Ventyx Biosciences Announces Initiation of Dosing in a Phase 1 Trial of VTX3232, a Novel CNS-Penetrant NLRP3 Inhibitor

June 14, 2023

Topline data from the Phase 1 SAD/MAD trial of VTX3232 are expected in H1 2024

ENCINITAS, Calif., June 14, 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 first subject has been dosed in a Phase 1 trial of VTX3232, a novel central nervous system (CNS)-penetrant NLRP3 inhibitor.

"VTX3232 is our fourth internally discovered compound to enter the clinic and an exciting addition to our broad, wholly-owned clinical-stage pipeline of orally-delivered small molecules targeting large disease populations with high unmet need," said Raju Mohan, Chief Executive Officer. "We believe we are well positioned to explore the therapeutic potential of NLRP3 inhibition and its effect on IL-1β biology across both systemic and neuroinflammatory diseases with VTX2735, which is peripherally restricted, and VTX3232, a novel CNS-penetrant NLRP3 inhibitor that is chemically differentiated from VTX2735."

The Phase 1 trial of VTX3232 is a two-part, randomized, double-blind, placebo-controlled single ascending dose (SAD) and multiple ascending dose (MAD) trial designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of VTX3232 in adult healthy volunteers. The trial will explore a broad range of doses and will include serial cerebrospinal fluid (CSF) sampling to assess brain exposure. Topline results from the trial are expected in the first half of 2024. There is a growing body of preclinical data suggesting NLRP3's role as a central driver of neuroinflammation and thus we believe VTX3232 may have therapeutic potential in a range of neuroinflammatory conditions with high unmet medical need, including Parkinson's disease, Alzheimer's disease and amyotrophic lateral sclerosis (ALS), among others.

In addition to VTX3232, we are also evaluating VTX2735, a peripherally restricted NLRP3 inhibitor, in a Phase 2 proof-of-mechanism 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. Beyond CAPS, we believe VTX2735 may have therapeutic potential across a broad range of chronic inflammatory conditions that are characterized by NLRP3-induced excess IL-1β, including large dermatologic, rheumatic and cardiovascular disease.

About the NLRP3 Inflammasome

Upon activation, NLRP3 acts as a 'danger sensor' in the body, releasing the pro-inflammatory cytokines IL-1β and IL-18 and inducing uncontrolled, lytic cell death (pyroptosis). These processes lead to chronic inflammation, thereby implicating NLRP3 in a large number of systemic and neuroinflammatory diseases.

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 VTX2735 and VTX3232; the anticipated timing for releasing topline data for clinical trials of VTX2735 and VTX3232; and the therapeutic potential of VTX2735 and VTX3232 across a broad range of neuroinflammatory conditions and chronic inflammatory conditions, respectively. 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 or about 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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