Ventyx Biosciences Announces Pipeline Updates and Highlights Strategic Priorities at Investor R&D Day

January 26, 2023

Phase 2 clinical trials of VTX958 (TYK2 inhibitor) in plaque psoriasis, Crohn's disease and psoriatic arthritis are ongoing with topline Phase 2 data in plaque psoriasis expected in Q4 2023

The Phase 2 trial of VTX002 (S1P1R modulator) in ulcerative colitis is on track to complete enrollment by mid-2023; new pharmacodynamic data support best-in-class potential

Releases new data highlighting attractive profiles of NLRP3 inhibitors VTX2735 and VTX3232

Discloses new small molecule discovery program targeting IL-4Rα

Webcast of investor R&D Day to begin at 9:00 AM ET

ENCINITAS, Calif., Jan. 26, 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, is hosting an investor R&D Day today highlighting key aspects of Ventyx's clinical-stage and discovery programs.

"I am thrilled to highlight progress across our diverse, wholly-owned pipeline of differentiated small molecule drug candidates following a year of tremendous progress," said Raju Mohan, Chief Executive Officer. "2023 is shaping up to be a transformational year for Ventyx with several key clinical readouts anticipated, including topline Phase 2 data for VTX002 in ulcerative colitis, which is expected in H2 2023, and topline Phase 2 data for VTX958 in psoriasis, which is expected in Q4 2023. Meanwhile, our peripheral NLRP3 inhibitor VTX2735 is Phase 2 ready and we expect to initiate a Phase 1 trial for our CNS-penetrant NLRP3 inhibitor VTX3232 in H1 2023. Finally, we are excited to announce a new discovery-stage program to develop small molecule IL-4Rα antagonists. The progress made in this program showcases the strength of our discovery capabilities and further strengthens our novel, small-molecule immunology pipeline. We look forward to providing additional details on these programs at this event."

Pipeline Updates and Anticipated Catalysts

VTX958 (TYK2 Inhibitor)

- Enrollment is ongoing in the Phase 2 SERENITY trial of VTX958 in moderate-to-severe plaque psoriasis and the Phase 2 HARMONY trial in Crohn's disease, while screening activities have initiated for the Phase 2 TRANQUILITY trial in psoriatic arthritis. Topline data from the Phase 2 SERENITY psoriasis trial are anticipated in Q4 2023. Topline readouts from the Phase 2 HARMONY and Phase 2 TRANQUILITY trials are expected in 2024.

- We are developing an extended release (ER) tablet formulation for VTX958 in collaboration with leading formulation development partners. We expect to provide an update on the ER tablet development in mid-2023 following completion of in-human testing.

VTX002 (S1P1R Modulator)

- We continue to make significant progress enrolling the Phase 2 trial of VTX002 in moderate-to-severe ulcerative colitis. We expect to complete enrollment by mid-2023, and topline results are anticipated in the second half of 2023.

- Preliminary pharmacodynamic data from the open-label extension of the ongoing Phase 2 trial in ulcerative colitis may support the potential best-in-class profile of VTX002. Among patients completing Week 26 (13 weeks of blinded therapy followed by 13 weeks of open-label treatment with VTX002 60mg) as of January 15, 2023, a mean reduction from baseline in absolute lymphocyte count of 74% was observed. Reduction in absolute lymphocyte count is an important pharmacodynamic (PD) marker for efficacy in ulcerative colitis and we believe these preliminary data suggest VTX002 may achieve a stronger PD response compared to other S1P receptor modulators approved or in development for the treatment of ulcerative colitis.

VTX2735 (Peripheral NLRP3 Inhibitor)

- We are presenting additional data from the completed Phase 1 trial of VTX2735 in healthy volunteers, in which VTX2735 demonstrated excellent safety and target coverage. VTX2735 was well tolerated across all doses tested, with anticipated Phase 2 dose regimens expected to achieve IC_{90} coverage of IL-1β for 20 hours or more. VTX2735 also exhibited dose- and concentration-dependent inhibition of IL-1β *ex vivo* and significant reductions from baseline in high sensitivity C-reactive protein.

- We have completed non-clinical toxicology studies and developed a solid oral dose (tablet) to position VTX2735 as a Phase 2-ready compound.

- A Phase 2 proof-of-mechanism trial of VTX2735 in cryopyrin-associated autoinflammatory syndromes is expected to initiate in Q1 2023.

VTX3232 (CNS-penetrant NLRP3 Inhibitor)

- We expect to file an IND and initiate a Phase 1 trial for VTX3232 during the first half of 2023. The Phase 1 trial is expected to characterize the safety, target engagement and bioavailability of VTX3232 in the central nervous system of healthy volunteers.

Discovery Programs

- We are introducing a new discovery-stage program focused on small molecule antagonists of IL-4Rα, a target validated by biologics in multiple large autoimmune indications, including atopic dermatitis, asthma and eosinophilic esophagitis. We are advancing multiple internally discovered novel chemical series through lead optimization with the goal of establishing *in vivo* proof-of-concept and nominating a lead candidate in 2023.

R&D Day and Webcast Information

Ventyx Biosciences' investor R&D Day will take place today, Thursday, January 26 th, from 9:00AM to 11:30AM ET. A live webcast of the event will be available in the "Investors" section of the Ventyx website at www.ventyxbio.com. A webcast replay will also be available on this website shortly after conclusion of the event.

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 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: the potential of Ventyx's product candidates and the anticipated continued progression of the development pipeline for such product candidates; and the anticipated timing of commencement, enrollment and completion of clinical trials for Ventyx's product candidates, including anticipated milestones for Ventyx's product candidates; and the expected timeframe for funding Ventyx's operating plan with current cash, cash equivalents and marketable securities. 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, or from the ongoing military conflict in Ukraine, including clinical trial delays; 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 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; 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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