Ventyx Biosciences Announces Results from the Phase 2 Trial of VTX958 in Participants with Moderately to Severely Active Crohn's Disease

July 29, 2024

The Phase 2 trial of VTX958 in Crohn's disease did not meet its primary endpoint of change from baseline in mean CDAI score in either VTX958 dose group

Both VTX958 dose groups achieved nominal statistical significance on the key secondary endpoint of endoscopic response as measured by SES-CD

At this time, Ventyx does not anticipate conducting additional clinical trials of VTX958 with internal resources

SAN DIEGO, July 29, 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 results from the Phase 2 trial of its allosteric TYK2 inhibitor VTX958 in participants with moderately to severely active Crohn's disease.

The Phase 2 trial enrolled 109 participants randomized to one of two VTX958 doses (225 mg and 300 mg twice daily) or placebo for a 12-week induction treatment period, followed by a long-term extension period. The primary endpoint was the change in the mean Crohn's disease activity index (CDAI) score (a patient reported outcome) from baseline to Week 12. A key secondary endpoint in this trial was endoscopic response, defined as a 50% reduction in the simple endoscopic score for Crohn's disease (SES-CD).

The trial did not meet its primary endpoint of change in mean CDAI score from baseline to Week 12 due to a higher than anticipated placebo response.

A dose-dependent treatment effect was observed on the key secondary endpoint of endoscopic response, at both the 225 mg and 300 mg doses (nominal p-value <0.05 and <0.01, respectively). Endoscopic response, evaluated by centrally read endoscopy, is considered an objective outcome and a high priority treatment goal. Both doses of VTX958 also showed a greater magnitude of decrease compared to placebo in two key biomarkers of inflammation, C-reactive protein and fecal calprotectin. VTX958 was well tolerated in the Phase 2 trial. The overall safety profile was consistent with previously conducted trials of VTX958.

Based on these results, the Company intends to conduct further analyses of the data to better understand the discordance between symptomatic and endoscopic response data. At this time, Ventyx does not anticipate conducting additional clinical trials of VTX958 with internal resources.

The Company held cash, cash equivalents and marketable securities of $279.7M as of June 30, 2024, which we continue to believe are sufficient to fund planned operations into at least the second half of 2026.

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 inflammation and immunology 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 immunology 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: Ventyx's expectation that no further clinical trials of VTX958 will be conducted with internal resources; the continued analysis of the discordance between symptomatic and endoscopic response data, and any ability to draw conclusions therefrom; 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: whether any insights can be derived from the analysis of the discordance between symptomatic and endoscopic response data in the Phase 2 trial; potential delays in the commencement, enrollment and completion of clinical trials; 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; 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-K for the quarter ended March 31, 2024, filed on May 9, 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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