation for bezuclastinib, which highlights the FDA's recognition of the unmet need for patients with NonAdvanced Systemic Mastocytosis and the potential for bezuclastinib to redefine the treatment paradigm for this disease," said Andrew Robbins, Cogent's President and Chief Executive Officer. "In addition, we recently completed a very productive pre-NDA meeting discussing the results from the SUMMIT pivotal trial and look forward to our continued collaboration with the FDA as we prepare to submit our NDA for NonAdvSM by the end of 2025. We are excited that this designation supports eligibility for Priority Review as we prepare for our planned commercial launch."

The Breakthrough Therapy Designation is based on positive results from the registration-directed SUMMIT trial in which bezuclastinib achieved statistical significance across all primary and key secondary endpoints in patients with NonAdvSM, including the consistent benefit observed in populations with high unmet need. Top-line data were announced in July 2025, and additional data are expected to be presented at an upcoming scientific conference.

Breakthrough Therapy Designation is intended to expedite the review of medicines that treat a serious or life-threatening condition and have shown preliminary clinical evidence indicating the potential for substantial improvement over available therapies. The benefits of Breakthrough Therapy Designation include the eligibility for Priority Review, rolling submission of portions of the application, and the FDA's organizational commitment to the company to help determine the most efficient route to approval.

Timing of Additional Pivotal Trial Results
In addition, Cogent also announced that it plans to report top-line results from the Phase 3 PEAK trial in Gastrointestinal Stromal Tumors (GIST) patients in November 2025 and report top-line results from the registration-directed APEX trial in Advanced Systemic Mastocytosis (AdvSM) patients in December 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. In addition to bezuclastinib, the Cogent Research Team is developing a portfolio of novel targeted therapies to help patients fighting serious, genetically driven diseases initially targeting mutations in FGFR2, ErbB2, PI3Ka 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 plans to present detailed results from its SUMMIT clinical trial at

an upcoming scientific conference later this year; the company's plan to submit an NDA for patients with NonAdvSM by the end of 2025; the potential for bezuclastinib to redefine the treatment paradigm for patients with NonAdvSM; the company's planned commercial launch of bezuclastinib; the anticipated benefits of Breakthrough Therapy Designation; the company's plans to report top-line results from its Phase 3 PEAK clinical trial in GIST patients in November 2025; and the company's plans to report top-line results from its registration-directed APEX clinical trial in AdvSM patients in December 2025. 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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