

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported):
October 9, 2023**

Ventyx Biosciences, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-40928
(Commission
File Number)

83-2996852
(IRS Employer
Identification No.)

12790 El Camino Real, Suite 200
San Diego, CA 92130
(Address of principal executive offices, including zip code)

(760) 593-4832
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common Stock, \$0.0001 par value per share	VTYX	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Information.

On October 9, 2023, Ventyx Biosciences, Inc. (the "Company") issued a press release announcing topline Phase 2 data for its novel oral S1P1 receptor modulator, VTX002. The press release is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Also on October 9, 2023, the Company hosted a public webcast to discuss the topline phase 2 data for VTX002. The slide presentation used in the webcast is attached hereto as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated October 9, 2023.
99.2	Corporate Presentation, dated October 9, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

VENTYX BIOSCIENCES, INC.

By: /s/ Raju Mohan

Raju Mohan, Ph.D.

Chief Executive Officer

Date: October 10, 2023



Ventyx Biosciences Announces Positive Results from the Phase 2 Trial of VTX002 in Patients with Moderate-to-Severely Active Ulcerative Colitis

VTX002 60 mg achieved the primary endpoint of clinical remission with a high rate of complete endoscopic remission

Both 30 mg and 60 mg doses of VTX002 demonstrated an excellent safety and tolerability profile

Ventyx to host conference call and webcast today at 4:30 PM ET

SAN DIEGO, October 9, 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 positive results from the Phase 2 trial of VTX002, a novel oral S1P1 receptor modulator, in patients with moderate-to-severely active ulcerative colitis (UC).

“We are very excited to share the positive Phase 2 results for VTX002, which we believe establish VTX002 as a potential best-in-disease oral therapy for UC based on its combined efficacy and safety profile,” said Raju Mohan, Ph.D., Founder and Chief Executive Officer.

The Phase 2 trial of VTX002 was a 13-week, randomized, double-blind, placebo-controlled, dose-ranging trial evaluating the efficacy and safety of two oral doses of VTX002 (30 mg and 60 mg once daily) in patients with moderate-to-severely active UC. The primary endpoint was the proportion of patients achieving clinical remission at Week 13 as defined by the modified Mayo Clinic Score. Secondary endpoints included endoscopic, histologic, and symptomatic outcome measures. Topline results are summarized below:

- 28% of patients on the 60 mg dose and 24% of patients on the 30 mg dose achieved the primary endpoint of clinical remission at Week 13 compared to 11% of patients on placebo (p=0.018 for 60 mg; p=0.041 for 30 mg).
- 29% of patients on the 60 mg dose and 21% of patients on the 30 mg dose achieved the secondary endpoint of complete endoscopic remission (Mayo endoscopic subscore of 0) at Week 13 compared to 7% of patients on placebo (p=0.001 for 60 mg; p=0.014 for 30 mg).
- Dose response was observed between the 30 mg and 60 mg doses of VTX002 across key endpoints, providing evidence of clinical benefit with a greater mean reduction in absolute lymphocyte count achieved with the 60 mg dose relative to the 30 mg dose.

VTX002 was well tolerated in both dose cohorts, with no treatment-related serious adverse events observed. There were no serious or opportunistic infections. There were no instances of atrioventricular block or bradycardia. No cases of macular edema were observed in the trial. Full results from the Phase 2 trial will be presented at a future medical meeting.

“The positive Phase 2 data for VTX002 establish a highly attractive profile for an oral agent in moderate-to-severely active UC, with the 60 mg dose achieving a compelling clinical remission rate, an unprecedented rate of complete endoscopic remission, and an excellent safety and tolerability profile” said William Sandborn, M.D., President and Chief Medical Officer. “I would like to thank all of the patients and investigators for their participation in this trial.”

Bruce Sands, M.D., M.S., Chief of the Dr. Henry D. Janowitz Division of Gastroenterology at Mount Sinai, and the Dr. Burrill B. Crohn Professor of Medicine, Icahn School of Medicine at Mount Sinai added, “There remains substantial unmet need for novel therapies in moderate-to-severely active ulcerative colitis, and particularly for safe and effective oral agents. I am excited to see the positive results from the VTX002 Phase 2 trial.” Dr. Sands is the primary investigator for this trial, and a paid consultant for Ventyx Biosciences, Inc. with stock and stock options in the company.

Conference Call Information

Ventyx will host a conference call today at 4:30 p.m. ET to discuss the results from the Phase 2 trial of VTX002 in patients with moderate-to-severely active UC. To participate in the conference call, please dial (800) 225-9448 (U.S.) or (203) 518-9708 (international) and reference passcode VTYX1009. A live webcast will be available in the Investors section of the company’s website at www.ventyxbio.com. A recording of the webcast will be available for thirty days following the call.

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, SIP1R and NLRP3, positioning us to become a leader in the development of oral immunology therapies. 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 potential of Ventyx's product candidates and the anticipated continued progression of the development pipeline for such product candidates; and the therapeutic and commercial potential of VTX002 in 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; 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 June 30, 2023, filed on August 10, 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.

