Cogent Biosciences Announces Detailed Data from APEX Pivotal Trial of Bezuclastinib in Patients with Advanced Systemic Mastocytosis at the 2026 European Hematology Association (EHA) Congress

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-- Bezuclastinib demonstrated rapid and deep clinical benefit in AdvSM patients resulting in an updated objective response rate (CR+CRh+PR+CI) of 65% per mIWG criteria and 81% ORR per PPR criteria –

-- Bezuclastinib demonstrated a powerful effect on mast cell burden with 91% of patients achieving ≥50% reduction in variant allele frequency and 89% of patients achieving ≥50% reduction in bone marrow mast cells or clearance of aggregates –

-- Bezuclastinib continues to demonstrate a favorable safety and tolerability profile –

-- APEX NDA to be submitted in June 2026 –

WALTHAM, Mass. and BOULDER, Colo., June 12, 2026 (GLOBE NEWSWIRE) -- Cogent Biosciences, Inc. (Nasdaq: COGT), a biotechnology company focused on developing precision therapies for genetically defined diseases, today announced detailed and updated clinical results from the registration-directed APEX clinical trial of bezuclastinib in patients with advanced systemic mastocytosis (AdvSM) demonstrating clinically meaningful results as measured by consensus criteria used to assess patient response. The company also shared a more detailed review of the pathobiology data in AdvSM patients from the APEX trial, reinforcing the rapid and deep clinical benefit bezuclastinib has demonstrated in these patients. The data will be presented at the 2026 European Hematology Association (EHA) Congress taking place in Stockholm, Sweden, June 11-14, 2026.

“We are excited to share updated and detailed results from the APEX trial in AdvSM patients, building upon previously announced results from bezuclastinib in the SUMMIT trial in NonAdvSM patients,” said Andrew Robbins, Cogent’s President and Chief Executive Officer. “The results shown across these two trials demonstrate that a selective, potent KIT D816V inhibitor like bezuclastinib will have tremendous opportunity to become the new standard of care and change the lives of patients living with systemic mastocytosis. We are on track to complete the APEX NDA submission in the very near future and plan to launch bezuclastinib later this year in both systemic mastocytosis and GIST following FDA approval.”

As of the updated data cutoff of March 31, 2026 in Part 2 of the APEX trial, 81 AdvSM patients were treated with 150 mg of bezuclastinib, including 57 patients with SM-AHN, 11 patients with ASM and 13 patients with MCL. The primary endpoint of response per mIWG-MRT-ECNM was assessed on 68 evaluable patients and showed 65% ORR (CR+CRh+PR+CI), including 57% of patients who achieved CR, CRh or PR as best response.

Additional highlights include:

- Key secondary endpoint of response per pure pathological response (PPR) criteria was assessed on 81 patients which showed an 81% ORR (CR+CRh+PR).
- Bezuclastinib demonstrated reversal of bone marrow pathobiology including rapid and deep reductions in aberrant CD25 and CD30 expression, normalization of mast cell morphology, normalization of bone marrow cellularity, and improvement in myelofibrosis.
- Bezuclastinib demonstrated durable clinical activity and prolonged PFS with a 12-month PFS rate of 79% and a 12-month OS rate of 87%. Median duration of PFS and OS were immature at the time of the data cutoff.
- Bezuclastinib achieved clear and clinically significant reductions in objective disease markers for these AdvSM patients:

Outcome measure	**Bezuclastinib**
Proportion with ≥50% reduction in serum tryptase (n=80)	89%
Proportion with ≥50% reduction in bone marrow mast cells or clearance of aggregates (n=80)	89%
Proportion with ≥50% reduction in KIT D816V variant allele frequency (n=43)	91%

“The results from the APEX trial demonstrate clear evidence of bezuclastinib’s rapid and deep clinical activity in patients with advanced systemic mastocytosis,” said Daniel J. DeAngelo, M.D., Ph.D., Chief of the Division of Leukemia at the Dana-Farber Cancer Institute and Professor of Medicine, Harvard Medical School. "Coupled with an impressive safety and tolerability profile

minimizing off-target toxicities that allows for long-term therapeutic dosing, bezuclastinib will become an important treatment option for patients with advanced SM."

Pathobiology Data

Cogent will also present new data highlighting the impact bezuclastinib has at a cellular level in patients with AdvSM. In the APEX study, bezuclastinib demonstrated robust improvement in disease pathology, with effects observed as early as eight weeks, including high PPR rates, improvement (including normalization) in bone marrow mast cell distribution, improvement in broader bone marrow characteristics and a majority of patients achieving normalization of serum tryptase. In addition, approximately one-third of patients treated with bezuclastinib achieved undetectable levels of KIT D816V VAF, signifying modification of the underlying AdvSM disease with bezuclastinib treatment.

APEX Safety and Tolerability

As of the data cutoff, bezuclastinib continued to be well-tolerated, with infrequent need for dose reduction or discontinuation for treatment-related adverse events (TRAEs). The most frequent TRAEs reported on bezuclastinib treatment were hair color change (31%), neutropenia (31%), altered taste (28%), thrombocytopenia (25%), and ALT/AST elevations (21%). The majority of transaminase elevations were of low grade, asymptomatic and reversible. Of the two patients who experienced Grade 3 transaminase elevation, one discontinued treatment and one remains on therapy following dose reduction.

The EHA posters and presentation will be available on the Cogent website at: https://www.cogentbio.com/pipeline-publications/#posters-publications

Bezuclastinib - Expanded Access Program

Working with the FDA, Cogent has established active Expanded Access Programs (EAPs) for U.S. patients SM or GIST who meet disease-specific criteria and could benefit from treatment with bezuclastinib or the combination of bezuclastinib and sunitinib. For more information please visit: **https://www.cogentbio.com/bezuclastinib-program-development/#our-expanded-access-policy**

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 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 an IND for bezuclastinib in AdvSM in June 2026; the expectation that bezuclastinib will become the new standard of care and change the lives of patients living with systemic mastocytosis; the company's plans to launch bezuclastinib commercially later this year in both systemic mastocytosis and GIST following FDA approval; and the expectation that bezuclastinib will become an important treatment option for patients with AdvSM. 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, 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.

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