Cogent Biosciences to Initiate New Drug Application (NDA) Submission for Bezuclastinib Under Real-Time Oncology Review (RTOR)

January 20, 2026

- *PEAK trial first ever study to demonstrate statistical significance over an active comparator in GIST patients, with bezuclastinib plus sunitinib combination demonstrating mPFS of 16.5 months and ORR of 46% in patients who had received prior treatment with imatinib*

- *Cogent is expected to initiate the RTOR process immediately; completion of the PEAK NDA submission expected in April 2026*

WALTHAM, Mass. and BOULDER, Colo., Jan. 20, 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 agreed to accept 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 under the Real-Time Oncology Review (RTOR) program.

"This milestone reflects the FDA's recognition of the significant unmet need facing patients with imatinib resistant GIST," said Andrew Robbins, Cogent's President and Chief Executive Officer. "Based on positive results from the PEAK trial, the bezuclastinib combination has the potential to be the first new approval in this patient population in over 20 years. We look forward to the continued, close collaboration with the FDA as we advance bezuclastinib toward commercialization."

As announced in November 2025, the bezuclastinib combination in the PEAK trial demonstrated a substantial and highly statistically significant clinical benefit on the primary endpoint of progression free survival (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 overall response rate (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. At the time of this analysis, data for overall survival remains immature.

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 FDA's RTOR program allows an applicant to pre-submit components of its NDA to allow the FDA to review clinical trial data before the complete filing is submitted and aims to provide a more efficient review process to ensure safe and effective treatments are available to patients as early as possible. Cogent is expected to initiate the RTOR process immediately with completion of the NDA submission expected in April 2026.

Full results from the PEAK trial will be presented at a major medical meeting during the first half of 2026.
Additionally, Cogent expects to initiate in mid-2026 a Phase 2 trial investigating the benefit of the bezuclastinib combination for first-line GIST patients with exon 9 mutations who are naive to, or recently initiated treatment with, imatinib.

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 FGFR2/3, 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 (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 company's expectation that it will initiate the RTOR process immediately and complete its NDA submission for bezuclastinib in GIST in April 2026; the potential for the bezuclastinib combination to be the first approved therapy for GIST patients in over 20 years; plans to present the full results from the PEAK trial at a major medical meeting during the first half of 2026 and the expectation to initiate in mid-2026 a Phase 2 trial

investigating the benefit of the bezuclastinib combination for first-line GIST patients with exon 9 mutations who are naive to, or recently initiated treatment with, imatinib. 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 and/or 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