Investor Relations Contact

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ICR Westwicke
(415) 513-1284
IR@ventyxbio.com

VTX002 Phase 2 Ulcerative Colitis Results

October 9, 2023



Forward Looking Statements

Ventyx Biosciences, Inc. ("Ventyx" or the "Company") cautions you that statements contained in this presentation 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: the potential of Ventyx's product candidates and the anticipated continued progression of the development pipeline for such product candidates; and the therapeutic and commercial potential of VTX002 in 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 presentation 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 quarterly period ended June 30, 2023, filed on August 10, 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.

This presentation includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties as well as our own estimates of potential market opportunities. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Our estimates of the potential market opportunities for our products include several key assumptions based on our industry knowledge, industry publications, third-party research and other surveys, which may be based on a small sample size and may fail to accurately reflect market opportunities. While we believe that our internal assumptions are reliable, such assumptions have not been verified by any third party. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of important factors that could cause results to differ materially from those expressed in the estimates made by third parties and by us.

Trademarks in this presentation are the property of their respective owners and used for informational and education purposes only.

Introduction

Raju Mohan, Ph.D.
Founder and Chief Executive Officer



VTX002 Phase 2 Ulcerative Colitis Results

Speakers and Participants

Ventyx Management Team



Raju Mohan, PhD

CHIEF EXECUTIVE OFFICER,
FOUNDER & DIRECTOR



William Sandborn, MD

PRESIDENT & CHIEF MEDICAL
OFFICER



Martin Auster, MD

CHIEF FINANCIAL OFFICER



Chris Krueger, JD

CHIEF BUSINESS OFFICER

Guest Speaker and KOL



Bruce Sands, MD

CHIEF OF GASTROENTEROLOGY
MOUNT SINAI HEALTH SYSTEM



Dr. Sands is the primary investigator for this trial and a paid consultant for Ventyx Biosciences, Inc. with stock and stock options in the company.

VTX002 Phase 2 Ulcerative Colitis Results

William Sandborn, M.D.
President and CMO



Executive Summary - Phase 2 Trial in Ulcerative Colitis

Data Establish VTX002 as a Potential Best-in-Disease Oral Agent

➤ Potential best-in-disease oral efficacy and safety profile:

- Highly **differentiated efficacy** on stringent and objective outcome measures
 - Compelling clinical remission rate
 - Unprecedented rate of complete endoscopic remission
 - Achievement of endoscopic remission/normalization is a high priority treatment objective
- **Excellent safety profile:**
 - No atrioventricular block or bradycardia
 - No serious or opportunistic infections
 - No macular edema

➤ Phase 2 data support further development of VTX002 in ulcerative colitis

VTX002 Phase 2 UC Trial

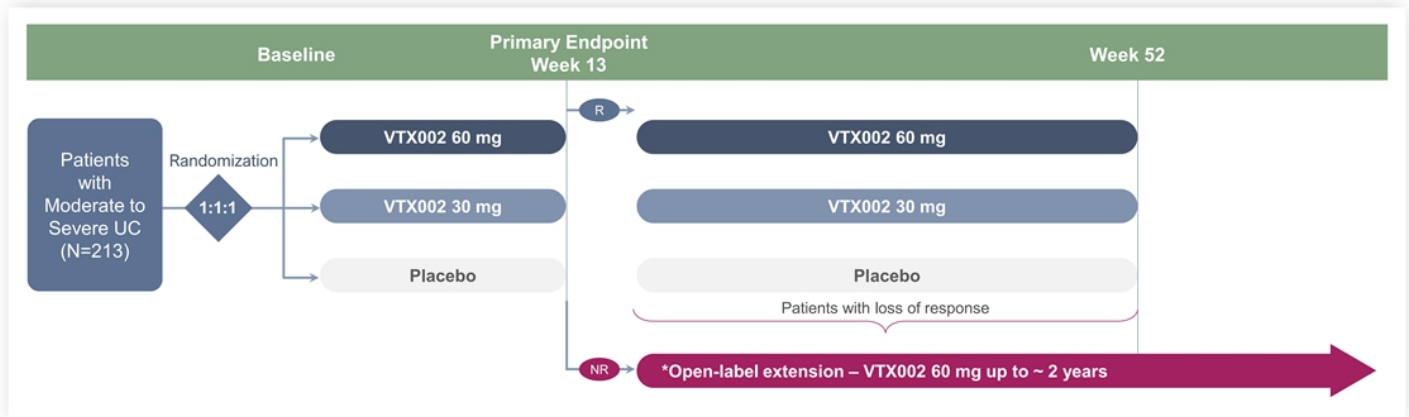
Trial Design Overview

Key eligibility criteria:

