Cogent Biosciences Announces Submission of New Drug Application for Bezuclastinib in Gastrointestinal Stromal Tumors (GIST)

April 1, 2026

- *Bezuclastinib NDA submitted under the FDA's RTOR program based on positive results from Phase 3 PEAK trial; bezuclastinib previously granted Breakthrough Therapy Designation in GIST*

- *Bezuclastinib combination demonstrated 16.5 month mPFS and 46% ORR in imatinib-resistant GIST patients, dramatically improving upon the current standard of care*

WALTHAM, Mass. and BOULDER, Colo., April 01, 2026 (GLOBE NEWSWIRE) -- Cogent Biosciences, Inc. (Nasdaq: COGT), a biotechnology company focused on developing precision therapies for genetically defined diseases, today announced the completion of the submission of its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for bezuclastinib in patients with Gastrointestinal Stromal Tumors (GIST) who have received prior treatment with imatinib. Based on the positive results from the PEAK trial, the bezuclastinib NDA was submitted under the FDA's Real-Time Oncology Review (RTOR) program, which is intended to enable a more streamlined review process. Bezuclastinib was also granted Breakthrough Therapy Designation as a treatment for GIST earlier this year.

"We are excited to complete our PEAK NDA submission which marks a significant step toward bringing a new therapy to patients with second-line GIST," said Andrew Robbins, President and Chief Executive Officer. "Based on the strength of the PEAK data, we believe the bezuclastinib combination has the potential to meaningfully change the treatment landscape for these patients. We are grateful to the patients, investigators, and study teams who made this possible."

Pivotal data from PEAK, a global, randomized Phase 3 clinical trial evaluating bezuclastinib in combination with sunitinib vs. sunitinib monotherapy in patients with GIST who have received prior treatment with imatinib, were reported in November 2025. As disclosed in the top-line results, the bezuclastinib combination 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 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. 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. Data for overall survival remains immature.

At the time of data cutoff, based on the number of ongoing patients receiving treatment on the bezuclastinib combination arm, the estimated mean duration of treatment for the bezuclastinib combination is projected to exceed 19 months.

Cogent plans to present full results from the PEAK trial at a major medical meeting during the first half of 2026. Additionally, Cogent is on track this quarter 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. The NDA submission with bezuclastinib in Advanced Systemic Mastocytosis (AdvSM) also remains on track for the first half of 2026.

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. A growing number of sites now offer access to the bezuclastinib EAPs. For more information please visit: **https://www.cogentbio.com/bezuclastinib-program-development/#our-expanded-access-policy**

Inducement Grants Under Nasdaq Listing Rule 5635(c)(4)
Cogent also announced today that, on March 30, 2026, the Compensation Committee of Cogent's Board of Directors, made up entirely of independent directors, approved the grants of "inducement" equity awards to six new employees under the company's 2020 Inducement Plan with a grant date of March 30, 2026. The awards were approved in accordance with Listing Rule 5635(c)(4) of the corporate governance rules of the Nasdaq Stock Market. The employees received, in the aggregate, (i) nonqualified options to purchase 21,100 shares of Cogent common stock and (ii) 15,700 restricted stock units (RSUs). Each option has a 10-year term, an exercise price equal to the closing price of Cogent's common stock on the grant date, and a 4-year vesting schedule with 25% vesting on the 1-year anniversary of the grant date and the remainder vesting in equal monthly installments over the subsequent 36 months, provided such employee remains employed through each such vesting date. The RSUs vest annually in equal installments over 4 years from the grant date, provided such employee remains employed through

each such vesting date.

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** (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 plan to bring a new therapy to patients with second-line GIST; the company's belief that the bezuclastinib combination has the potential to meaningfully change the treatment landscape for patients with second-line GIST; the company's projection for the estimated mean duration of treatment for the bezuclastinib combination; the company's expectation to present full results from the PEAK trial at a major medical meeting during the first half of 2026; the company's plans this quarter 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; and the company's plans to submit an NDA for bezuclastinib in AdvSM in the first half of 2026. 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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