Ventyx Biosciences Announces Results from the Phase 2 Trial of VTX958 in Patients with Moderate to Severe Plaque Psoriasis and Provides Corporate Update

November 6, 2023

VTX958 225 mg BID and 300 mg BID doses achieved statistical significance on the primary endpoint (PASI 75) and all key secondary endpoints at Week 16

Efficacy results did not meet the internal target to support further development of VTX958 in psoriasis; Ventyx to terminate Phase 2 trials of VTX958 in plaque psoriasis and psoriatic arthritis

The ongoing Phase 2 trial of VTX958 in Crohn's disease will continue to enroll; Ventyx intends to conduct an interim efficacy analysis in Q1 2024

Cash, cash equivalents and marketable securities of $300.8M as of September 30, 2023

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

SAN DIEGO, Nov. 06, 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 results from the Phase 2 trial of VTX958 in patients with moderate to severe plaque psoriasis and provided a corporate update.

"While the Phase 2 trial of VTX958 in plaque psoriasis met the primary and key secondary endpoints, we are disappointed by the magnitude of efficacy observed, despite having achieved target levels of drug exposure in the trial," said Raju Mohan, Ph.D., Founder and Chief Executive Officer. "Although these results do not support further development of VTX958 in the highly competitive psoriasis and psoriatic arthritis indications, I want to thank the patients and investigators for their participation. I would also like to thank the Ventyx team for their diligence and dedication in executing these trials."

The Phase 2 SERENITY trial of VTX958 was a 16-week, randomized, double-blind, placebo-controlled, dose-ranging trial evaluating the efficacy and safety of four oral doses of VTX958 (50 mg BID, 300 mg QD, 225 mg BID, and 300 mg BID) in patients with moderate to severe plaque psoriasis. The primary endpoint was the proportion of participants achieving a 75% reduction in the Psoriasis Area and Severity Index (PASI 75) at Week 16. Both high doses of VTX958 (225 mg BID and 300 mg BID) achieved statistical significance on the primary endpoint and all key secondary endpoints at Week 16. No drug-related serious adverse events were observed.

Although the trial achieved its primary endpoint, the magnitude of efficacy observed did not meet our internal target to support advancement of VTX958 in plaque psoriasis. Accordingly, we will terminate ongoing activities in the Phase 2 plaque psoriasis trial effective immediately. Based on these results, we have also elected to terminate the ongoing Phase 2 trial of VTX958 in psoriatic arthritis. The ongoing Phase 2 trial of VTX958 in Crohn's disease will continue to enroll and we intend to conduct an interim efficacy analysis in the first quarter of 2024.

Additional Pipeline Updates

- **VTX002 (S1P1R Modulator):** In October 2023, we announced positive results from the Phase 2 trial of VTX002 in patients with moderately to severely active ulcerative colitis (UC). We believe these data establish VTX002 as a potential best-in-disease oral agent in UC based on its differentiated efficacy profile, including a high rate of complete endoscopic remission, and its potential best-in-class safety profile. We expect to provide an update on the open-label extension of the Phase 2 trial in the first quarter of 2024.
- **VTX2735 (Peripheral NLRP3 Inhibitor):** We are evaluating VTX2735 in a Phase 2 trial in patients with familial cold autoinflammatory syndrome (FCAS). FCAS is the most common subset of cryopyrin-associated periodic syndrome (CAPS), a group of rare autoinflammatory conditions caused by gain-of-function mutations in the NLRP3 gene. Patient enrollment is progressing, and we expect to provide an update on the trial in the first quarter of 2024.
- **VTX3232 (CNS-penetrant NLRP3 Inhibitor):** We are conducting a Phase 1 trial of VTX3232 in adult healthy volunteers. The trial is designed to characterize the safety, pharmacokinetics and pharmacodynamics of VTX3232 in blood, and will also measure drug concentration and target engagement in cerebral spinal fluid. We expect to provide an update on the Phase 1 trial in the first quarter of 2024.
- **Cash Position:** Our cash, cash equivalents and marketable securities balance was $300.8M as of September 30, 2023.

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 VTX958 in patients with moderate to severe plaque psoriasis. To participate in the conference call, please dial (800) 225-9448 (U.S.) or (203) 518-9708 (international) and reference passcode VTYX1106. 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; the anticipated continuance of the Phase 2 trial of VTX958 in Crohn's disease; the therapeutic and commercial potential of VTX002 in ulcerative colitis, including its potential as a best-in-disease oral agent and its potential best-in-class safety profile; and the anticipated timing of updates regarding the VTX958 Phase 2 trial in Crohn's disease, the VTX3232 Phase 1 trial, the VTX2735 Phase 2 trial in CAPS, and the open-label extension of the VTX002 Phase 2 trial. 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 conflicts in Ukraine and the Middle East, 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.

Investor Relations Contact
Patti Bank
Managing Director
ICR Westwicke
(415) 513-1284
IR@ventyxbio.com