# Ventyx Biosciences Announces Dosing of the First Patient in the Phase 2 SERENITY Trial of VTX958 for the Treatment of Moderate to Severe Plaque Psoriasis

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*The Phase 2 trial in psoriasis will explore a broad range of doses based on Phase 1 data demonstrating class-leading safety and TYK2 target coverage*

*Phase 2 trials of VTX958 for psoriatic arthritis and Crohn's disease are on track to initiate by year end*

ENCINITAS, Calif., Dec. 01, 2022 (GLOBE NEWSWIRE) -- Ventyx Biosciences, Inc. (Nasdaq: VTYX) ("Ventyx"), a clinical-stage biopharmaceutical company focused on advancing novel oral therapies that address a range of inflammatory diseases with significant unmet medical need, today announced that the first patient has been dosed in a Phase 2 trial of its selective, allosteric TYK2 inhibitor VTX958 for the treatment of moderate to severe plaque psoriasis.

"Dosing of the first patient in the Phase 2 SERENITY trial of VTX958 is a major accomplishment for Ventyx and an important step towards providing a new treatment option for patients suffering from moderate to severe plaque psoriasis who are in need of more effective oral therapies," said Dr. William Sandborn, President and Chief Medical Officer. "Our Phase 1 single-ascending dose and multiple-ascending dose data established an excellent safety profile with dose-dependent pharmacokinetic and pharmacodynamic data supporting class-leading target coverage of TYK2-mediated pathways. The wide therapeutic window of VTX958 observed in our Phase 1 trial will allow us to explore a broad range of doses in Phase 2 trials, including doses designed to achieve biologic-like $IC_{90}$ coverage of TYK2-mediated cytokines, such as IL-23. Topline data from the Phase 2 SERENITY trial are expected in the fourth quarter of 2023. We plan to provide further updates across our wholly-owned development pipeline, including our three Phase 2 trials of VTX958, at our R&D day on January 26, 2023."

The Phase 2 SERENITY trial is a randomized, double-blind, placebo-controlled, dose-ranging trial to evaluate the safety and efficacy of VTX958 in patients with moderate to severe plaque psoriasis. The trial will enroll approximately 200 patients randomized to one of four VTX958 doses or placebo for a 16-week double-blind treatment period. The primary efficacy endpoint will evaluate the proportion of subjects achieving a 75% reduction in the Psoriasis Area and Severity Index (PASI-75) at week 16.

In addition to the SERENITY Phase 2 trial, Ventyx is on track to initiate two additional Phase 2 trials of VTX958 in psoriatic arthritis and Crohn's disease before the end of the year.

**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 three clinical-stage internally discovered 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, including that some have the potential to be best-in-class or may have therapeutic utility across a broad range of indications; and the anticipated timing of commencement, enrollment and completion of clinical trials for Ventyx's product candidates, including plans to advance VTX958 into Phase 2 trials in psoriatic arthritis and Crohn's disease; the anticipated timing for releasing top-line data for the Phase 2 randomized, placebo-controlled clinical trial for VTX958 in psoriasis; the potential of Ventyx's product candidates to address a broad range of immune-mediated diseases; and plans to advance 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; which may be impacted by disruptions in the supply chain, including raw materials needed for manufacturing, animals used in research, delays in site activations and enrollment of clinical trials; the results of preclinical studies and early clinical trials are not necessarily predictive of future results; the success of Ventyx's clinical trials and preclinical studies for its product candidates; interim results not necessarily being predictive of final results; the potential of one or more outcomes to materially change as the 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 our 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 our operations from the ongoing global outbreak of the COVID-19 pandemic, or 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 quarterly period ended September 30, 2022 filed on November 4, 2022, 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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