

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): November 29, 2022

X4 PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-38295
(Commission File Number)

27-3181608
(IRS Employer Identification No.)

61 North Beacon Street, 4th Floor
Boston, Massachusetts
(Address of principal executive offices)

02134
(Zip Code)

(857) 529-8300
(Registrant's telephone number, including area code)

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 each exchange on which registered
Common Stock, par value \$0.001 per share	XFOR	The Nasdaq Stock Market LLC

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 7.01 Regulation FD Disclosure.

On November 29, 2022, X4 Pharmaceuticals, Inc. (the “Company”) issued a press release announcing data from its Phase 3 clinical trial (“4WHIM”) evaluating its lead clinical candidate, mavorixafor, in people with Warts Hypogammaglobulinemia, Infections, and Myelokathexis (“WHIM”) syndrome.

A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. The information furnished under this Item 7.01, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission (the “SEC”) made by the Company, regardless of any general incorporation language in such filing.

Item 8.01 Other Events.

The Company from time to time presents and/or distributes to the investment community slide presentations to provide updates and summaries of its business. On November 29, 2022, at 4:30 p.m., Eastern Time, the Company will host a conference call and webcast to discuss the data from its 4WHIM clinical trial evaluating mavorixafor in people with WHIM syndrome. A copy of its “Positive 4WHIM Phase 3 Top-Line Results” slide presentation is being filed herewith as Exhibit 99.2 to this Current Report on Form 8-K and incorporated herein by reference. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.2.

A live audio webcast of the presentation will be available under “Events and Presentations” in the “Investors” section of the Company’s website at www.x4pharma.com. The webcast will be archived on the Company’s website for at least 30 days. The information contained in, or that can be accessed through, the Company’s website is not a part of this filing.

Statements contained under this Item 8.01, including Exhibit 99.2, regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, express or implied statements regarding the clinical development and therapeutic potential of mavorixafor for the treatment of WHIM syndrome, chronic and other neutropenias, and of the Company’s other product candidates; the Company’s possible exploration of additional opportunities for mavorixafor; the expected availability, content and timing of clinical data from the Company’s ongoing clinical trials of mavorixafor; anticipated regulatory filings and the timing thereof; clinical trial design; patient prevalence; market opportunities; and the Company’s cash runway and ability to satisfy covenants in agreements with third parties.

Any forward-looking statements are based on management’s current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include, without limitation: uncertainties inherent in the initiation and completion of preclinical studies and clinical trials and clinical development; the risk that trials and studies may be delayed, including, but not limited to, as a result of the effects of the ongoing COVID-19 pandemic, and may not have satisfactory outcomes; the risk that the outcomes of preclinical studies or earlier clinical trials will not be predictive of later clinical trial results; the risk that initial or interim results from a clinical trial may not be predictive of the final results of the trial or the results of future trials; the potential adverse effects arising from the testing or use of mavorixafor or other product candidates; the risk that patient prevalence, market or opportunity estimates may be inaccurate risks related to the Company’s ability to raise additional capital; risks related to the substantial doubt about the Company’s ability to continue as a going concern; and other risks and uncertainties, including those described in the section entitled “Risk Factors” in the Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 filed with the SEC on November 3, 2022 and in other filings the Company makes with the SEC from time to time. The Company undertakes no obligation to update the information herein, including Exhibit 99.2, to reflect new events or circumstances, except as required by law.

Item 9.01 Exhibit No.	Financial Statements and Exhibits. Description
99.1	Press Release, dated November 29, 2022
99.2	Conference Call Presentation, dated November 29, 2022
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.

X4 PHARMACEUTICALS, INC.

Date: November 29, 2022

By: /s/ Adam Mostafa
Adam Mostafa
Chief Financial Officer

Exhibit 99.1



X4 Pharmaceuticals Announces Positive Top-Line Results from 4WHIM Global, Pivotal Phase 3 Trial of Once-Daily, Oral Mavorixafor in WHIM Syndrome

4WHIM trial meets primary endpoint and first key secondary endpoint, with mavorixafor achieving statistically significant and clinically relevant longer times above threshold levels for both absolute neutrophil ($P < 0.0001$) and absolute lymphocyte counts ($P < 0.0001$) versus placebo

Mavorixafor was generally well tolerated in the trial

Company to host a conference call and webcast today at 4:30 p.m. ET

BOSTON, November 29, 2022 – X4 Pharmaceuticals (Nasdaq: XFOR), a leader in the discovery and development of novel small-molecule therapeutics to benefit people with diseases of the immune system, today announced positive top-line results from the global, pivotal Phase 3 clinical trial (4WHIM) of its lead investigational therapy, mavorixafor, a novel CXCR4 antagonist, in people with WHIM syndrome.