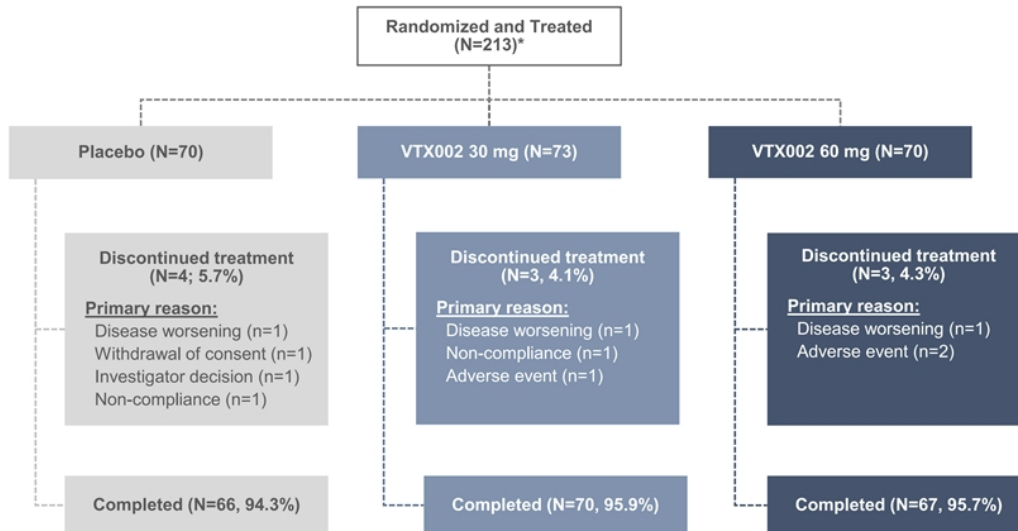
- Patients with moderately to severely active UC as defined by the Modified (3-component) Mayo Score
- Insufficient response, loss of response, and/or intolerance to conventional or advanced therapies

Endpoints:

- **Primary Endpoint:** Clinical remission at Week 13 as defined by the Modified Mayo Score
- **Key Secondary Endpoints:** Endoscopic improvement; symptomatic remission; histologic remission; endoscopic improvement-histologic remission



Subject Disposition: High Trial Completion Rate



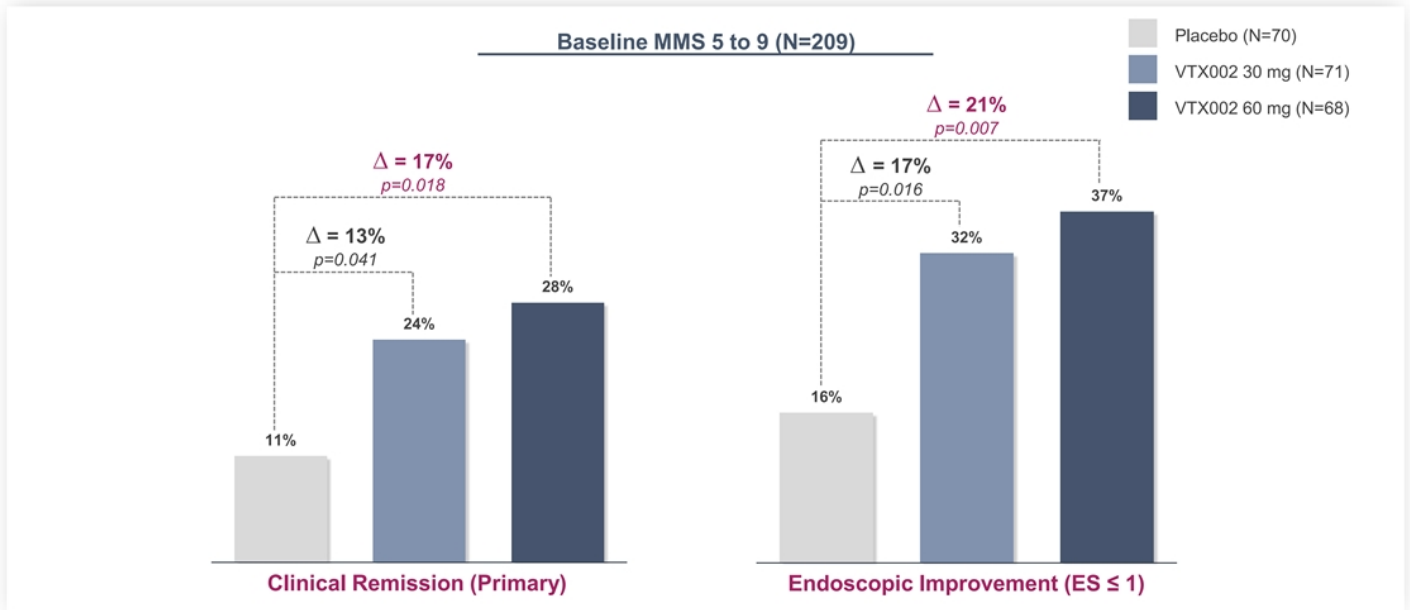
*Protocol originally allowed participants with baseline MMS of 4 to 9. Inclusion criteria were subsequently amended to allow baseline MMS of 5 to 9. Four participants with baseline MMS of 4 were randomized and treated. These participants are excluded from the primary efficacy analysis set but included in the safety analysis set. MMS: Modified Mayo Score. ES: Mayo Endoscopic Subscore. RB: Mayo Rectal Bleeding Subscore.

