Cogent Biosciences Announces Anticipated 2026 Commercial and Clinical Milestones for Bezuclastinib and Precision Therapies Portfolio

January 12, 2026

- *New Drug Application (NDA) for NonAdvSM submitted in December 2025, NDA submission for AdvSM on track for 1H 2026*
- *NDA submission for GIST on track for April 2026; bezuclastinib has the potential to be the first new therapy for second-line GIST in over 20 years*
- *Clinical data presentations from all three pivotal trials, PEAK, SUMMIT and APEX, expected at major medical meetings in 1H 2026*
- *Investigational New Drug (IND) applications expected in 2026 for potentially best-in-class pan-KRAS(ON) and selective JAK2 V617F inhibitors*
- *Strong financial position with ~$900 million cash to begin 2026, sufficient to fund commercial launches and operations well into 2028*
- *Company to present at the 44th Annual J.P. Morgan Healthcare Conference on Tuesday, January 13, 2026 at 8:15 am PT/11:15 am ET*

WALTHAM, Mass. and BOULDER, Colo., Jan. 12, 2026 (GLOBE NEWSWIRE) -- **Cogent Biosciences, Inc.** (Nasdaq: COGT), a biotechnology company focused on developing precision therapies for genetically defined diseases, today highlighted the company's key 2026 milestones ahead of its presentation at J.P. Morgan's 44th annual healthcare conference.

"2025 was marked by exceptional progress at Cogent Biosciences," said Andrew Robbins, President and Chief Executive Officer. "We reported positive results from all three pivotal trials of bezuclastinib in patients with GIST and Systemic Mastocytosis, submitted our first NDA for bezuclastinib in patients with NonAdvSM based on the strength of the SUMMIT data, and put ourselves in a very strong financial position entering the new year. During 2026, we will transform Cogent into a fully integrated commercial stage company with plans to launch bezuclastinib in the second half of the year. In addition, we are investing for the future and plan to submit INDs in 2026 for both our pan-KRAS inhibitor and recently announced JAK2 V617F inhibitor. Our plans are supported by a highly experienced team with proven launch experience backed by a strong balance sheet. We are poised for success and extremely excited about the meaningful impact we can have for patients."

In 2026, Cogent plans to achieve the following milestones:

Bezuclastinib

- Acceptance of the New Drug Application (NDA) for bezuclastinib in NonAdvanced Systemic Mastocytosis (NonAdvSM) by the end of February 2026
- Submit an NDA in April 2026 for bezuclastinib in patients with advanced Gastrointestinal Stromal Tumors (GIST) previously treated with imatinib based on the strength of the PEAK pivotal trial
- Submit an NDA in 1H 2026 for bezuclastinib in patients with Advanced Systemic Mastocytosis (AdvSM) based on the strength of the APEX pivotal trial
- Present detailed, updated clinical data from each of the three pivotal trials (SUMMIT, PEAK, APEX) at major medical meetings during 1H 2026
- Commercialize bezuclastinib following potential FDA approval in 2H 2026

Pipeline

- Submit Investigational New Drug (IND) applications for CGT1815, Cogent's novel, selective pan-KRAS(ON) inhibitor and CGT1145, Cogent's novel, selective JAK2 V617F inhibitor
- Present clinical data on CGT4859, Cogent's selective and potent FGFR 2/3 inhibitor, from its Phase 1/2 study in patients with alterations in FGFR2 or FGFR3
- Complete dose escalation for both CGT4255, Cogent's CNS-penetrant, selective mutant ErbB2 inhibitor, and CGT6297, Cogent's selective PI3Kα inhibitor

Bezuclastinib Expanded Access Programs

Working with the FDA, Cogent has established active Expanded Access Programs 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 investigational sites now offer access to the bezuclastinib EAPs. For more information please visit:

https://www.cogentbio.com/bezuclastinib-program-development/#our-expanded-access-policy

New Leadership Appointment

Cogent also announced today that Abb Hayden has joined Cogent as Senior Vice President, Sales. Mr. Hayden joins Cogent with over 25 years of industry experience. Previously he served as Vice President of Commercial at Syndax Pharmaceuticals. While at Syndax, he played an integral part in building the commercial infrastructure leading the Field Sales, Marketing, and Clinical Education team to launch Revuforj and Niktimvo. Prior to Syndax, he held roles of increasing responsibility at Adaptive Biotechnologies, Onyx Pharmaceuticals, and Eli Lilly. Mr. Hayden is a graduate of the University of Central Arkansas.

J.P. Morgan Presentation Details

Cogent will participate in a presentation and Q&A session at the 44th Annual J.P. Morgan Healthcare Conference on Tuesday, January 13, 2026, beginning at 8:15 a.m. PT (11:15 a.m. ET). A live webcast will be accessible in the "Investors & Media" section of the company's website, www.cogentbio.com, and will be archived for 30 days following the event.

Inducement Grants Under Nasdaq Listing Rule 5635(c)(4)
Cogent also announced today that, on January 9, 2026, the Compensation Committee of Cogent's Board of Directors, made up entirely of independent directors, approved the grant of "inducement" equity awards to five new employees under the company's 2020 Inducement Plan with a grant date of January 9, 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 66,700 shares of Cogent common stock and (ii) 9,700 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. The company also has an ongoing Phase 1 study of its novel internally discovered FGFR2/3 inhibitor. 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 expectation that the FDA will accept our NDA for bezuclastinib in NonAdvSM by the end of February 2026 and approve it for commercial use in the second half of 2026; plans to submit an NDA in April 2026 for bezuclastinib in GIST; plans to submit an NDA in the first half of 2026 for bezuclastinib in AdvSM; plans to present updated clinical data from each of the SUMMIT, PEAK and APEX trials at major medical meetings in the first half of 2026; plans to launch bezuclastinib commercially in the second half of 2026 following FDA approval; plans to submit INDs in 2026 for both our pan-KRAS and JAK2 V617F inhibitors; the potential for bezuclastinib to be the first new therapy for second-line GIST in over 20 years; the expectation that our cash runway is sufficient to fund commercial launches and operations well into 2028; the expectation that Cogent will transform into a fully integrated commercial stage company in 2026; plans to present clinical data in 2026 on CGT4859 and plans to complete dose escalation in 2026 for both CGT4255 and CGT6297. 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 or 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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