Key Top-Line 4WHIM Trial Results:

- 4WHIM met its primary endpoint, with mavorixafor achieving clinical and statistical superiority over placebo when measuring TAT_{ANC} , or the length of time that participants' absolute neutrophil counts (ANC) remained above a clinically meaningful threshold of 500 cells per microliter (severe neutropenia), over 24-hour periods at 4 time points throughout the 52-week trial. Mean TAT_{ANC} was 15.04 hours in the treatment group versus 2.75 hours in the placebo group ($P < 0.0001$).
- 4WHIM also met a key secondary endpoint, with mavorixafor achieving clinical and statistical superiority over placebo when measuring TAT_{ALC} , or the length of time that participants' absolute lymphocyte counts (ALC) remained above a clinically meaningful threshold of 1,000 cells per microliter (lymphopenia), over 24-hour periods at 4 time points throughout the 52-week trial. Mean TAT_{ALC} was 15.80 hours in the treatment group versus 4.55 hours in the placebo group ($P < 0.0001$).
- Increases in both TAT_{ANC} and TAT_{ALC} were maintained versus placebo and baseline across 52 weeks, demonstrating durability of treatment effect during the trial.
- Mavorixafor was generally well tolerated in the trial, with no treatment-related serious adverse events reported and no discontinuations for safety events.
- Following completion of the placebo-controlled portion of the trial, more than 90% of the eligible participants opted to receive treatment with mavorixafor in the open-label trial extension.
- Additional data review and analysis of the secondary and exploratory endpoints of the 4WHIM trial are ongoing, with plans to present detailed results at a future medical meeting.

"Mavorixafor is the first and only oral investigational therapy to demonstrate durable improvements in severe chronic neutropenia and lymphopenia, the hallmarks of WHIM syndrome," said Murray Stewart, DM FRCP, X4's interim Chief Medical Officer. "Following achievement of these key trial endpoints, we are now preparing to meet with U.S. regulatory authorities in the first half of 2023 to discuss next steps

in advancing mavorixafor further towards a submission for regulatory approval and commercialization as the potential first treatment for people with WHIM syndrome.”

Teresa Tarrant, M.D., Associate Professor of Medicine, Rheumatology, and Immunology at Duke University School of Medicine and a principal investigator in the 4WHIM trial, commented on the results: “WHIM syndrome is a combined immunodeficiency where patients experience chronically low blood levels of neutrophils and lymphocytes, leaving them susceptible to increased infection risk and risk of certain cancers. I am encouraged by these results for mavorixafor and look forward to the continued advancement of this potential new therapy for my patients with WHIM syndrome.”

“Needless to say, we are thrilled with these positive results, only made possible through the commitment of the study participants who put their trust in us, through the dedication of physicians and healthcare professionals at participating clinical trial sites, and through the unabated years of effort by our X4 employees,” said Paula Ragan, Ph.D., President, and Chief Executive Officer of X4. “These data not only give us strong confidence in the potential of mavorixafor to make a difference in the lives of those with WHIM syndrome and their families, but also strengthen our resolve to further evaluate mavorixafor in people living with chronic neutropenic disorders beyond those with WHIM.”

Conference Call and Webcast

X4 will host a conference call and webcast today at 4:30 pm ET to discuss results from the company’s Phase 3 trial of its lead candidate, mavorixafor, in the treatment of WHIM syndrome. The conference call can be accessed by dialing 1-877-451-6152 within the United States or 1-201-389-0879 internationally, followed by the conference ID: 13734531. The live webcast can be accessed on the investor relations section of X4 Pharmaceuticals’ website at www.x4pharma.com. Following the completion of the call, a webcast replay of the conference call will be available on the website

About Mavorixafor and WHIM Syndrome

WHIM (warts, hypogammaglobulinemia, infections, and myelokathexis) syndrome is a rare, inherited, combined immunodeficiency disease caused by reduced mobilization and trafficking of white blood cells from the bone marrow due to over-signaling of the CXCR4/CXCL12 pathway. People with WHIM syndrome characteristically have very low blood levels of neutrophils (neutropenia) and lymphocytes (lymphopenia), and as a result, experience frequent, recurrent infections with a high risk of lung disease, refractory warts from underlying human papillomavirus (HPV) infection, limited antibody production due to low levels of immunoglobulin, and an increased risk of developing certain types of cancer. Mavorixafor is an investigational small-molecule antagonist of CXCR4 being developed as a once-daily oral therapy to correct the dysfunction resulting from the underlying genetic causes of WHIM. For the WHIM indication, mavorixafor has been granted Breakthrough Therapy Designation, Fast Track Designation, and Rare Pediatric Designation in the U.S., and Orphan Drug Status in both the U.S. and European Union.