Baseline Demographics and Disease Characteristics

	Placebo (N=70)	VTX002 30 mg (N=73)	VTX002 60 mg (N=70)
Age, years, mean (SD)	40 (14)	42 (15)	39 (14)
Female, n (%)	32 (46%)	26 (36%)	39 (56%)
Geographic Region, n (%)			
North America	10 (14%)	16 (22%)	10 (14%)
Europe	54 (77%)	53 (73%)	53 (76%)
Other	6 (9%)	4 (6%)	7 (10%)
Duration of UC, years, mean (SD)	6.9 (6.6)	6.5 (6.3)	6.8 (6.3)
Extent of UC, n (%)			
Proctitis	7 (10%)	6 (8%)	5 (7%)
Proctosigmoiditis	26 (37%)	30 (41%)	31 (44%)
Pancolitis	32 (46%)	32 (44%)	31 (44%)
Other	5 (7%)	5 (7%)	3 (4%)
Modified Mayo Score (3 component), mean (SD)	6.8 (1.2)	6.7 (0.9)	6.5 (1.1)
Mayo Endoscopic Subscore, n (%)			
2	36 (51%)	36 (49%)	32 (46%)
3	34 (49%)	37 (51%)	38 (54%)
Corticosteroid use at baseline, n (%)	22 (31%)	22 (30%)	22 (31%)
Prior use of advanced therapies, n (%)	17 (24%)	18 (25%)	14 (20%)
Prior failure of anti-TNF α	11 (16%)	13 (18%)	8 (11%)
Prior failure of vedolizumab	6 (9%)	7 (10%)	3 (4%)
Prior failure of JAK inhibitor	3 (4%)	2 (3%)	1 (1%)

Compelling Clinical Remission and Endoscopic Improvement

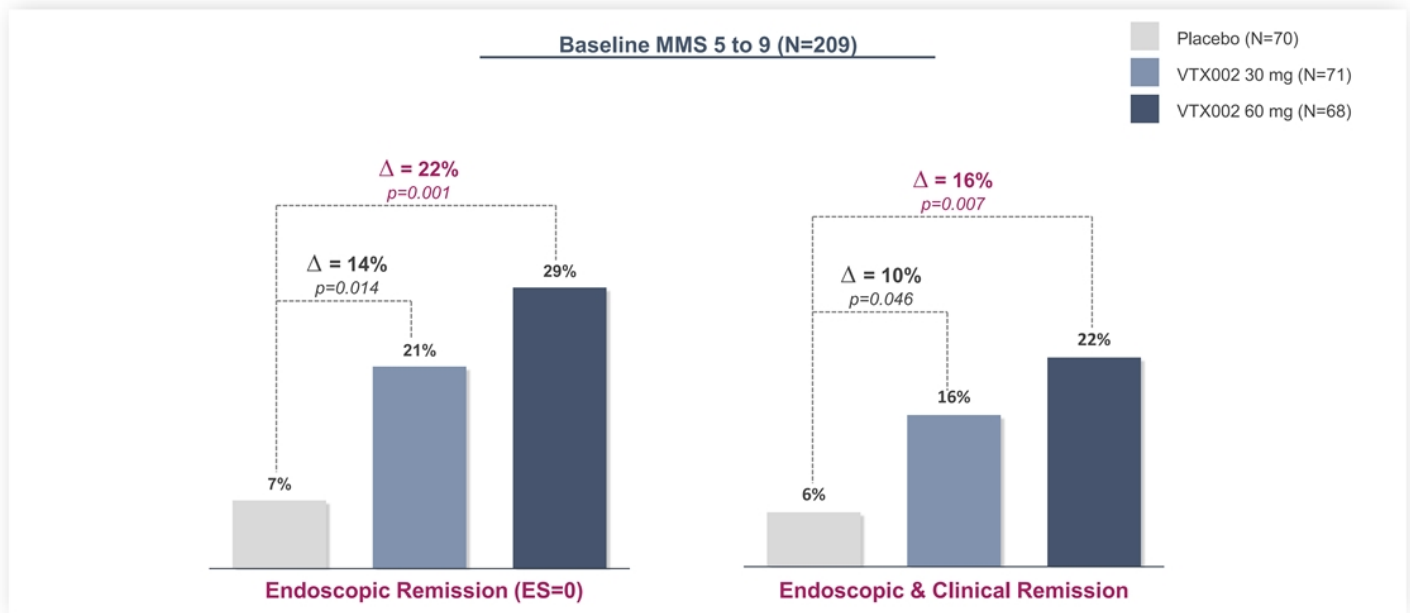
Primary and Secondary Endpoint at Week 13 vs. Placebo



Clinical remission by modified Mayo Score (MMS) is defined as stool frequency subscore = 0 or 1, rectal bleeding subscore = 0, and endoscopic subscore ≤ 1 (excluding friability). Endoscopic improvement is defined as a Mayo endoscopic subscore of 0 or 1. P-value for testing the treatment difference is based on Cochran-Mantel-Haenszel test adjusted for prior use of advanced therapies, baseline corticosteroid use and baseline disease activity. Full analysis set with non-responder imputation. Source: Ventyx data on file.

