Cogent Biosciences Announces Planned 2024 Milestones for Bezuclastinib and Emerging Portfolio of Selective and Potent Targeted Therapeutics

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- *Plan to initiate global, registration-directed SUMMIT Part 2 study of bezuclastinib in NonAdvSM patients during 1H 2024; present results from complete SUMMIT Part 1 at 2024 AAAAI annual conference in Q1 2024*
- *On track to complete enrollment in global, pivotal Phase 3 PEAK study of bezuclastinib + sunitinib in 2nd-line GIST patients by end of 2024*
- *On track to complete enrollment in registration-directed Phase 2 APEX study of bezuclastinib in AdvSM patients by end of 2024*
- *Plan to initiate Phase 1 trial of CGT4859, a potential best-in-class, potent, selective and reversible FGFR2 inhibitor in 2H 2024*
- *Company to present at J.P. Morgan 42nd annual healthcare conference today, Tuesday, January 9 at 4:30 p.m. PT / 7:30 p.m. ET*

WALTHAM, Mass. and BOULDER, Colo., Jan. 09, 2024 (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 2024 milestones ahead of its presentation at J.P. Morgan's 42nd annual healthcare conference.

"Given the foundation that was established in 2023, we are well positioned to move Cogent forward aggressively this year, including a cash runway expected to carry us into 2026," said Andrew Robbins, President and CEO of Cogent Biosciences. "We strongly believe in bezuclastinib's potential to become the best-in-class cKIT exon 17/18 inhibitor, and in 2024, we plan to complete enrollment in both the PEAK and APEX trials, each of which have the potential, if successful, to support a regulatory approval for bezuclastinib. In addition, we are excited to further describe the differentiation that bezuclastinib offers patients when presenting the results from the complete SUMMIT Part 1 at AAAAI, setting us up to initiate our third bezuclastinib pivotal trial in the first half of the year. Beyond bezuclastinib, the Cogent Research team is creating exceptional molecules, including a growing portfolio of potential best-in-class breast cancer programs."

In 2024, the Company plans to achieve the following milestones:

Bezuclastinib – Systemic Mastocytosis (SM)

- Present data from the complete SUMMIT Part 1 trial in patients with Non-Advanced Systemic Mastocytosis (NonAdvSM) at the 2024 American Academy of Allergy, Asthma & Immunology (AAAAI) annual conference in February
- Initiate SUMMIT Part 2 in 1H 2024, a global, registration-directed, randomized, placebo-controlled trial of bezuclastinib in NonAdvSM patients
- Finalize, including alignment with regulators, Cogent's MS2D2, a novel patient reported outcomes (PRO) tool designed to measure symptomatic severity and improvement for patients enrolled in the SUMMIT study. Once available, provide Total Symptom Score (TSS) results from SUMMIT Part 1 utilizing MS2D2
- Complete enrollment in the registration-directed APEX Phase 2 trial in patients with Advanced Systemic Mastocytosis (AdvSM)

Bezuclastinib – Gastrointestinal Stromal Tumors (GIST)

- Complete enrollment of global, randomized Phase 3 PEAK trial studying the combination of bezuclastinib and sunitinib versus sunitinib alone in imatinib-resistant GIST patients

CGT4859 (FGFR2 inhibitor)

- Initiate Phase 1 trial of the first Cogent-discovered pipeline program, designed as a potent, selective, reversible FGFR2 inhibitor with best-in-class potential

Preclinical Pipeline

- Initiate IND-enabling studies for lead candidate from potent, selective ErbB2 program, highlighted by potential best-in-class brain penetrant properties
- Select lead candidate and initiate IND-enabling studies from ongoing PI3Kα program, designed to potently and selective target the H1047R driver mutation, which affects >30,000 cancer patients each year

J.P. Morgan Presentation Details

Cogent will participate in a presentation and Q&A session at the 42nd Annual J.P. Morgan Healthcare Conference in San Francisco today, Tuesday, January 9, 2024, beginning at 4:30 p.m. PT (7:30 p.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.

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 and PI3Kα (genes/pathways). 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: planned corporate milestones for 2024, anticipated cash runway into 2026, the potential of bezuclastinib to become a best-in-class cKIT exon 17/18 inhibitor, the potential for CGT4859 to be a best-in-class FGFR2 inhibitor, the potential for the company's PEAK and APEX trials, if successful, to support regulatory approvals for bezuclastinib, the potential for the research portfolio to become best-in-class breast cancer programs, and the potential for bezuclastinib plus sunitinib to be a best-in-class combination therapy for GIST patients. 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.

Contact:

Christi Waarich
Senior Director, Investor Relations
christi.waarich@cogentbio.com
617-830-1653