About the 4WHIM Phase 3 Clinical Trial

The 4WHIM Phase 3 clinical trial was a global, randomized, double-blind, placebo-controlled, multicenter study designed to evaluate the efficacy and safety of oral, once-daily mavorixafor in people with genetically confirmed WHIM syndrome. Originally designed to enroll 18-28 patients, the trial enrolled 31 patients aged 12 and older who received either 400 mg mavorixafor (n=14) or placebo (n=17) orally once daily for 52 weeks.

About X4 Pharmaceuticals

X4 Pharmaceuticals is a late-stage clinical biopharmaceutical company leading the discovery and development of novel therapies for people with diseases of the immune system. Our lead clinical candidate is mavorixafor, a small molecule antagonist of chemokine receptor CXCR4 that is being developed as an oral, once-daily therapy. Due to mavorixafor’s ability to antagonize CXCR4 and improve the mobilization of white blood cells, we believe that mavorixafor has the potential to provide therapeutic benefit across a variety of immune system diseases, including a range of chronic neutropenic disorders, including WHIM syndrome, a rare, primary immunodeficiency. Following announcement of positive top-line data from our global, pivotal, 4WHIM Phase 3 clinical trial, we are preparing a U.S. regulatory submission seeking approval of oral, once-daily mavorixafor in the treatment

of people aged 12 years and older with WHIM syndrome. We are also currently advancing mavoxixafor into a Phase 2 clinical trial in people with chronic neutropenic disorders, following positive results from a Phase 1b clinical trial of mavoxixafor in people with congenital, idiopathic, and cyclic neutropenia. We continue to leverage our insights into CXCR4 and immune system biology at our corporate headquarters in Boston, Massachusetts and at our research center of excellence in Vienna, Austria. For more information, please visit our website at www.x4pharma.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. These statements may be identified by the words “may,” “will,” “could,” “would,” “should,” “expect,” “plan,” “anticipate,” “intend,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue,” “target,” or other similar terms or expressions that concern X4’s expectations, strategy, plans, or intentions. Forward-looking statements include, without limitation, express or implied statements regarding the clinical development and therapeutic potential of mavoxixafor in WHIM syndrome; the anticipated reporting of data and future development plans of mavoxixafor in WHIM syndrome; interactions with regulators and the timing thereof, including anticipated timing of submission for U.S. regulatory approval of mavoxixafor in WHIM; expectations regarding the potential efficacy and commercial potential of mavoxixafor; and management’s ability to achieve its goals. Any forward-looking statements in this press release are based on management’s current expectations and beliefs. Actual events or results may differ materially from those expressed or implied by any forward-looking statements contained herein, including, without limitation, on account of uncertainties inherent in the initiation and completion of clinical trials and clinical development; the risk that trials and studies may not have satisfactory outcomes; the risk that the outcomes of preclinical studies or earlier clinical trials will not be predictive of later clinical trial results; the risk that initial or interim results from a clinical trial may not be predictive of the final results of the trial or the results of future trials; the potential adverse effects arising from the testing or use of mavoxixafor or other product candidates; the risk that the FDA may not support and accept a regulatory submission for mavoxixafor, and X4’s interactions with the FDA may not have satisfactory outcomes; the risks related to X4’s ability to raise additional capital; and other risks and uncertainties, including those described in the section entitled “Risk Factors” in X4’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 filed with the Securities and Exchange Commission (SEC) on November 3, 2022, and in other filings X4 makes with the SEC from time to time. X4 undertakes no obligation to update the information contained in this press release to reflect new events or circumstances, except as required by law.