Unprecedented Rate of Complete Endoscopic Remission

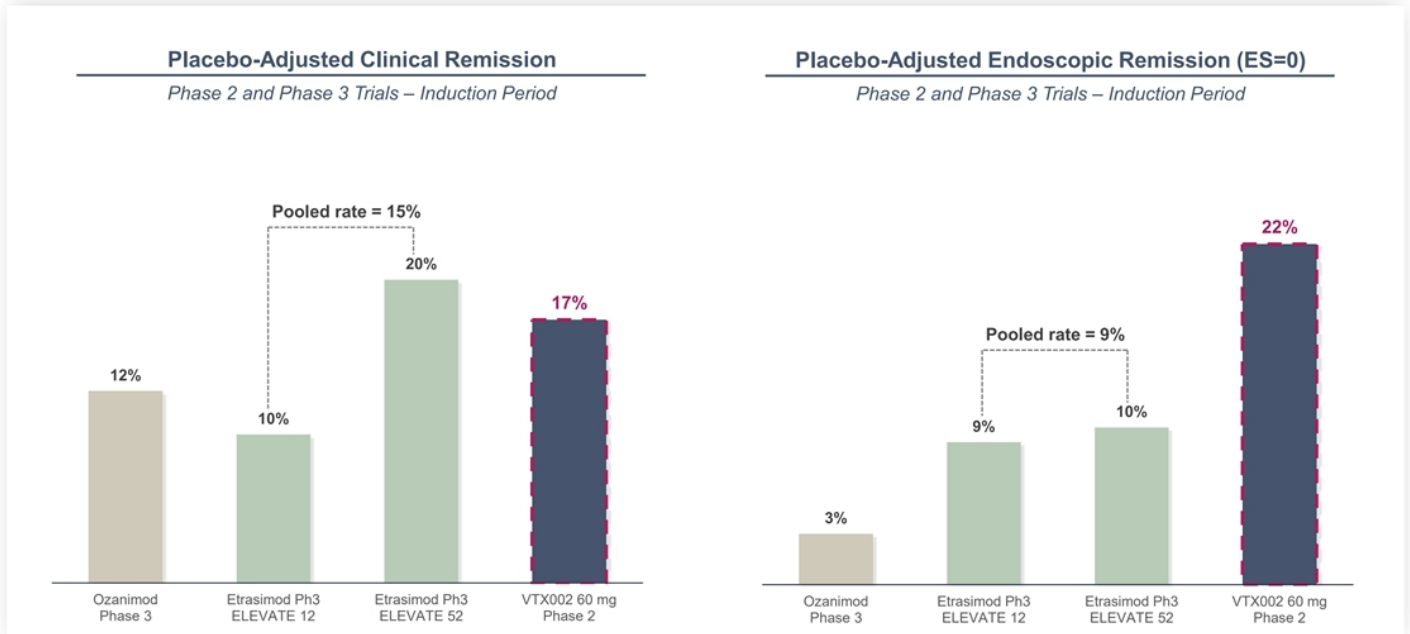
Secondary Endpoints at Week 13 vs. Placebo



Clinical remission by modified Mayo Score (MMS) is defined as stool frequency subscore = 0 or 1, rectal bleeding subscore = 0, and endoscopic subscore ≤ 1 (excluding friability). Endoscopic remission is defined as a Mayo endoscopic subscore of 0. P-value for testing the treatment difference is based on Cochran-Mantel-Haenszel test adjusted for prior use of advanced therapies, baseline corticosteroid use and baseline disease activity. Full analysis set with non-responder imputation. Source: Ventyx data on file.

