Cogent Biosciences Announces FDA Approval and Launch of EKITNA™ (bezuclastinib) for the Treatment of Patients with Gastrointestinal Stromal Tumors (GIST) Who Have Received Prior Treatment with Imatinib

November 24, 2026

FDA approval based on results from pivotal Phase 3 PEAK trial; first ever GIST treatment to demonstrate a statistically significant progression-free survival benefit versus an active comparator

EKITNA plus sunitinib demonstrated 16.5 month mPFS and 46% ORR; mean Duration of Treatment now estimated at 23.3 months in this patient population

EKITNA now available by prescription in the U.S. with patient support offered through Cogent Connect™

Cogent to host investor conference call today at 10:30 AM Eastern Time

EKITNA logo

EKITNA logo

EKITNA Bottle and Package



EKITNA bottle and package

WALTHAM, Mass. and BOULDER, Colo., Nov. 24, 2026 (GLOBE NEWSWIRE) -- Cogent Biosciences, Inc. (Nasdaq: COGT), a commercial-stage biotechnology company focused on developing precision therapies for genetically defined diseases, today announced that the U.S. Food and Drug Administration (FDA) has approved EKITNA™ (bezuclastinib), a kinase inhibitor indicated for the treatment of adult patients with advanced gastrointestinal stromal tumors (GIST) who have received prior treatment with imatinib. EKITNA is the first treatment approved in this setting in over 20 years.

“Today’s FDA approval of EKITNA marks an enormous milestone for people living with GIST and a historic milestone for Cogent. After seeing the incredible results of the PEAK trial, we were confident this day would come, and we are excited that it is finally here,” said Andrew Robbins, President and Chief Executive Officer of Cogent Biosciences. “On behalf of all Cogent employees, we are extremely proud to launch EKITNA, which brings new hope to GIST patients searching for better treatment options.”

The approval is based on data from the global, randomized Phase 3 PEAK trial evaluating EKITNA in combination with sunitinib vs. sunitinib monotherapy in patients with imatinib-resistant or intolerant GIST. As of the cutoff date, September 30, 2025, the EKITNA 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 EKITNA combination vs. 9.2 months for sunitinib monotherapy. Additionally, the EKITNA combination demonstrated an unprecedented ORR in imatinib-resistant/intolerant patients, with 46% of patients treated with the EKITNA combination achieving an objective response compared to 26% of patients treated with sunitinib.

“With today’s FDA approval of bezuclastinib in combination with sunitinib, we have a new standard of care treatment following imatinib for patients with GIST,” said Andrew 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. “This approval represents a major step forward for the GIST community and reflects the tireless progress made in improving the lives of people living with this disease.”

“This approval is an incredibly meaningful milestone for the GIST community that has waited many years hoping, advocating, and helping advance the research for a new treatment option,” said Sara Rothschild, Executive Director, The Life Raft Group. “On behalf of GIST patients, we share our excitement for the life-extending benefits that EKITNA will offer our community.”

Cogent Connect ™: EKITNA Access and Patient Support

Cogent is committed to ensuring that every GIST patient who can benefit from EKITNA is able to receive it, regardless of economic status. To this end, we are launching the Cogent Connect™ Patient Support Program, a broad-based program to

support healthcare professionals and patients navigate any and all access barriers. Please visit www.cogent-connect.com for more information.

Investor Conference Call and Webcast
Cogent will host an investor conference call today, November 24, 2026 at 10:30am Eastern Time to discuss the FDA approval of EKITNA. The live event can be accessed here: https://edge.media-server.com/mmc/p/q33u5n3y Following the live event, a replay will be available on the Investors section of the Company's website at investors.cogentbio.com.

EKITNA Indication for Use

EKITNA is a kinase inhibitor indicated in combination with sunitinib for the treatment of adult patients with advanced gastrointestinal stromal tumors (GIST) who have received prior treatment with imatinib.

Important Safety Information

Hepatotoxicity: EKITNA in combination with sunitinib can cause hepatotoxicity. Monitor AST, ALT, and bilirubin before initiating and during treatment with EKITNA. Interrupt, reduce the dose of, or discontinue EKITNA based on severity.

Warnings and Precautions

Hepatotoxicity

In patients who received EKITNA in combination with sunitinib, increased ALT/AST occurred in 43% of patients (8% Grade 3 events) and increased bilirubin occurred in 13% (0.5% Grade 3). Most first transaminase increases occurred within the first 4 months.

Embryo-Fetal Toxicity

EKITNA can cause fetal harm. Advise pregnant women and females of reproductive potential of the potential fetal risk. Verify pregnancy status prior to initiating EKITNA. Advise females of reproductive potential to use effective non-hormonal contraception during treatment and for 2 weeks after the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment and for 2 weeks after the final dose.

Adverse Reactions

The most common adverse reactions (≥20%) were diarrhea, increased liver transaminases, hypertension, dysgeusia, nausea, hair color changes, fatigue, abdominal pain, vomiting, decreased appetite, stomatitis, GERD, rash, dyspepsia, and pyrexia.

Drug Interactions and Use in Special Populations

- Avoid concomitant use with UGT1A1 inhibitors and inducers
- EKITNA may decrease plasma concentrations of hormonal contraceptives
- EKITNA may impair fertility in females and males
- Advise women not to breastfeed during treatment with EKITNA and for 2 weeks after the final dose

Please find full prescribing information, including Boxed Warning, at www.ekitna.com.

About Cogent Biosciences, Inc.
Cogent Biosciences is a commercial-stage biotechnology company focused on developing precision therapies for genetically defined diseases. 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: the availability and potential risks and benefits of the EKITNA combination; the expectation that the EKITNA combination will become the new standard of care for GIST patients following imatinib; the expectation that the EKITNA combination will provide life-extending benefits to GIST patients and the expectation that the Cogent Connect patient support program will enable healthcare professionals and patients to navigate any and all access barriers. 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 plans, operations and strategies. 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.

Photos accompanying this announcement are available at

https://www.globenewswire.com/NewsRoom/AttachmentNg/4f7b96fe-b4cc-45ac-b6cd-edd0eb10a47f

https://www.globenewswire.com/NewsRoom/AttachmentNg/8d63f47e-926c-4e52-825d-54f1cfe68de3

Contact: Christi Waarich Senior Director, Investor Relations christi.waarich@cogentbio.com 617-830-1653