Cogent Biosciences Announces Planned 2023 Milestones for Bezuclastinib and Emerging Portfolio of Selective and Potent Targeted Cancer Therapeutics

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- *Demonstrate significant progress toward leadership in Systemic Mastocytosis (SM), including mid-year Part 1 results from Phase 2 APEX trial in AdvSM patients and initial clinical data in 2H23 from Phase 2 SUMMIT trial in NonAdvSM patients*
- *Rapidly progress bezuclastinib in 2nd-line Gastrointestinal Stromal Tumors (GIST), with planned clinical update from lead-in portion of Phase 3 PEAK trial in 1H23, and expansion to >100 global clinical sites this year*
- *Select clinical candidates from ongoing FGFR2-mutant selective and ErbB2-mutant selective programs and disclose two additional novel targeted cancer therapeutic programs this year*
- *Company to present at J.P. Morgan 41st annual healthcare conference on Thursday, January 12 at 7:30 a.m. PT / 10:30 a.m. ET*

WALTHAM, Mass. and BOULDER, Colo., Jan. 09, 2023 (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 2023 milestones ahead of its presentation at J.P. Morgan's 41st annual healthcare conference this week.

"We made tremendous progress in 2022 demonstrating bezuclastinib's differentiated clinical profile in Systemic Mastocytosis while advancing an improved formulation of bezuclastinib through clinical studies that enabled the start of our global Phase 3 GIST trial," said Andrew Robbins, President and CEO of Cogent Biosciences. "In 2023, we look forward to continuing the rapid development of bezuclastinib toward leadership positions in both Systemic Mastocytosis and GIST, while we enhance our impressive, growing portfolio of targeted cancer therapeutics. By the end of 2023, we expect to have a portfolio of five distinct programs which will position us as a leader in precision medicine."

In 2023, the Company plans to achieve the following milestones:

Bezuclastinib – Systemic Mastocytosis (SM)

- Phase 2 APEX trial - announce results from planned Part 1 analysis including approximately 25-30 AdvSM patients in mid-2023, enabling dose selection for Part 2 trial expansion.
- Phase 2 SUMMIT trial - present initial clinical data in patients with NonAdvSM in the second half of 2023. Clinical results will include safety/tolerability, pharmacokinetics and measures of clinical activity.
- Initiate clinical investigation of bezuclastinib in SM patients with associated hematologic neoplasms (SM-AHN), allowing for concomitant use of AHN-directed therapies.

Bezuclastinib – Gastrointestinal Stromal Tumors (GIST)

- Present updated clinical results from refractory GIST patients in the lead-in cohort of the Phase 3 PEAK trial of the pan-KIT mutant regimen, bezuclastinib plus sunitinib, during the first half of 2023.
- Enrollment in the Phase 3 PEAK trial for 2nd-line GIST patients remains on track, with expansion to over 100 global clinical sites expected before the end of this year.

Preclinical Pipeline

- Select FGFR2-mutant selective clinical candidate and initiate IND-enabling GLP toxicology studies in the first half of 2023. This program is designed as a potential best-in-class, reversible, FGFR1-sparing, potent pan-FGFR2 mutant inhibitor that includes coverage of both key gatekeeper and molecular brake mutations (V564I, N549K).
- Select ErbB2-mutant selective clinical candidate in the second half of 2023. This program is designed as an EGFR-sparing, CNS-penetrant ErbB2 inhibitor that includes coverage of key mutations (YVMA, S310F, V842I, L755S) inadequately addressed by currently approved therapies.

- Present initial preclinical data on two additional novel target programs with best-in-class potential out of the Cogent Research Team's labs during 2023.

JPM Presentation Details

Cogent will participate in a presentation and Q&A session at the J.P. Morgan 41st Annual Healthcare Conference in San Francisco on Thursday, January 12, 2023, beginning at 7:30 a.m. PT (10:30 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 (SM), 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 FGFR2 and ErbB2. 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: Twitter and LinkedIn. Information that may be important to investors will be routinely posted on our website and Twitter.

Forward Looking Statement

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 planned 2023 milestones for bezuclastinib and its research pipeline, as follows: plans to announce Part 1 results from the Phase 2 APEX trial in mid-2023, plans to present initial clinical data from the Phase 2 SUMMIT trial in the second half of 2023, plans to initiate clinical investigation of bezuclastinib in patients with SM-AHN in 2023, plans to provide a clinical update from the lead-in portion of the Phase 3 PEAK trial in the first half of 2023 and the expectation to expand to more than 100 global clinical sites in 2023, the expectation to select a FGFR2 clinical candidate and initiate IND-enabling GLP toxicology studies in the first half of 2023, the expectation to select an ErbB2 clinical candidate in the second half of 2023, and plans to present initial preclinical data on two additional novel target programs with best-in-class potential in 2023. 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.

Contact:

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