Contacts:

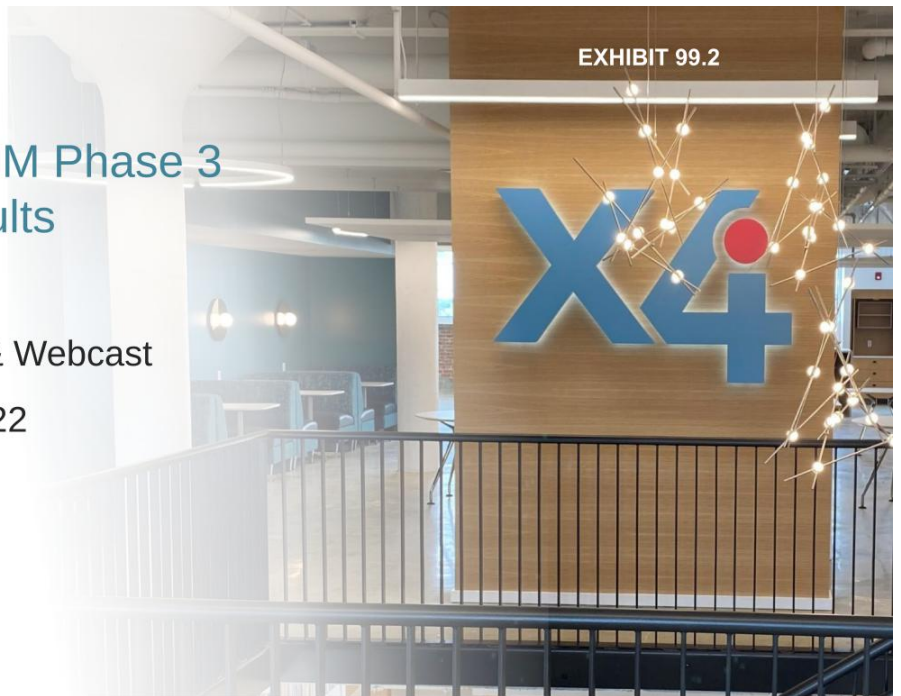
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Positive 4WHIM Phase 3 Top-Line Results

Conference Call & Webcast

November 29, 2022



This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. These statements may be identified by the words “may,” “will,” “could,” “would,” “should,” “expect,” “plan,” “anticipate,” “intend,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue,” “target,” or other similar terms or expressions that concern X4’s expectations, strategy, plans, or intentions. Forward-looking statements include, without limitation, express or implied statements regarding the clinical development and therapeutic potential of mavorixafor for the treatment of WHIM syndrome, chronic and other neutropenias, and of X4’s other product candidates; X4’s possible exploration of additional opportunities for mavorixafor; the expected availability, content and timing of clinical data from X4’s ongoing clinical trials of mavorixafor; anticipated regulatory filings and the timing thereof; clinical trial design; patient prevalence; market opportunities; and X4’s cash runway and ability to satisfy covenants in agreements with third parties.

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Certain information contained in this presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and X4’s own internal estimates and research. While X4 believes these third-party sources to be reliable as of the date of this presentation, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy, or completeness of, any information obtained from third-party sources. Finally, while X4 believes its own internal research is reliable, such research has not been verified or validated by any independent source.

On Today's Call



PAULA RAGAN, Ph.D.
President & CEO



MURRAY STEWART, DM, FRCP
Interim Chief Medical Officer



MARK BALDRY
Chief Commercial Officer



MARY DIBIASE, Ph.D.
Chief Operating Officer



ADAM MOSTAFA
Chief Financial Officer



ART TAVERAS, Ph.D.
Chief Scientific Officer



"I feel very passionate about helping other WHIM patients and am very grateful to all the staff at X4 who are helping us all."
- Leanne, WHIM patient

Mavorixafor – the First Potential Treatment for WHIM Syndrome

15.04 hours (P<0.0001)

Mean time of absolute neutrophil count above threshold¹ (TAT-ANC) over a 24-hour period, over 52 weeks, treatment vs. placebo (2.75 hours)

1. Threshold = 500 cells/ μ L; ANC levels below 500 are considered severe neutropenia

Combined primary immunodeficiency affecting both children and adults

- W**arts. Driven by underlying HPV infection that can increase the risk of HPV-related cancer
- H**ypogammaglobulinemia. Low antibody production
- I**nfections. Multiple, chronic infections in WHIM patients due to neutropenia and lymphopenia can lead to devastating, irreversible morbidities, fatalities
- M**yelokathexis. A "hyper-dense" population of immune cells in the bone marrow, reducing the ability to mature, mobilize for immune surveillance

