Cogent Biosciences Announces Additional Clinical Data from Part 1 of its Ongoing SUMMIT Trial Evaluating Bezuclastinib in Patients with NonAdvanced Systemic Mastocytosis (NonAdvSM)

June 14, 2024

Patients treated with 100 mg bezuclastinib showed substantial reduction in their most severe symptoms and mast cell reactions

Reductions were shown in all individual MS2D2 symptoms across domains and objective reduction in skin lesions corresponding with symptomatic improvement

WALTHAM, Mass. and BOULDER, Colo., June 14, 2024 (GLOBE NEWSWIRE) -- Cogent Biosciences, Inc. (Nasdaq: COGT), a biotechnology company focused on developing precision therapies for genetically defined diseases, today announced additional data from Part 1 of its ongoing SUMMIT clinical trial evaluating the selective KIT D816V inhibitor, bezuclastinib, in patients with nonadvanced systemic mastocytosis (NonAdvSM). The data are being presented today in a poster presentation at the 2024 European Hematology Association (EHA) Congress taking place in Madrid, Spain.

“We are excited to share additional analyses from SUMMIT Part 1 which highlight substantial symptomatic reductions as well as improvement in objective measures of disease,” said Andrew Robbins, Chief Executive Officer at Cogent Biosciences. “We remain on track to complete enrollment in the registration-directed SUMMIT Part 2 study in the second quarter of 2025 and report topline results by year-end 2025.”

“Nonadvanced systemic mastocytosis is a debilitating hematologic disorder and physicians and patients remain in search of more effective treatment options to fight this disease,” said Lindsay Rein, MD, Associate Professor of Medicine in the Division of Hematologic Malignancies and Cellular Therapy at Duke University. “I am impressed with the rapid patient response and reductions seen across all domains at 12 weeks as well as the safety and tolerability. I believe bezuclastinib shows promise in treating nonadvanced systemic mastocytosis where significant unmet needs remain.”

SUMMIT Trial Update

SUMMIT is a randomized, double-blind, placebo-controlled, global, multicenter, Phase 2 clinical trial of bezuclastinib in patients with NonAdvSM. Part 1 of the trial was designed to determine the recommended dose of bezuclastinib. In addition, the study was designed to explore the effects of bezuclastinib on the signs and symptoms of NonAdvSM, including assessment of disease-specific symptom severity using a novel patient-reported outcome measure, the Mastocytosis Symptom Severity Daily Diary (MS2D2). As of the cutoff date, December 18, 2023, patients in Part 1 treated at the recommended dose of 100 mg bezuclastinib demonstrated >90% reductions across all markers of mast cell burden. Additional data also show meaningful reduction in symptom severity and objective measures of disease, including:

- Substantial reduction in mast cell reactions (>50%) and patients’ most severe symptoms as measured by MS2D2
- Clinically meaningful reduction in all individual MS2D2 TSS symptoms and across domains, as well as additional symptoms including dizziness, diarrhea severity, and brain fog
- Clinically meaningful improvement in skin symptoms as well as objective reduction in skin lesions

Safety Data from SUMMIT Part 1

Consistent with results previously reported, as of the December 18, 2023 cutoff date, the recommended dose of 100 mg demonstrates a favorable safety and tolerability profile. There were no bleeding or cognitive impairment adverse events reported and no serious adverse events reported.

EHA Poster Details

Title: Symptom-Focused Results from SUMMIT Part 1: An Ongoing, Randomized, Double-Blind, Placebo-Controlled Phase 2 Clinical Trial of Bezuclastinib in Adult Patients with NonAdvanced Systemic Mastocytosis
Presenting Author: Lindsay Rein, MD
Abstract #: P1055
Poster Session Date and Time: June 14, 2024 at 18:00 – 19:00 CEST

The poster will be available in the Posters and Publications section of Cogent’s website.

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 therapeutic potential of bezuclastinib to treat NonAdvSM patients, the expectation to complete enrollment in SUMMIT Part 2 in the second quarter of 2025 and to report top-line results by year-end 2025, the expectation to complete enrollment in the APEX trial by the end of 2024 and to report top-line results mid-2025 and 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 year-end 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 Annual Report on Form 10-K filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings 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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