Ventyx Biosciences Announces Completion of Enrollment of the Phase 2 Trial of VTX002 in Ulcerative Colitis and the Phase 2 Trial of VTX958 in Plaque Psoriasis

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Topline results from the Phase 2 trial of VTX002 (S1P1R modulator) in ulcerative colitis and the Phase 2 trial of VTX958 (TYK2 inhibitor) in plaque psoriasis are expected in Q4 2023

ENCINITAS, Calif., June 07, 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 that the Company has completed patient enrollment in the Phase 2 trial of VTX002 in ulcerative colitis and the Phase 2 SERENITY trial of VTX958 in plaque psoriasis.

"I am very proud of our team's execution as we mark another important milestone for Ventyx and for ulcerative colitis and plaque psoriasis patients," said Dr. William Sandborn, President and Chief Medical Officer. "We believe the robust enrollment activity in these trials demonstrates tremendous interest from patients and investigators in novel oral therapies for autoimmune diseases. We look forward to reporting topline data from the Phase 2 trial of VTX002 in ulcerative colitis early in the fourth quarter of 2023, followed by topline results from the Phase 2 SERENITY trial of VTX958 in plaque psoriasis, which are also expected in the fourth quarter of 2023."

The Phase 2 trial of VTX002, an oral, selective, peripherally restricted S1P1R modulator, is a randomized, double-blind, placebo-controlled clinical trial in patients with moderately to severely active ulcerative colitis. The trial design includes a target enrollment of approximately 180 patients randomized to one of two VTX002 doses or placebo for a 13-week induction treatment period, followed by a 39-week blinded long-term extension period. The primary efficacy endpoint is the proportion of subjects achieving clinical remission at Week 13 as defined by the modified Mayo Score.

The Phase 2 SERENITY trial of VTX958, an oral, selective, allosteric TYK2 inhibitor, is a randomized, double-blind, placebo-controlled, dose-ranging trial in patients with moderate to severe plaque psoriasis. The trial design includes a target enrollment of approximately 200 patients randomized to one of four VTX958 doses or placebo for a 16-week treatment period, followed by a 16-week blinded long-term extension period. The primary efficacy endpoint is the proportion of subjects achieving a 75% reduction in the Psoriasis Area and Severity Index (PASI 75) at week 16.

In addition to the Phase 2 SERENITY trial, Phase 2 trials of VTX958 continue to enroll patients in moderately to severely active Crohn's disease (HARMONY) and in active psoriatic arthritis (TRANQUILITY), with topline results from both trials expected in 2024.

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 Encinitas, 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: management's beliefs regarding the potential of Ventyx's product candidates; the anticipated timing of enrollment and completion of clinical trials for Ventyx's product candidates; and the anticipated timing for releasing topline data for clinical trials of Ventyx's product candidates. 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 March 31, 2023, filed on May 11, 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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