No targeted therapies approved to treat underlying cause

Range of Assessments Help Establish a WHIM Diagnosis

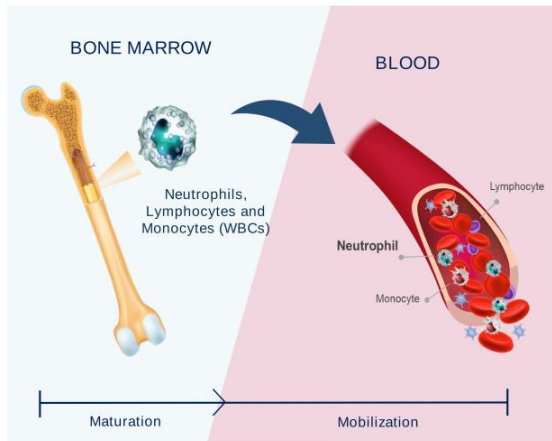
Primary Clinical Assessments

- Neutropenia & lymphopenia (low ANC and ALC)
- Repeat infections with long-term effects
- In some: wart lesions; cervical test for HPV
- In some: Low immunoglobulin (Ig) levels

Additional Assessments

- Bone Marrow Biopsy
- Genetic Testing
- Family History



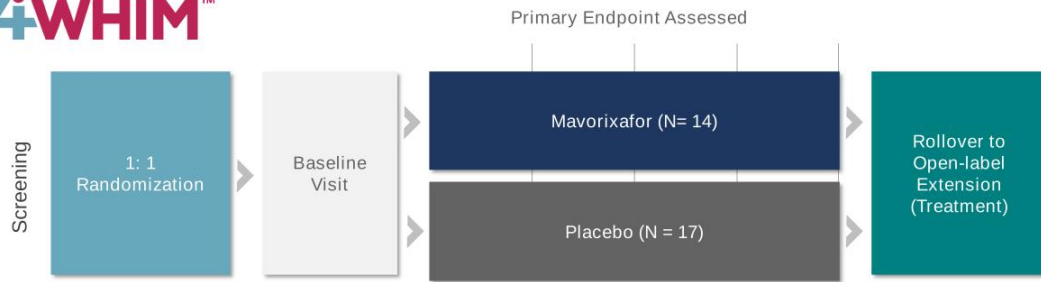


White Blood Cells (WBCs) are retained in the bone marrow by the CXCL12/CXCR4 axis creating a **“reserve”**

- Bone marrow produces WBCs, including neutrophils and lymphocytes
- Creates reserves to fight infection, short and long term

Mavorixafor shown to inhibit CXCR4 signaling and increase maturation and mobilization of WBCs into the blood

- Demonstrated reduction of neutropenia in Phase 1b CN and Phase 2 WHIM clinical studies
- Phase 3 study assessing impact on neutropenia, lymphopenia, and clinical aspects of WHIM syndrome



Top-Line Assessments (Today)

- Mean TAT_{ANC} - mean of the 13, 26, 39, and 52-week assessments
- Mean TAT_{ALC} - mean of the 13, 26, 39, and 52-week assessments
- Safety and tolerability across 52 weeks

>90% of patients have continued in open label extension (OLE)

Additional secondary and exploratory clinical endpoints expected in 1H 2023

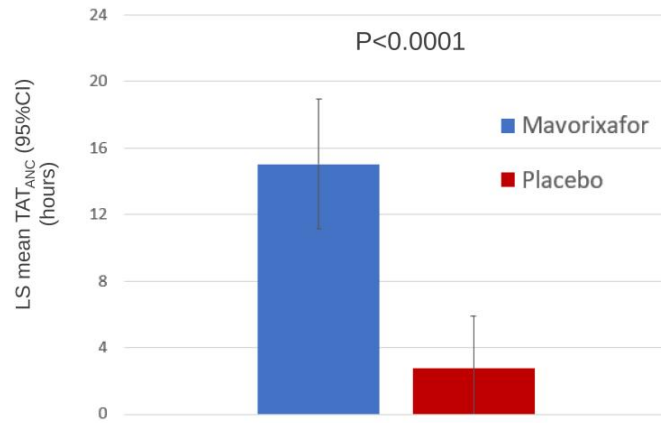
GOAL LABEL: Indicated for the treatment of people aged 12 and above diagnosed with WHIM syndrome