VTX002 Is a Potential Best-in-Disease Oral Agent

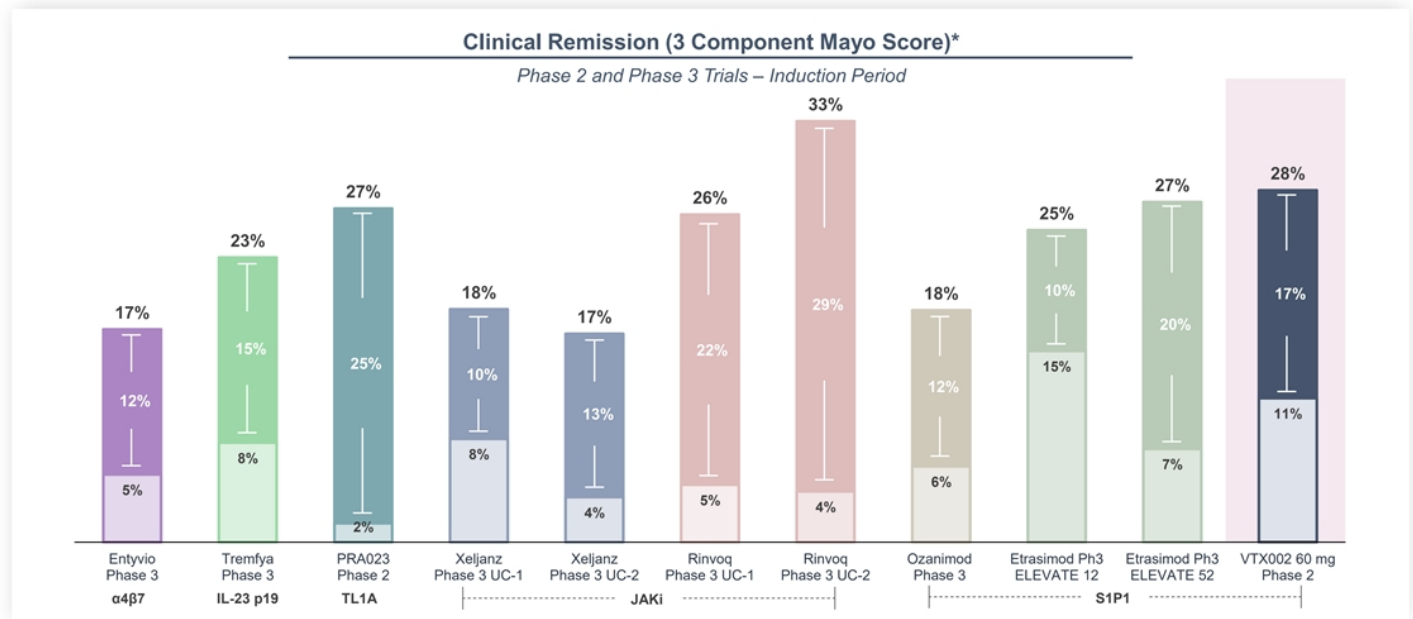
S1P1 Modulator Competitive Landscape – Clinical Remission and Endoscopic Remission



Note: Charts represent cross-trial comparisons and not results of a head-to-head study. Caution should be exercised when comparing across trials due to differences in trial design and patient characteristics. Source: Sandborn et al. N Engl J Med 2021;385:1280-91. Sandborn et al. Lancet 2023;401:1159-71. Ventix data on file.

Highly Competitive Clinical Remission Rate

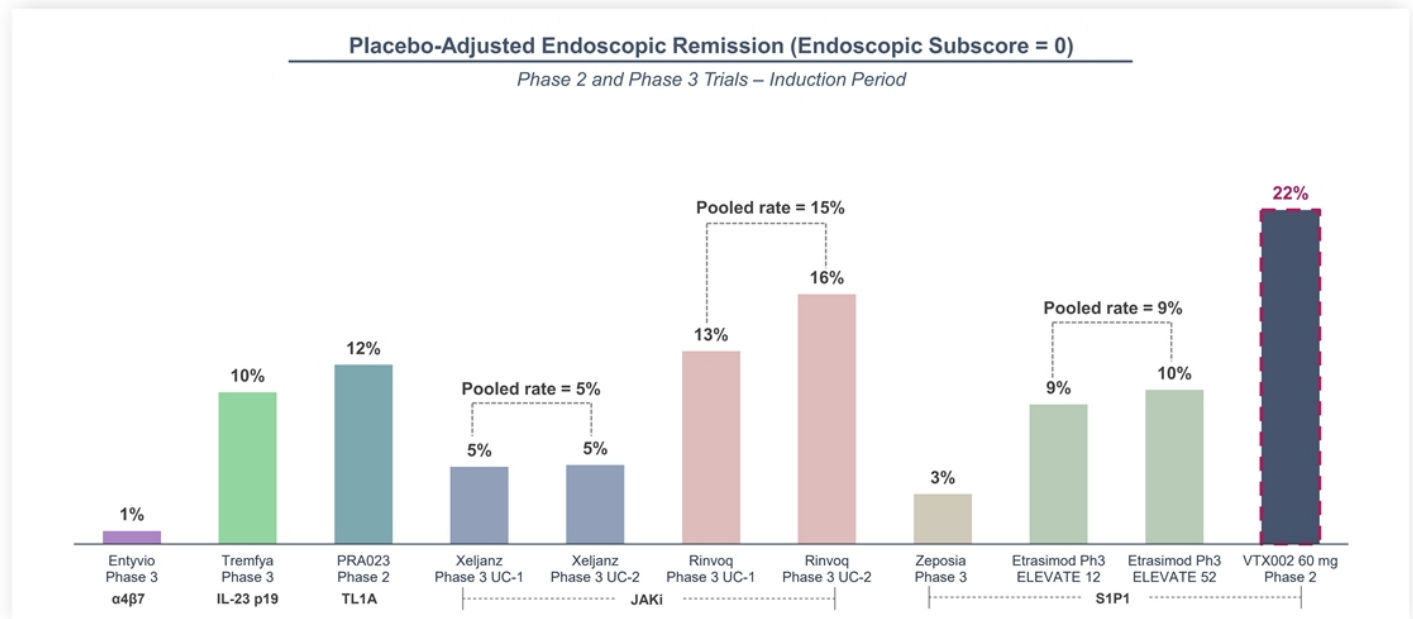
Competitive Landscape – Absolute and Placebo-Adjusted Clinical Remission



*Entyvio clinical remission is based on the 4 Component Mayo Score; all others use the 3 Component Mayo Score.
 Note: Charts represent cross-trial comparisons and not results of a head-to-head study. Caution should be exercised when comparing across trials due to differences in trial design and patient characteristics.
 Source: Danese et al. Lancet 2022; 399:2113–28. Feagan et al. N Engl J Med 2013; 369:699-710. Sandborn et al. N Engl J Med 2017;376:1723-36. Sandborn et al. N Engl J Med 2021;385:1280-91. Sandborn et al. Lancet 2023;401:1159–71. PRA023: Danese et. al. (ECCO 2023). Tremfya: JNJ Ph3 topline press release. Ventyx data on file.

