Cogent Biosciences Announces Planned 2025 Milestones for Bezuclastinib and Emerging Portfolio of Selective and Potent Targeted Therapeutics

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- *Plan to report top-line results from registration-directed SUMMIT trial in NonAdvSM patients in July 2025*
- *Plan to report top-line results from pivotal PEAK Phase 3 trial in 2nd-line GIST patients by end of 2025*
- *Plan to report top-line results from registration-directed APEX trial in AdvSM patients in 2H 2025*
- *Company to present at J.P. Morgan 43rd annual healthcare conference tomorrow, Tuesday, January 14 at 7:30 a.m. PT /10:30 a.m. ET*

WALTHAM, Mass. and BOULDER, Colo., Jan. 13, 2025 (GLOBE NEWSWIRE) -- **Cogent Biosciences, Inc.** (Nasdaq: COGT), a biotechnology company focused on developing precision therapies for genetically defined diseases, today highlighted the company's key 2025 milestones ahead of its presentation at J.P. Morgan's 43rd annual healthcare conference.

"2025 will be a transformational year at Cogent Biosciences," said Andrew Robbins, President and Chief Executive Officer. "During the year, we plan to report top-line results from all three registration-directed bezuclastinib studies, and if successful, move forward with our first New Drug Application (NDA) submission by the end of 2025. With both SUMMIT and PEAK enrollment finishing several months ahead of schedule, we are confident that physicians and patients are highly aware of bezuclastinib's potential and are also eagerly awaiting these clinical trial results. We believe bezuclastinib could change the lives of thousands of patients fighting SM and GIST and has the potential to be the first potent, CNS-sparing, selective KIT mutant inhibitor. In addition, we continue to advance our pipeline of novel small molecule programs, including an ongoing Phase 1 study of our novel FGFR2 inhibitor, CGT4859, and plan to file INDs for both our ErbB2 and PI3Kα programs during the year. With a strong balance sheet, we are well positioned to prepare Cogent for our evolution into a commercial-stage company."

In 2025, the Company plans to achieve the following milestones:

Bezuclastinib – Systemic Mastocytosis (SM)

- Report top-line results in July 2025 from the SUMMIT trial. SUMMIT is a registration-directed, global, randomized, placebo-controlled trial of bezuclastinib in patients with Non-Advanced Systemic Mastocytosis (NonAdvSM).
- Report top-line results during the second half of 2025 from the APEX trial. APEX is a registration-directed, global, open-label trial of bezuclastinib in patients with Advanced Systemic Mastocytosis (AdvSM).
- Submit the first bezuclastinib New Drug Application (NDA) by the end of 2025.

Bezuclastinib – Gastrointestinal Stromal Tumors (GIST)

- Report top-line results by the end of 2025 from the pivotal Phase 3 PEAK trial. PEAK is a global, blinded, randomized clinical trial studying the combination of bezuclastinib and sunitinib versus sunitinib alone in patients with imatinib-resistant gastrointestinal stromal tumors (GIST).

Bezuclastinib - Expanded Access Program

- During Q1 2025, initiate Expanded Access Programs (EAP) in the U.S. for SM and GIST patients to receive investigational bezuclastinib after meeting certain eligibility criteria.

CGT4859 (FGFR2 inhibitor)

- Enroll patients in the ongoing Phase 1 trial with CGT4859, a reversible, selective FGFR2 inhibitor in patients with

documented FGFR mutations, including advanced cholangiocarcinoma. The trial is designed to explore the safety, tolerability and clinical activity of escalating doses of CGT4859 with a goal of selecting an active and well tolerated dose for further clinical investigation.

Preclinical Pipeline

- Submit an IND application for CGT4255, a potent, selective ErbB2 inhibitor, highlighted by potential best-in-class brain-penetrant properties.

- Submit an IND application for CGT6297, a potent allosteric inhibitor of PI3Kα, with 25-fold selectivity over PI3Kα WT.

J.P. Morgan Presentation Details

Cogent will participate in a presentation and Q&A session at the 43rd Annual J.P. Morgan Healthcare Conference on Tuesday, January 14, 2025, beginning at 7:30 a.m. PT (10:30 a.m. ET). A live webcast will be accessible in the "Investors & Media" section of the company's website, www.cogentbio.com, and will be archived for 30 days following the event.

Inducement Grants Under Nasdaq Listing Rule 5635(c)(4)

Cogent also announced today that, on January 7, 2025, the Compensation Committee of Cogent's Board of Directors, made up entirely of independent directors, approved the grant of "inducement" equity awards to nine new employees under the company's 2020 Inducement Plan with a grant date of January 13, 2025. The awards were approved in accordance with Listing Rule 5635(c)(4) of the corporate governance rules of the Nasdaq Stock Market. The employees received, in the aggregate, nonqualified options to purchase 135,000 shares of Cogent common stock. Each option has a 10-year term, an exercise price equal to the closing price of Cogent's common stock on the grant date, and a 4-year vesting schedule with 25% vesting on the 1-year anniversary of the grant date and the remainder vesting in equal monthly installments over the subsequent 36 months, provided such employee remains employed through each such vesting date.

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: plans to report top-line results from SUMMIT in July 2025; plans to report top-line results from PEAK by the end of 2025; plans to report top-line results from APEX in the second half of 2025; plans to file the company's first NDA by the end of 2025; plans to file INDs for the company's ErbB2 and PI3Kα programs in 2025; plans to initiate EAPs in the United States for SM and GIST patients in the first quarter of 2025 and clinical development plans and timelines for the company's ongoing Phase 1 trial with CGT4859. 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 or 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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