Demographics & Screening Metrics

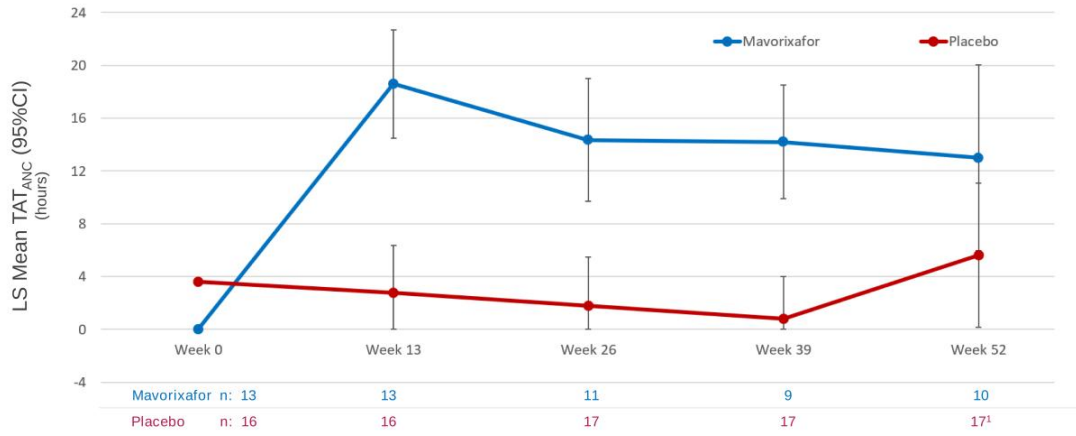


	Mavorixafor (N=14)	Placebo (N=17)
Adolescents (12 to <18 years)		
n (%)	7 (50)	8 (47)
Adults (≥18 years)		
n (%)	7 (50)	9 (53)
Female Gender		
n (%)	9 (64)	9 (53)
Previous Immunoglobulin Usage		
n (%)	6 (43)	8 (47)
Screening ANC (cells/μL)		
n	14	17
mean (SD)	173 (112)	194 (123)
median (min, max)	150 (40, 390)	200 (0, 400)
Screening ALC (cells/μL)		
n	14	17
mean (SD)	496 (237)	1015 (1983)
median (min, max)	420 (260, 1070)	520 (100, 8560)

- Mavorixafor significantly improved the time above the threshold of ANC vs. placebo in intent-to-treat (ITT) population
- Mean TAT_{ANC} was 15.04 hours for mavorixafor vs. 2.75 hours for placebo
- 5.5-fold improvement in TAT_{ANC} compared with placebo



TAT_{ANC} vs. Time on Treatment: Mavoxifafor Durably Increased TAT_{ANC} Over 52 Weeks (ITT population)

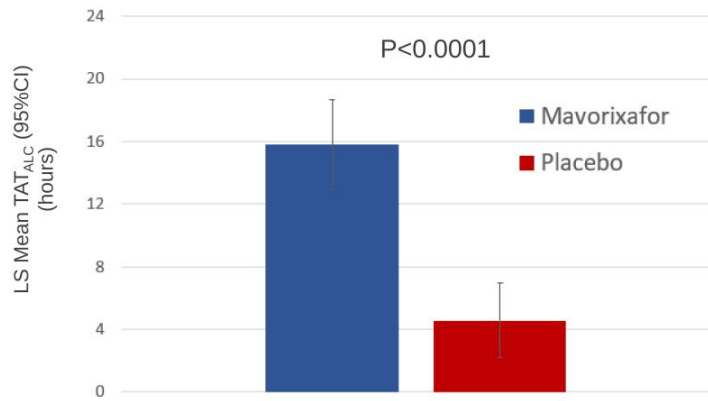


TAT_{ANC} was increased and maintained over 52 weeks vs. placebo and vs. baseline