Unprecedented Rate of Complete Endoscopic Remission

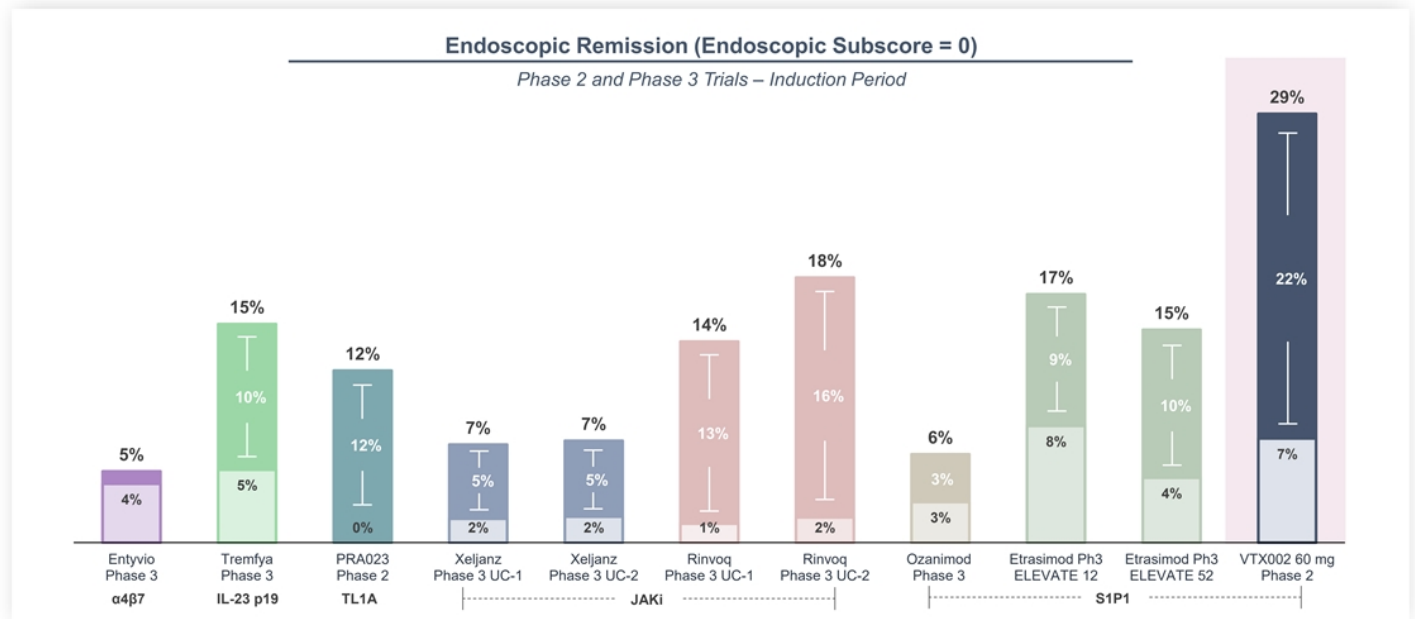
Competitive Landscape – Placebo-Adjusted Endoscopic Remission (ES=0)



Note: Charts represent cross-trial comparisons and not results of a head-to-head study. Caution should be exercised when comparing across trials due to differences in trial design and patient characteristics. Source: PRA023: Danese et al. (ECCO 2023). Danese et al. Lancet 2022; 399:2113–28. Feagan et al. N Engl J Med 2013; 369:699-710. Sandborn et al. N Engl J Med 2017;376:1723-36. Sandborn et al. N Engl J Med 2021;385:1280-91. Sandborn et al. Lancet 2023;401:1159–71. Tremfya: JNJ Ph3 topline press release. Ventyx data on file.

Unprecedented Rate of Complete Endoscopic Remission

Competitive Landscape – Absolute and Placebo-Adjusted Endoscopic Remission (ES=0)



Lighter bar represents placebo. Darker bar represents active dose. Delta is included between.

