
**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): April 1, 2019

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.)

955 Massachusetts Avenue, 4th Floor
Cambridge, Massachusetts
(Address of principal executive offices)

02139
(Zip Code)

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

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):

- 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))

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.

In connection with the business update described in Item 8.01 of this Current Report on Form 8-K, X4 Pharmaceuticals, Inc. (the "Company") updated its corporate slide presentation, which is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. The Company's updated corporate presentation will also be posted to the Company's website, www.x4pharma.com. The Company plans to use its website to disseminate future updates to its corporate presentation and does not intend to file or furnish a Form 8-K alerting investors each time the presentation is updated.

The information set forth in this Item 7.01 is being furnished pursuant to Item 7.01 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, and it shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or under the Exchange Act, whether made before or after the date hereof, except as expressly provided by specific reference in such a filing.

By filing this Current Report on Form 8-K and furnishing the information in this Item 7.01, the Company makes no admission as to the materiality of Item 7.01 in this report or the presentation available on the Company's website. The information contained in the presentation is summary information that is intended to be considered in the context of the Company's filings with the Securities and Exchange Commission (the "SEC") and other public announcements that the Company makes, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in this Current Report on Form 8-K, although it may do so from time to time as its management believes is appropriate or as required by applicable law. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases, by updating its website or through other public disclosure.

Item 8.01 Other Events.

On April 1, 2019, the Company provided a business update. A copy of the Company's press release containing such business update is attached hereto as Exhibit 99.2. The information set forth in the press release is incorporated by reference into this Item 8.01 of this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Corporate Presentation dated April 2019.
99.2	Press release dated April 1, 2019.

The press release may contain hypertext links to information on our website. The information on our website is not incorporated by reference into this Current Report on Form 8-K and does not constitute a part of this Form 8-K.

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.

Date: April 1, 2019

X4 PHARMACEUTICALS, INC.

By: /s/ Paula Ragan, Ph.D.

Paula Ragan, Ph.D.

President and Chief Executive Officer



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**RARE
DISEASES**

April 2019



Forward Looking Statements

Certain statements in this presentation, particularly statements relating to: our plans for, or progress, scope, cost, duration or results or timing for the initiation, completion or availability of results of development of mavorixafor (X4P-001) or any of our other product candidates or programs, including regarding the Phase 3 clinical trial of mavorixafor for the treatment of patients with WHIM syndrome, the target indication(s) for development, the size, design, population, location, conduct, objective, duration or endpoints of any clinical trial, or the timing for initiation or completion of or reporting of results from any clinical trial, the potential benefits of mavorixafor, or any other product candidate or program or the commercial opportunity in any target indication; the potential benefits of orphan drug designation; and our corporate strategies, prospects, projections and goals, may constitute “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and are usually identified by the use of words such as “anticipates,” “believes,” “estimates,” “expects,” “intends,” “may,” “plans,” “projects,” “seeks,” “should,” “will,” “would,” and variations of such words or similar expressions.

We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act and are making this statement for purposes of complying with those safe harbor provisions. Various important factors could cause actual results or events to differ materially from the forward-looking statements that we make, including, but not limited to, the risk that trials and studies may be delayed and may not have satisfactory outcomes, potential adverse effects arising from the testing or use of mavorixafor or other product candidates, the risk that costs required to develop mavorixafor or other product candidates or to expand our operations will be higher than anticipated, the risks associated with our capital needs and other risks described in the “Risk Factors” section of the Registration Statement on Form S-4 we filed with the Securities and Exchange Commission (the “SEC”) and declared effective by the SEC on February 14, 2019 and in the other filings we make with the SEC from time to time. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. We do not assume any obligation to update any forward-looking statements, except as required by law.

Overview: Building a Global Rare Disease Franchise



Developing treatments designed to have a clear and profound impact for patients suffering with rare diseases, including WHIM syndrome, and patients with rare cancers

- **Novel therapeutics designed to improve immune cell trafficking**
- **Founded in 2014, listed on Nasdaq:XFOR in March 2019**
- **Lead product candidate mavorixafor (X4P-001), first-in-class, oral, small molecule allosteric antagonist of chemokine receptor CXCR4**
- **Multiple clinical trials planned, including Phase 3 trial of mavorixafor (X4P-001) in WHIM syndrome**
- **Potential expansion opportunities across rare disease landscape**
- **Experienced leadership team in rare disease – includes several former members of Genzyme leadership team**
- **Headquarters in Cambridge, MA and R&D facility in Vienna, Austria**

