Cogent Biosciences Announces Breakthrough Therapy Designation for Bezuclastinib in Combination with Sunitinib for Patients with Gastrointestinal Stromal Tumors (GIST)

January 26, 2026

- *Cogent will submit the PEAK New Drug Application (NDA) under previously announced RTOR designation; on track to complete NDA submission in April 2026*

WALTHAM, Mass. and BOULDER, Colo., Jan. 26, 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 granted Breakthrough Therapy Designation (BTD) for bezuclastinib in combination with sunitinib for patients with Gastrointestinal Stromal Tumors (GIST) who have received prior treatment with imatinib.

“We are excited to announce this Breakthrough Therapy Designation which recognizes the potential for the bezuclastinib combination to substantially improve upon the currently available treatment options for patients with imatinib-resistant GIST,” said Andrew Robbins, Cogent’s President and Chief Executive Officer. “We look forward to the continued collaboration with the FDA as we work to bring the first new treatment option in over twenty years to this patient population.”

This Breakthrough Therapy Designation is based on results from the PEAK trial which 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. The combination was well tolerated, and no new safety risks were observed when compared to the known safety profile of sunitinib. Breakthrough Therapy Designation is intended to expedite the review of medicines that treat a serious or life-threatening condition and have shown clinical evidence indicating the potential for substantial improvement over available therapies.

Earlier this month, the FDA agreed to accept Cogent’s NDA under the FDA’s Real-Time Oncology Review (RTOR) program which 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 plans to present full results from the PEAK trial at a major medical meeting during the first half of 2026. Additionally, in mid-2026 Cogent expects to initiate a Phase 2 trial investigating the benefit of the bezuclastinib plus sunitinib 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 plans to submit its PEAK NDA under RTOR and to complete the NDA submission in April 2026; the potential for the bezuclastinib combination to substantially improve upon the currently available treatment options for patients with imatinib-resistant GIST; the anticipated benefits of FDA’s RTOR and Breakthrough Therapy Designation; 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 plus sunitinib 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.

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