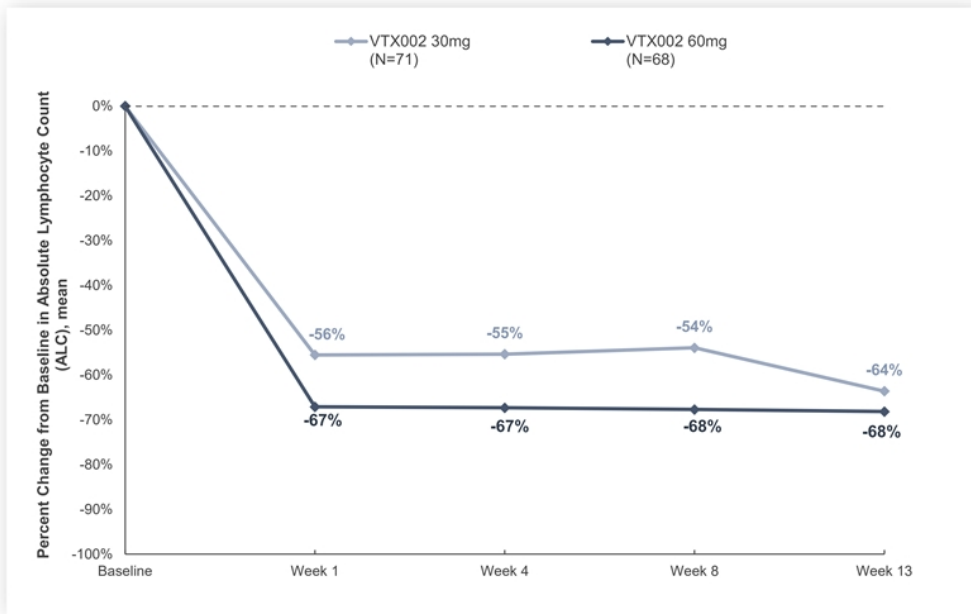
Note: Charts represent cross-trial comparisons and not results of a head-to-head study. Caution should be exercised when comparing across trials due to differences in trial design and patient characteristics.

Source: PRA023; Danese et al. (ECCO 2023). Danese et al. Lancet 2022; 399:2113–28. Feagan et al. N Engl J Med 2013; 369:699-710. Sandborn et al. N Engl J Med 2017;376:1723-36.

Sandborn et al. N Engl J Med 2021;385:1280-91. Sandborn et al. Lancet 2023;401:1159–71. Tremfya; JNJ Ph3 topline press release. Ventyx data on file.

Pharmacodynamic Effect Is Consistent with Dose Response

Absolute Lymphocyte Count (ALC) Percent Change from Baseline



- Rapid, robust and dose-dependent reductions in absolute lymphocyte count (ALC) observed
- VTX002 60 mg achieved a **differentiated pharmacodynamic effect** compared to predecessor S1P1 receptor modulators in UC
- **Clear dose response** on stringent clinical outcomes supports the benefits of incremental ALC reductions beyond the ~50% level achieved by etrasimod & ozanimod

VTX002 Was Safe and Well Tolerated

Summary of Adverse Events through Week 13

Treatment Emergent Adverse Events	Placebo (N=70)	VTX002 30 mg (N=73)	VTX002 60 mg (N=70)
Subject with any adverse event, n (%)	24 (34%)	34 (47%)	33 (47%)
Adverse event related to study drug, n (%)	3 (4%)	7 (10%)	11 (16%)
Adverse event leading to study drug discontinuation, n (%)*	0	1 (1%)	2 (4%)
Any Serious Adverse Event (SAE), n (%)†	0	2 (3%)	3 (4%)
SAE related to study drug, n (%)	0	0	0
Death	0	0	0

*Subjects with AEs leading to discontinuation: Decreased appetite and fatigue (Grade 2, 30 mg, unrelated to study drug); headache (Grade 2, 60 mg); exacerbation of UC (Grade 3, 60 mg, unrelated).

† Subjects with SAEs: rectal hemorrhage (Grade 3, 30 mg, unrelated), cholecystitis (Grade 3, 30 mg, unrelated), pulmonary edema (Grade 3, 60 mg, unrelated – patient with hypertension and diabetes, pulmonary edema resolved with diuretic therapy); ulcerative colitis (Grade 3, 60 mg, unrelated); anemia (Grade 3, 60 mg, unrelated)

VTX002 Was Safe and Well Tolerated

Adverse Events of Interest through Week 13

Adverse Events of Interest	Placebo (N=70)	VTX002 30 mg (N=73)	VTX002 60 mg (N=70)
Cardiovascular events, n (%)	3 (4%)	0	1 (1%)
Hypertension	3 (4%)	0	1 (1%)
Atrioventricular block	0	0	0
Bradycardia	0	0	0
Any severe infection (Grade 3 or higher)	0	0	0
Any opportunistic infection	0	0	0
Herpes zoster	0	1 (1%)	0
Macular edema	0	0	0

No serious or opportunistic infections, atrioventricular block or bradycardia, or macular edema observed

Conclusions from Phase 2 Trial in Ulcerative Colitis

Phase 2 Data Establish VTX002 as a Potential Best-in-Disease Oral Agent

➤ Potential best-in-disease oral efficacy and safety profile:

- Highly **differentiated efficacy** on stringent and objective outcome measures
 - Compelling clinical remission rate
 - Unprecedented rate of complete endoscopic remission
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➤ Phase 2 data support further development of VTX002 in ulcerative colitis



Q&A Session

Ventyx Management Team and Guest KOL



Bruce Sands, MD

CHIEF OF GASTROENTEROLOGY
MOUNT SINAI HEALTH SYSTEM