Cogent Biosciences Announces FDA Acceptance of New Drug Application (NDA) with Priority Review for Bezuclastinib in Combination with Sunitinib for Patients with GIST

May 28, 2026

NDA acceptance with Priority Review builds upon previous assignment of Breakthrough Therapy Designation and Real-Time Oncology Review following Phase 3 PEAK results; PDUFA date set for November 30, 2026

Bezuclastinib combination is first treatment ever to demonstrate statistically significant advantage against an active comparator in GIST patients; median PFS of 16.5 months versus 9.2 months (HR=0.50, CI: 0.39-0.65, p<0.0001) for bezuclastinib combination compared to sunitinib alone

Full results from the Phase 3 PEAK trial to be shared in oral presentation at ASCO on Saturday, May 30, 2026

WALTHAM, Mass. and BOULDER, Colo., May 28, 2026 (GLOBE NEWSWIRE) -- Cogent Biosciences, Inc. (Nasdaq: COGT), a biotechnology company focused on developing precision therapies for genetically defined diseases, today announced that the U.S. Food and Drug Administration (FDA) has accepted its New Drug Application (NDA) for bezuclastinib in combination with sunitinib for patients with Gastrointestinal Stromal Tumors (GIST) who have received prior treatment with imatinib. The FDA has granted the application Priority Review and assigned a Prescription Drug User Fee Act (PDUFA) target action date of November 30, 2026. In addition, the FDA communicated that at this time, there is no plan to hold an advisory committee, nor have they identified any potential review issues.

“We are excited to announce that our bezuclastinib NDA for patients with GIST has been accepted for review by the FDA,” said Andrew Robbins, President and Chief Executive Officer of Cogent Biosciences. “We look forward to presenting the full, groundbreaking results from the PEAK trial at ASCO this weekend, and our preparations for expected bezuclastinib launches in both GIST and systemic mastocytosis later this year are well underway.”

PEAK Phase 3 Trial Results

As reported in November 2025, PEAK is a global, randomized Phase 3 clinical trial evaluating bezuclastinib in combination with sunitinib vs. sunitinib monotherapy in patients with imatinib-resistant or intolerant GIST. As of the cutoff date, September 30, 2025, the bezuclastinib combination demonstrated a substantial and highly statistically significant clinical benefit on the primary endpoint of PFS, reducing risk of disease progression or death compared to the current standard of care by 50% (hazard ratio of 0.50, 95% CI: 0.39 – 0.65). mPFS, as assessed by blinded independent central review, was 16.5 months for the bezuclastinib combination vs. 9.2 months for sunitinib monotherapy. Additionally, the bezuclastinib combination demonstrated an unprecedented ORR in imatinib-resistant patients, with 46% of patients treated with the bezuclastinib combination achieving an objective response compared to 26% of patients treated with sunitinib. Data for overall survival remains immature.

Safety Data

As of the data cutoff, the bezuclastinib combination was generally well tolerated, and no unique risks were observed with the novel combination when compared to the known safety profile of sunitinib. The most commonly reported Grade 3+ treatment emergent adverse events in either arm (bezuclastinib combination vs. sunitinib) included: Hypertension (29.4% vs. 27.4%), Neutropenia (15.2% vs. 15.4%), ALT/AST increased (10.8% vs. 1.4%), Anemia (9.3% vs. 4.8%) and Diarrhea (7.8% vs. 7.2%). 7.4% of patients on the bezuclastinib combination and 3.8% of patients on sunitinib monotherapy discontinued study treatment(s) due to treatment related adverse events. Hepatic adverse events were predominantly transient and manageable lab abnormalities; the majority of which were low grade, non-serious, reversible and asymptomatic. In the combination arm, ALT/AST elevations led to bezuclastinib dose reductions in 12.7% of patients with only 3 subjects (1.5%) discontinuing bezuclastinib for ALT/AST elevations. All Grade 3 ALT/AST elevations resolved, and no Grade 4 elevations were reported.

PEAK Phase 3 – ASCO Oral Presentation Details

Abstract Title: Primary Results of the Phase 3 Peak Study of bezuclastinib + sunitinib vs sunitinib Monotherapy in Advanced Gastrointestinal Stromal Tumors (GIST)
Abstract Number for Publication: 11500
Presenter: Andrew J. 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
Session Date and Time: May 30, 2026, 3:00 PM-6:00 PM CT (4:00 PM-7:00 PM ET)

Session Title: Oral Abstract Session - Sarcoma
Location: South Building, Floor 1, Grand Ballroom, S100bc - McCormick Place Convention Center, Chicago, IL

Bezuclastinib - Expanded Access Program

Working with the FDA, Cogent has established active Expanded Access Programs (EAPs) for U.S. patients with GIST or SM who meet disease-specific criteria and could benefit from treatment with bezuclastinib or the combination of bezuclastinib and sunitinib. For more information please visit: **https://www.cogentbio.com/bezuclastinib-program-development/#our-expanded-access-policy**

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, the Cogent Research Team is developing a portfolio of novel targeted therapies to help patients fighting serious, genetically driven diseases targeting mutations in ErbB2, PI3Kα, KRAS and JAK2. 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 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: plans to present the full results from the PEAK trial at ASCO this weekend and the expected launch of bezuclastinib in both GIST and SM later this year. 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, as supplemented by Quarterly Reports on Form 10-Q and other filings Cogent makes with the SEC from time to time . 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 a 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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