Ventyx Biosciences Announces First Patient Dosed in a Phase 2 Clinical Trial of VTX002 for the Treatment of Moderate-to-Severe Ulcerative Colitis

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VTX002 is an oral, peripherally-restricted, selective sphingosine 1 phosphate receptor 1 (S1P1) receptor modulator internally discovered and developed by the team at Ventyx

ENCINITAS, Calif., Dec. 06, 2021 (GLOBE NEWSWIRE) -- Ventyx Biosciences, Inc. (Nasdaq: VTYX) ("Ventyx" or the "Company"), a clinical-stage biopharmaceutical company focused on advancing new therapies for millions of patients living with inflammatory diseases and autoimmune disorders, announced today that the first patient has been dosed in a Phase 2 randomized, placebo-controlled trial of VTX002 for the treatment of moderate-to-severe ulcerative colitis (UC).

"S1P1 receptor modulators are an important emerging class for patients with moderate to severe ulcerative colitis, many of whom continue to experience significant burden from their symptoms and have limited oral treatment options available," said William Sandborn, MD, Chairman of the Company's Clinical Advisory Board. "VTX002 demonstrated robust lymphocyte lowering and rapid lymphocyte recovery in a Phase 1 trial in healthy subjects. I look forward to seeing the results of the VTX002 Phase 2 program, which is designed to confirm its differentiated efficacy and safety profile in patients."

"Advancing VTX002 into a Phase 2 trial marks another significant milestone for Ventyx and speaks to the team's ongoing commitment to advance innovative new therapies for patients," said Raju Mohan, Chief Executive Officer of Ventyx. "Given the large addressable market for ulcerative colitis, we believe VTX002 has the potential to make a meaningful difference for the approximately one million patients in the United States afflicted by this disease."

In a Phase 1 multiple ascending dose trial in healthy volunteers, VTX002 was well tolerated at all doses tested with no serious adverse events. In addition, VTX002 demonstrated a dose-dependent steady-state reduction in absolute lymphocyte count of up to 65%, which is a well-established biomarker for S1P1 receptor-mediated diseases.

The Phase 2 trial is a randomized, placebo-controlled, clinical trial in moderate-to-severe UC patients. The trial design includes a 13-week induction treatment period followed by a 39-week open label extension (OLE) with a primary efficacy endpoint of clinical remission at Week 13 as defined by the 3-Component Mayo Score.

About VTX002

VTX002 is a peripherally-restricted, potent and selective, orally bioavailable small molecule modulator of the S1P1 receptor. Discovered by the Ventyx team, VTX002 has the potential to improve therapeutic benefit in autoimmune diseases, such as ulcerative colitis. S1P1 receptors play a central role in the regulation of lymphocyte trafficking from lymph nodes to the peripheral blood. S1P1 receptor modulators, such as VTX002, sequester lymphocytes in the lymph nodes, resulting in fewer immune cells in the circulating blood to exacerbate inflammation.

About Ventyx

Ventyx is a clinical-stage biopharmaceutical company focused on advancing new therapies for millions of patients living with inflammatory diseases and autoimmune disorders. In addition to VTX002, our clinical stage pipeline includes VTX958, a Phase 1 allosteric TYK2 inhibitor for the treatment of a broad range of autoimmune diseases and VTX2735, a Phase 1 peripheral inhibitor of the NLRP3 inflammasome, which is a mediator of multiple inflammatory conditions. 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 the Company's current beliefs and expectations. Such forward-looking statements include, but are not limited to, statements regarding: anticipated safety and efficacy results regarding the VTX002 Phase 2 clinical trials; and the potential of VTX002 to improve the conditions of patients with moderate-to-severe 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; disruption to our operations from the ongoing global outbreak of the COVID-19 pandemic, including clinical trial delays; the Company's dependence on third parties in connection with product manufacturing, research and preclinical and clinical testing; 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 do not necessarily predict final results and one or more of the outcomes may 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; and other risks described in the Company's prior press releases and the Company's filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in the Company's final prospectus filed pursuant to Rule 424(b)(4) on October 21, 2021, 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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