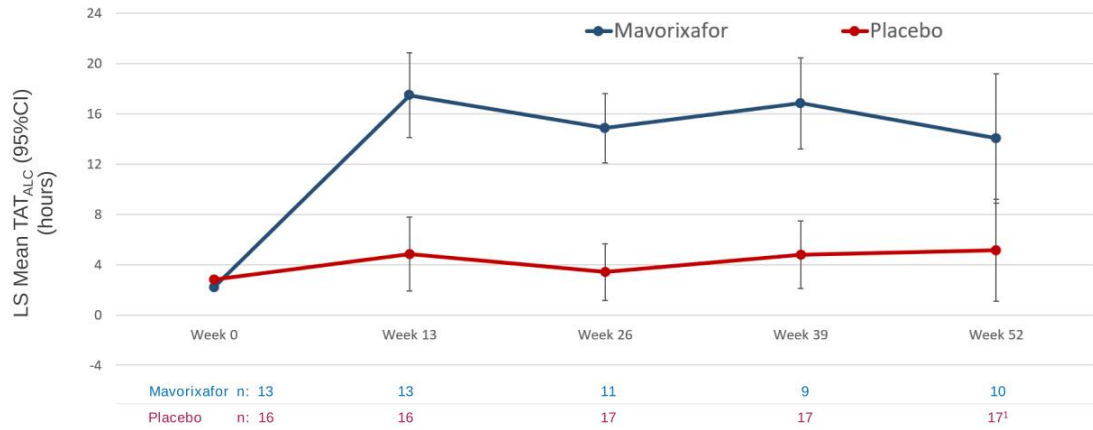
Average increase of ~12.3 hours vs. placebo over the 52-week treatment period

1. At week 52, 3 of 17 placebo patients were given mavoxifafor in advance of their TAT measurements as they entered the open-label portion of the study. All data are included in ITT analysis.

- Mavorixafor significantly improved the time above the threshold of ALC vs. placebo in ITT population
- Mean TAT_{ALC} of 15.80 hours for mavorixafor vs. 4.55 hours for placebo
- 3.5-fold improvement in TAT_{ALC} compared with placebo



TAT_{ALC} vs. Time on Treatment: Mavorixafor Durably Increased TAT_{ALC} Over 52 Weeks (ITT population)



TAT_{ALC} was increased and maintained over 52 weeks vs. placebo and vs. baseline

Increase of ~11.3 hours vs. placebo over the 52-week treatment period

1. At week 52, 3 of 17 placebo patients were given mavorixafor in advance of their TAT measurements as they entered the open-label portion of the study. All data are included in ITT analysis.

Top-Line Safety Data Summary for Randomization Period



	Mavorixafor (N=14)	Placebo (N=17)
	n (%)	n (%)
Summary		
Any TEAE	14 (100)	17 (100)
Treatment-related TEAE	7 (50)	3 (18)
Any Serious AE	5 (36)	2 (12)
Treatment-related Serious AE	0	0
Discontinuations due to AE	0	0
Treatment-limiting toxicity	0	0

Mavorixafor was generally well tolerated

No treatment-related Serious Adverse Events (SAEs)

No discontinuations due to safety events

SAEs included: infections, glioma, thrombocytopenia - none deemed treatment related



Met primary endpoint ($P < 0.0001$) of TAT_{ANC} – clinically meaningful correction of severe chronic neutropenia



Durability of TAT_{ANC} response shown over 52 weeks of treatment



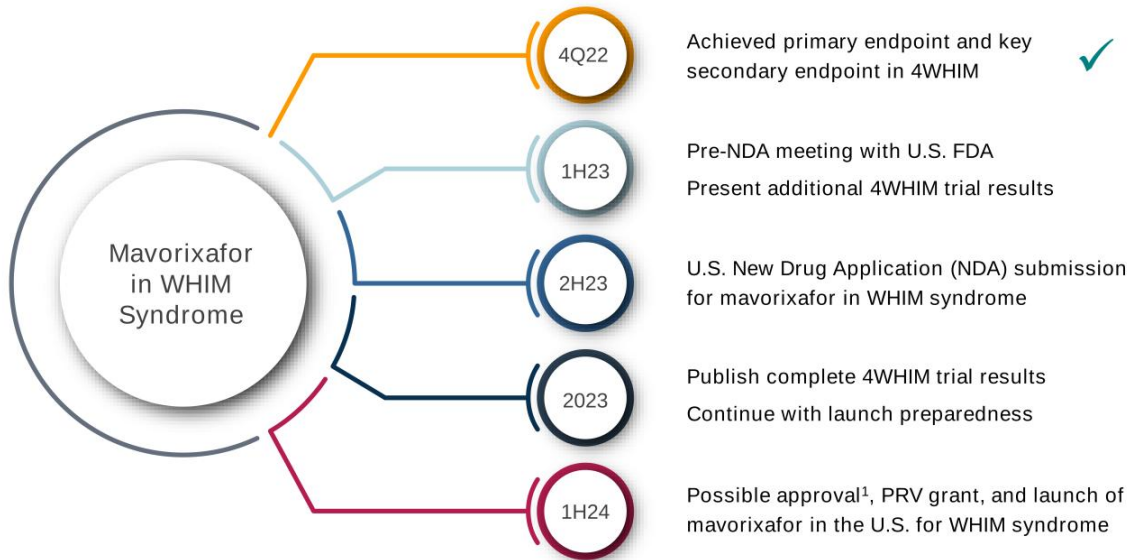
Met first secondary endpoint ($P < 0.0001$) of TAT_{ALC} - clinically meaningful correction of lymphopenia



