



Cogent Biosciences Announces Positive Updated Lead-In Data from Ongoing Phase 3 PEAK Trial Evaluating Bezucastinib in Combination with Sunitinib in Patients with Gastrointestinal Stromal Tumors (GIST) at ASCO Annual Meeting

May 23, 2024

- *Bezuclastinib + sunitinib combination therapy reached median progression free survival (mPFS) of 19.4-months and 33% ORR in subset of advanced GIST patients with one prior treatment*
- *Encouraging long-term safety and tolerability with combination bezuclastinib and sunitinib therapy in Part 1*
- *PEAK Phase 3 guidance accelerated with enrollment completion now expected in 3Q 2024*
- *Company announces new advanced GIST clinical trial sponsored by the Sarcoma Alliance for Research through Collaboration (SARC) and in collaboration with The Life Raft Group and Dana-Farber Cancer Institute*

WALTHAM, Mass. and BOULDER, Colo., May 23, 2024 (GLOBE NEWSWIRE) -- [Cogent Biosciences, Inc.](#) (Nasdaq: COGT), a biotechnology company focused on developing precision therapies for genetically defined diseases, today announced positive updated lead-in data from the company's ongoing Phase 3 PEAK trial evaluating the selective and potent KIT mutant inhibitor, bezuclastinib, in combination with sunitinib, in patients with Gastrointestinal Stromal Tumors (GIST). The data will be presented in a poster presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL on June 1. Cogent also announced today a new Phase 2 clinical trial of bezuclastinib plus sunitinib in later line GIST patients, sponsored by the Sarcoma Alliance for Research through Collaboration (SARC) and in collaboration with The Life Raft Group and Dana-Farber Cancer Institute.

"These data presented today reinforce our excitement that the combination of bezuclastinib and sunitinib has the potential to become a new standard of care for advanced GIST patients," said Andrew Robbins, President and Chief Executive Officer at Cogent Biosciences. "Coupled with the impressive clinical activity demonstrated by the combination, the addition of bezuclastinib to sunitinib continues to be generally well-tolerated with an encouraging safety profile. We are pleased to report that the pace of enrollment in PEAK is significantly ahead of schedule, and we now expect enrollment to complete in the third quarter of 2024."

"We are also excited today to announce a collaboration with SARC, The Life Raft Group and Dana-Farber on a new Phase 2 clinical trial assessing the potential benefit of bezuclastinib with sunitinib in later line GIST patients who are not eligible for the PEAK study and currently have very limited treatment options," continued Mr. Robbins.

"There is tremendous need for additional treatment options for GIST patients," said Andrew Wagner M.D., Ph.D., Senior Physician, Center for Sarcoma and Bone Oncology, Dana-Farber Cancer Institute, and Associate Professor of Medicine, Harvard Medical School. "Today's updated lead-in data from the bezuclastinib combination are very promising, and I remain excited about the ongoing PEAK trial. Additionally, with the announcement of this new study today, we have a clinical trial which allows us to explore the use of bezuclastinib with sunitinib in patients who are not eligible for the PEAK study."

PEAK Trial Update

PEAK is a randomized, open-label, global, Phase 3 clinical trial evaluating bezuclastinib in combination with sunitinib vs sunitinib alone in GIST patients previously treated with imatinib. In the updated lead-in data being presented at ASCO, as of the cutoff date, April 1, 2024, the 42 patients in Part 1 have been on study for a median of 15.3 months. The median progression-free survival (mPFS) during treatment with bezuclastinib and sunitinib was 10.2 months in all patients. In a subset of second-line GIST patients with only prior imatinib, which most closely resembles patients currently enrolling in Part 2 of PEAK, the data demonstrate a mPFS of 19.4 months. In addition, the objective response rate (ORR) in all patients treated with bezuclastinib and sunitinib was 27.5% and in the subset of second-line patients the ORR was 33.3%, per investigator assessment. Combination treatment resulted in a disease control rate of 80% in all patients and 100% in patients with prior imatinib only.

Safety Data

As of the data cutoff, the combination of bezuclastinib and sunitinib does not appear to add to the severity of adverse events known to be associated with sunitinib monotherapy and is well-tolerated. The majority of treatment-emergent adverse events (TEAEs) were low-grade and reversible. No additional serious adverse reactions or discontinuations due to TEAEs have been reported since the last presentation of data in November 2023.

ASCO Poster Details

Title: Peak part 1 summary: A phase 3, randomized, open-label multicenter clinical study of bezuclastinib (CGT9486) and sunitinib combination versus sunitinib in patients with gastrointestinal stromal tumors (GIST)

Session Type and Title: Poster Session – Sarcoma

Session Date and Time: June 1, 2024, 1:30 PM-4:30 PM CDT

The poster will be available in the [Posters and Publications](#) portion of the Cogent website at approximately 8:00 AM ET on June 1.

Phase 2 SARC Trial

The open label, single arm Phase 2 trial sponsored by SARC and in collaboration with The Life Raft Group and Dana-Farber Cancer Institute is

designed to evaluate the mPFS as well as the safety and tolerability of bezucastinib plus sunitinib in 40 patients with GIST who have previously progressed on sunitinib. This trial will focus on later line patients, where limited treatment options are available. Additional details can be found on clinicaltrials.gov; Identifier [NCT06208748](https://clinicaltrials.gov/ct2/show/study/NCT06208748). For more information about SARC or The Life Raft Group, please visit www.sarcctrials.org or www.liferaftgroup.org.

Bezuclastinib Clinical Development

Enrollment continues in the Phase 3 registration-enabling PEAK study, which will include approximately 388 second-line, post imatinib GIST patients. Due to rapid enrollment, the Company now expects PEAK enrollment to be completed in the third quarter of 2024 with top-line results still expected by the end of 2025. Cogent remains on-track to complete enrollment in APEX in patients with advanced systemic mastocytosis (AdvSM) by the end of 2024 and report top-line results mid-2025 and complete enrollment in SUMMIT Part 2 in the second quarter of 2025 and report top-line results by the end of 2025.

Upcoming Investor Conference

Cogent will participate in the Jefferies Global Healthcare Conference on Wednesday, June 5 at 2:30 p.m. ET. A live webcast will be available on the Investors & Media page of Cogent's website at investors.cogentbio.com/events. A replay will be available approximately two hours after completion of the event and will be archived for up to 30 days.

About Cogent Biosciences, Inc.

Cogent Biosciences is a biotechnology company focused on developing precision therapies for genetically defined diseases. The most advanced clinical program, bezucastinib, is a selective tyrosine kinase inhibitor that is designed to potentially 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 bezucastinib, 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. 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 long-term safety and tolerability profile of the combination of bezucastinib and sunitinib therapy, the potential for the combination of bezucastinib and sunitinib to become a new standard of care for advanced GIST patients, the updated guidance that the Company now expects PEAK enrollment to be completed in the third quarter of 2024 with top-line results still expected by the end of 2025, the expectation that PEAK will include approximately 388 second-line post imatinib GIST patients, the expectation to complete enrollment in APEX by the end of 2024 and to report top-line results mid-2025 and the expectation to complete enrollment in SUMMIT Part 2 in the second quarter of 2025 and to report top-line results by the end of 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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