Cogent Biosciences Provides 2022 Corporate Guidance

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APEX, SUMMIT and PEAK bezuclastinib clinical trials all initiated and enrolling
APEX preliminary clinical data readout expected in the first half of 2022
R&D investor event planned April 2022 to detail robust discovery pipeline

CAMBRIDGE, Mass. and BOULDER, Colo., Jan. 5, 2022 /PRNewswire/ -- Cogent Biosciences, Inc. (Nasdaq: COGT), a biotechnology company focused on developing precision therapies for genetically defined diseases, today provided 2021 year-end updates and corporate guidance for 2022.

"I am proud of the substantial progress the Cogent team made in 2021. In addition to achieving our key corporate milestones of initiating three late-stage clinical trials of bezuclastinib, our highly potent and selective KIT mutant inhibitor, we also formed the Cogent Research Team which is focused on building a portfolio of best-in-class small molecules for patients with significant unmet medical need," said Andrew Robbins, President and CEO of Cogent Biosciences. "In 2022, we will advance the APEX, SUMMIT and PEAK clinical trials, with preliminary clinical data expected from APEX in the first half of 2022. In addition, we look forward to moving into our new research headquarters in Boulder and to sharing more details about the impressive research pipeline the Cogent Research Team has created in a very short period of time."

Key Highlights

- **Bezuclastinib now under investigation in three late-stage clinical trials**
  - **APEX clinical trial in patients with Advanced Systemic Mastocytosis (AdvSM)**: In mid-2021, Cogent initiated APEX, a Phase 2 clinical study of bezuclastinib in patients with AdvSM. APEX is an open-label, global, multicenter study evaluating the safety, efficacy, pharmacokinetic, and pharmacodynamic profiles of bezuclastinib. We expect to report preliminary clinical data at a scientific conference during the first half of 2022, including safety and tolerability data as well as bezuclastinib's impact on serum tryptase levels, a validated biomarker of mast cell activity. Learn more about the APEX trial at cogentclinicaltrials.com/apex/.
  - **SUMMIT clinical trial in patients with Nonadvanced Systemic Mastocytosis (NonAdvSM)**: In the fall of 2021, Cogent initiated SUMMIT, a randomized, double-blind, placebo-controlled, global Phase 2 clinical trial. The study is designed to explore the safety and efficacy of bezuclastinib in patients with moderate to severe Indolent Systemic Mastocytosis (ISM) or Smoldering Systemic Mastocytosis (SSM). Learn more about the SUMMIT trial at cogentclinicaltrials.com/summit/.
  - **PEAK clinical trial in patients with Gastrointestinal Stromal Tumors (GIST)**: During the fourth quarter of 2021, Cogent initiated PEAK, a randomized, open-label, global Phase 3 clinical trial. The PEAK study is designed to explore the efficacy of bezuclastinib in combination with sunitinib compared to sunitinib alone in patients with locally advanced, unresectable or metastatic GIST who have received prior treatment with imatinib.

- **Preclinical data highlights bezuclastinib as potent KIT inhibitor with minimal CNS activity and PDGFR inhibition**
  - During the third quarter of 2021, Cogent presented preclinical data providing further evidence of bezuclastinib as a differentiated, potent, and selective KIT mutant inhibitor with minimal brain penetration that avoids targeting PDGFR isoforms. These data were presented in a virtual poster at the 2021 AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics.

- **Cogent Research Team created to generate robust pipeline of potential best-in-class molecules**
  - **Cogent Research Team:** During the second quarter of 2021, the company announced the formation of its Cogent Research Team, a highly-experienced, Boulder-based discovery and research team focused on pioneering best-in-class, small molecule therapeutics to expand Cogent's pipeline.
    - The Cogent Research Team is led by John Robinson, PhD, and already has grown to over 35 employees. This spring, the team will move into its newly-built, state-of-the-art research facility in Boulder.
  - **Cogent Scientific Advisory Board:** In mid-2021, the company formed the Cogent Scientific Advisory Board, which is comprised of world-class experts involved in the discovery and development of novel therapeutics for patients with genetically driven diseases. This group has been brought together to provide external perspective for the Cogent Research Team as it develops a robust portfolio of novel, small molecule discovery programs designed to address significant patient unmet needs.
  - **R&D Investor Event:** In April 2022, Cogent will host an R&D investor event to introduce the Cogent Research Team, outline its strategy and focus to create best-in-class small molecules, highlight additional preclinical data demonstrating the potential differentiated profile for bezuclastinib and present early data from its growing pipeline of novel, small molecule targeted therapy programs.

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. Cogent Biosciences is based in Cambridge, MA and Boulder, CO. Visit our website for more information at www.cogentbio.com. Follow Cogent Biosciences on social media: Twitter and LinkedIn. Information that may be important to investors will be routinely posted on our website and Twitter.

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: 2022 corporate guidance, including the expectation to present preliminary clinical data from APEX in the first half of 2022, the plan to host an R&D investor event in April 2022 and the expectation to open a new research facility in Boulder; discussion of the company's business and operations; future product development plans; clinical development plans and timelines for its lead program, bezuclastinib; and the potential for bezuclastinib to be a best-in-class KIT mutant inhibitor. 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 filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings 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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