Durability of TAT_{ALC} response shown over 52 weeks of treatment



Mavorixafor was generally well tolerated with no treatment-related serious adverse events reported



1. Timeline assumes granting of priority review by U.S. Food and Drug Administration



THANK YOU!

Study participants and their families

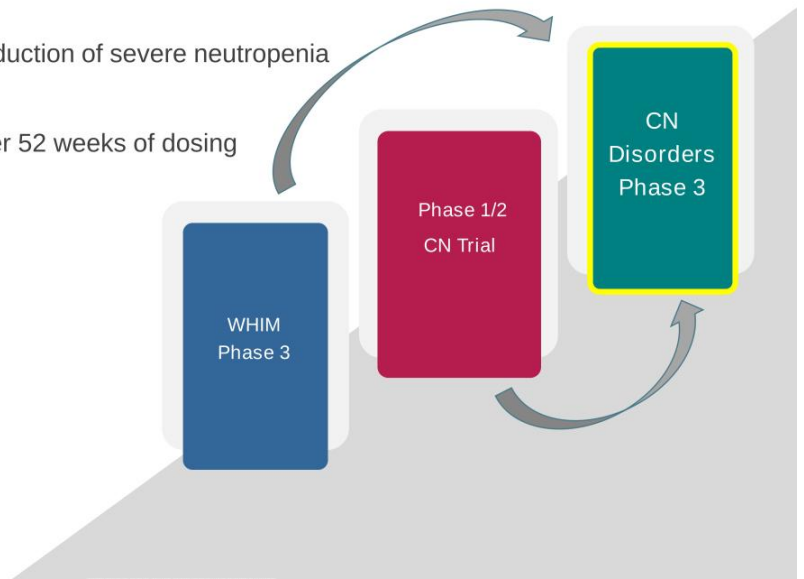
Clinicians, healthcare providers &
study sites

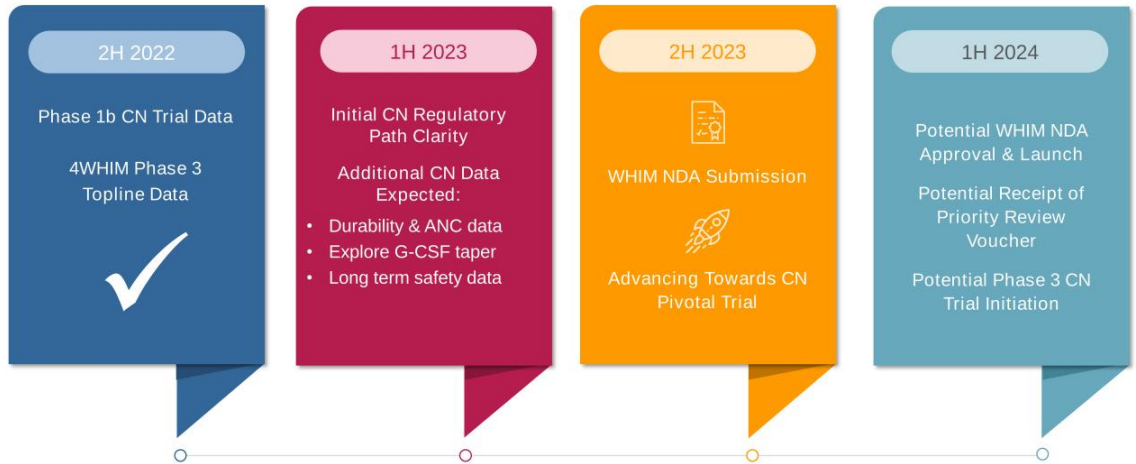
X4 employees



Successful WHIM Phase 3 Supports Plan to Initiate CN Phase 3

- ✓ Primary Endpoint (TAT_{ANC}) = reduction of severe neutropenia
 - ✓ Placebo-controlled design
- ✓ Favorable tolerability profile over 52 weeks of dosing
- ✓ Durable response





Q&A



