Ventyx Biosciences Announces Positive Results from the Phase 2 Trial of VTX002 in Patients with Moderate-to-Severely Active Ulcerative Colitis

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VTX002 60 mg achieved the primary endpoint of clinical remission with a high rate of complete endoscopic remission

Both 30 mg and 60 mg doses of VTX002 demonstrated an excellent safety and tolerability profile

Ventyx to host conference call and webcast today at 4:30 PM ET

SAN DIEGO, Oct. 09, 2023 (GLOBE NEWSWIRE) -- Ventyx Biosciences, Inc. (Nasdaq: VTYX) ("Ventyx"), a clinical-stage biopharmaceutical company focused on advancing novel oral therapies that address a broad range of inflammatory diseases with significant unmet medical need, today announced positive results from the Phase 2 trial of VTX002, a novel oral S1P1 receptor modulator, in patients with moderate-to-severely active ulcerative colitis (UC).

"We are very excited to share the positive Phase 2 results for VTX002, which we believe establish VTX002 as a potential best-in-disease oral therapy for UC based on its combined efficacy and safety profile," said Raju Mohan, Ph.D., Founder and Chief Executive Officer.

The Phase 2 trial of VTX002 was a 13-week, randomized, double-blind, placebo-controlled, dose-ranging trial evaluating the efficacy and safety of two oral doses of VTX002 (30 mg and 60 mg once daily) in patients with moderate-to-severely active UC. The primary endpoint was the proportion of patients achieving clinical remission at Week 13 as defined by the modified Mayo Clinic Score. Secondary endpoints included endoscopic, histologic, and symptomatic outcome measures. Topline results are summarized below:

- 28% of patients on the 60 mg dose and 24% of patients on the 30 mg dose achieved the primary endpoint of clinical remission at Week 13 compared to 11% of patients on placebo (p=0.018 for 60 mg; p=0.041 for 30 mg).
- 29% of patients on the 60 mg dose and 21% of patients on the 30 mg dose achieved the secondary endpoint of complete endoscopic remission (Mayo endoscopic subscore of 0) at Week 13 compared to 7% of patients on placebo (p=0.001 for 60 mg; p=0.014 for 30 mg).
- Dose response was observed between the 30 mg and 60 mg doses of VTX002 across key endpoints, providing evidence of clinical benefit with a greater mean reduction in absolute lymphocyte count achieved with the 60 mg dose relative to the 30 mg dose.

VTX002 was well tolerated in both dose cohorts, with no treatment-related serious adverse events observed. There were no serious or opportunistic infections. There were no instances of atrioventricular block or bradycardia. No cases of macular edema were observed in the trial. Full results from the Phase 2 trial will be presented at a future medical meeting.

"The positive Phase 2 data for VTX002 establish a highly attractive profile for an oral agent in moderate-to-severely active UC, with the 60 mg dose achieving a compelling clinical remission rate, an unprecedented rate of complete endoscopic remission, and an excellent safety and tolerability profile," said William Sandborn, M.D., President and Chief Medical Officer. "I would like to thank all of the patients and investigators for their participation in this trial."

Bruce Sands, M.D., M.S., Chief of the Dr. Henry D. Janowitz Division of Gastroenterology at Mount Sinai, and the Dr. Burrill B. Crohn Professor of Medicine, Icahn School of Medicine at Mount Sinai added, "There remains substantial unmet need for novel therapies in moderate-to-severely active ulcerative colitis, and particularly for safe and effective oral agents. I am excited to see the positive results from the VTX002 Phase 2 trial." Dr. Sands is the primary investigator for this trial, and a paid consultant for Ventyx Biosciences, Inc. with stock and stock options in the company.

Conference Call Information

Ventyx will host a conference call today at 4:30 p.m. ET to discuss the results from the Phase 2 trial of VTX002 in patients with moderate-to-severely active UC. To participate in the conference call, please dial (800) 225-9448 (U.S.) or (203) 518-9708 (international) and reference passcode VTYX1009. A live webcast will be available in the Investors section of the company's website at www.ventyxbio.com. A recording of the webcast will be available for thirty days following the call.

About Ventyx Biosciences

Ventyx is a clinical-stage biopharmaceutical company focused on developing innovative oral medicines for patients living with autoimmune and inflammatory disorders. We believe our ability to efficiently discover and develop differentiated drug candidates will allow us to address important unmet medical need with novel oral therapies that can shift immunology markets from injectable to oral drugs. Our current pipeline includes internally discovered clinical programs targeting TYK2, S1P1R and NLRP3, positioning us to become a leader in the development of oral immunology therapies. Ventyx is headquartered in San Diego, California. For more information about Ventyx, please visit www.ventyxbio.com.

Forward-Looking Statements

Ventyx cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. These statements are based on Ventyx's current beliefs and expectations. Such forward-looking statements include, but are not limited to, statements regarding: the potential of Ventyx's product candidates and the anticipated continued progression of the development pipeline for such product

candidates; and the therapeutic and commercial potential of VTX002 in ulcerative colitis. The inclusion of forward-looking statements should not be regarded as a representation by Ventyx that any of its plans will be achieved. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in Ventyx's business, including, without limitation: potential delays in the commencement, enrollment and completion of clinical trials; Ventyx's dependence on third parties in connection with product manufacturing, research and preclinical and clinical testing; disruptions in the supply chain, including raw materials needed for manufacturing and animals used in research, delays in site activations and enrollment of clinical trials; the results of preclinical studies; early clinical trials not necessarily being predictive of future results; interim results not necessarily being predictive of final results; the potential of one or more outcomes to materially change as a trial continues and more patient data become available and following more comprehensive audit and verification procedures; regulatory developments in the United States and foreign countries; unexpected adverse side effects or inadequate efficacy of Ventyx's product candidates that may limit their development, regulatory approval and/or commercialization, or may result in recalls or product liability claims; Ventyx's ability to obtain and maintain intellectual property protection for its product candidates; the use of capital resources by Ventyx sooner than expected; disruption to Ventyx's operations from the ongoing military conflict in Ukraine, including clinical trial delays; and other risks described in Ventyx's prior press releases and Ventyx's filings with the Securities and Exchange Commission (SEC), including in Part II, Item 1A (Risk Factors) of Ventyx's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, filed on August 10, 2023, and any subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Ventyx undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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