Cogent Biosciences Announces Positive FDA Meeting and Alignment on MS2D2, a Novel Patient Reported Outcome Measure for the SUMMIT Trial

June 27, 2024

Enrollment in SUMMIT Part 2 remains on track for completion in Q2 2025 with top-line results expected by end of 2025

WALTHAM, Mass. and BOULDER, Colo., June 27, 2024 (GLOBE NEWSWIRE) -- Cogent Biosciences, Inc. (Nasdaq: COGT), a biotechnology company focused on developing precision therapies for genetically defined diseases, today announced it has reached alignment with the U.S. Food and Drug Administration (FDA) on the Company's novel patient reported outcome measure, Mastocytosis Symptom Severity Daily Diary (MS2D2), for use in Part 2 of the registration-directed SUMMIT trial evaluating bezuclastinib in Nonadvanced Systemic Mastocytosis (NonAdvSM) patients.

"We recently completed a positive discussion with the FDA on the use of MS2D2 in our SUMMIT trial for Nonadvanced Systemic Mastocytosis patients," said Andrew Robbins, Cogent's President and Chief Executive Officer. "We remain on track to complete enrollment in SUMMIT Part 2 in the second quarter of 2025 and report top-line results by year-end 2025."

Cogent's questionnaire, MS2D2, asks patients about their symptoms at baseline and measures the increase or decrease in those symptoms throughout the trial. A subset including the eleven most frequent and severe symptoms will form the basis of the total symptom score (TSS), which will be used to measure the primary endpoint of the SUMMIT Part 2 trial.

Bezuclastinib Clinical Development
Cogent remains on-track to complete enrollment in SUMMIT Part 2 in the second quarter of 2025 and report top-line results by the end of 2025. The Company also remains on track to complete enrollment in the APEX study in patients with Advanced Systemic Mastocytosis (AdvSM) by the end of 2024 and report top-line results mid-2025. Enrollment continues in the Phase 3 registration-enabling PEAK study, which will include approximately 388 second-line, post imatinib patients with Gastrointestinal Stromal Tumors (GIST). Due to rapid enrollment, the Company expects PEAK enrollment to be completed in the third quarter of 2024 with top-line results expected by the end of 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 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 expectation to complete enrollment in SUMMIT Part 2 in Q2 2025 and to report top-line results by the end of 2025, the expectation to complete enrollment in the APEX trial by the end of 2024 and to report top-line results mid-2025, the expectation to complete enrollment of approximately 388 GIST patients in the PEAK trial in the third quarter of 2024 and to report top-line results by the end of 2025 and the calculation of the total symptom score (TSS) that will be used to measure the primary endpoint of the SUMMIT Part 2 trial. 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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