Ventyx Biosciences Announces Initiation of Dosing in a Phase 2a Trial of VTX3232 in Patients with Early Parkinson's Disease

September 6, 2024

Results from this trial are expected in 2025

SAN DIEGO, Sept. 06, 2024 (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 patient has been dosed in a Phase 2a trial of VTX3232 in patients with early Parkinson's disease.

"We are excited to initiate this trial of VTX3232 in patients with early Parkinson's disease," said Mark Forman, MD, PhD, Chief Medical Officer. "There is a compelling body of evidence from the literature suggesting a strong mechanistic rationale for targeting NLRP3-driven neuroinflammation in Parkinson's disease and that microglial NLRP3 activation may play an important role in Parkinson's disease pathogenesis and neurodegeneration. This trial will evaluate the effects of VTX3232 on disease- and target-relevant biomarkers and will also include exploratory PET neuroimaging to measure the impact of VTX3232 on microglial activation. These measures may provide early insights into the potential of VTX3232 to disrupt Parkinson's disease pathology with NLRP3 inhibition in the CNS."

The Phase 2a trial of VTX3232 in early Parkinson's disease is expected to enroll approximately ten patients for a 28-day open-label treatment period. The trial's primary endpoint is safety and tolerability. Other outcome measures include pharmacokinetics and relevant biomarkers in plasma and cerebrospinal fluid. We expect to report topline results from this trial in 2025.

About VTX3232

VTX3232 is an oral, selective, CNS-penetrant NLRP3 inhibitor with potential therapeutic utility for a range of neuroinflammatory and neurodegenerative conditions, including Parkinson's disease, cardiometabolic disease, Alzheimer's disease, and multiple sclerosis, among others. In the first quarter of this year, we announced results from a Phase 1 trial of VTX3232 in adult healthy volunteers where steady-state exposures achieved with once-daily doses of VTX3232 exceeded the interleukin-1β (IL-1β) IC_{90} in both plasma and cerebrospinal fluid over 24 hours. We believe these data support the potential for VTX3232 to emerge as a best-in-class CNS-penetrant NLRP3 inhibitor for the treatment of neuroinflammatory diseases.

About Ventyx Biosciences

Ventyx is a clinical-stage biopharmaceutical company focused on advancing novel oral therapies for patients living with inflammatory diseases. 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 inflammation markets from injectable to oral drugs. Our current pipeline includes internally discovered clinical programs targeting NLRP3, S1P1R and TYK2, positioning us to become a leader in the development of oral therapies for peripheral and neuroinflammatory diseases. 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 relationship between NLRP3-driven neuroinflammation and Parkinson's disease; the relationship between microglial NLRP3 activation and Parkinson's disease; the potential of VTX3232 to emerge as a best-in-class CNS-penetrant NLRP3 inhibitor for the treatment of neuroinflammatory diseases; the potential therapeutic utility for VTX3232 in neuroinflammatory and neurodegenerative conditions, including Parkinson's disease, cardiometabolic disease, Alzheimer's disease, and multiple sclerosis; the design of the Phase 2a clinical trial of VTX3232 to be conducted by Ventyx, including the total number of patients and total duration of the trial; the ability to measure the disruption of Parkinson's disease pathology through PET neuroimaging; the timing of clinical updates for the Phase 2a Trial of VTX3232, including the reporting of any topline results from that study in 2025. 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 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 and clinical trials; early clinical trials not necessarily being predictive of future results; the ongoing contributions to scientific literature as pertains to the relationships between NLRP3, neuroinflammation and Parkinson's disease; 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; 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, 2024, filed on August 8, 2024, and Ventyx's 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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