Proven Leadership Team with Rare Disease Expertise

Key management and advisors involved with R&D and launch of only approved CXCR4 antagonist - Mozobil

	Paula Ragan, PhD CEO	 		Mary DiBiase, PhD VP of Technical Operations and Quality	
	Ken Gorelick, MD CMO	 		Celeste DiJohnson VP of Clinical Operations	
	Adam Mostafa CFO	 		Tarek Ebrahim, MD VP of Medical Affairs	
	Nic Scalfarotto, DVM VP of Regulatory Affairs	 			

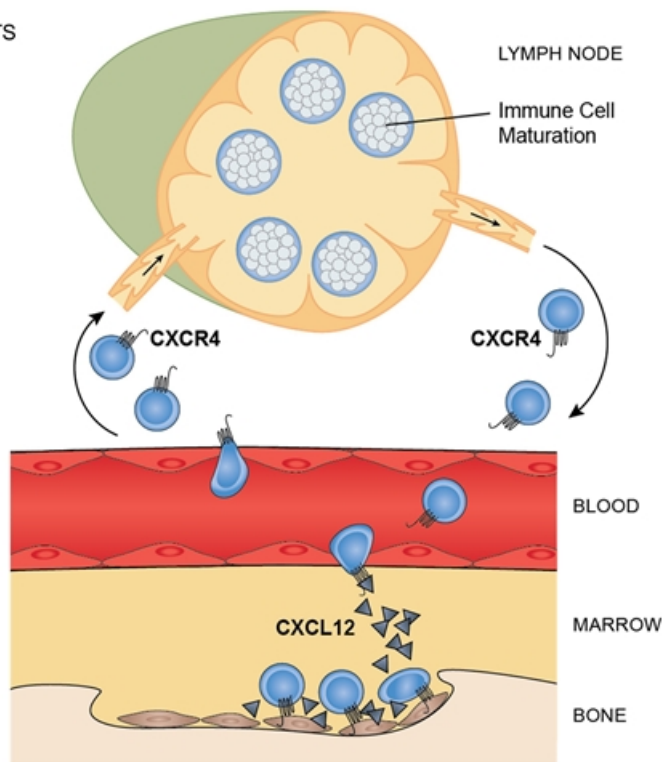
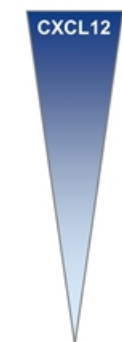
Pipeline

Product Candidate	Indication	Stage of Development			
		Preclinical	Phase 1	Phase 2	Phase 3
Mavorixafor (X4P-001)	WHIM syndrome	Phase 2/3			
	Severe Congenital Neutropenia (SCN)	Phase 1			
	Waldenstrom's Macroglobulinemia (WM)	Phase 1/2			
	Clear cell renal cell carcinoma* (ccRCC) (Combination with Inlyta®)	Phase 2a			
X4P-002	Glioblastoma multiforme (GBM)				
X4P-003	Primary immuno-deficiencies (PID)				

- Two oncology trials have concluded: P1b biomarker in melanoma and P1b in ccRCC. Final publications expected in 4Q19
- Intend to enter into a strategic partnership for future development and potential commercialization for mavorixafor for ccRCC and other potential immuno-oncology indications

CXCR4/CXCL12 and Immune System Responses

CHEMOKINE GRADIENTS



Homeostasis

- Neutrophil homing
- Lymphocyte homing
- Dendritic cell trafficking

Infection Response

- Bacterial
- Viruses
- Fungal/Other

Cancer

- Chemo-resistance/mets
- CTL trafficking
- Suppressor cell trafficking

Adapted from *Blood* 2013 121:1501-1509

WHIM Syndrome: Significant Unmet Medical Need

Warts Hypogammaglobulinemia Infections Myelokathexis

- Rare genetic primary immunodeficiency disease that results from “gain-of-function” mutations in the single gene that encodes the CXCR4 receptor
- Patients typically have chronic, critically low white blood cell counts, including neutrophils and lymphocytes, which are necessary to mount a healthy immune response to bacterial and viral infections
- Debilitating disease progression given treatment options limited to addressing different symptoms focused on prevention and management of infections
- WHIM syndrome included in FDA’s guidance (March 2019) for Severely Debilitating or Life-Threatening Hematologic Disorders
- Proof of concept in WHIM previously demonstrated with Mozobil (twice-daily injectable CXCR4 antagonist)¹



No therapies approved or to our knowledge in development to address underlying cause of multi-faceted disease – genetic defect of CXCR4 receptor

1. McDermott et al; Blood, 2014

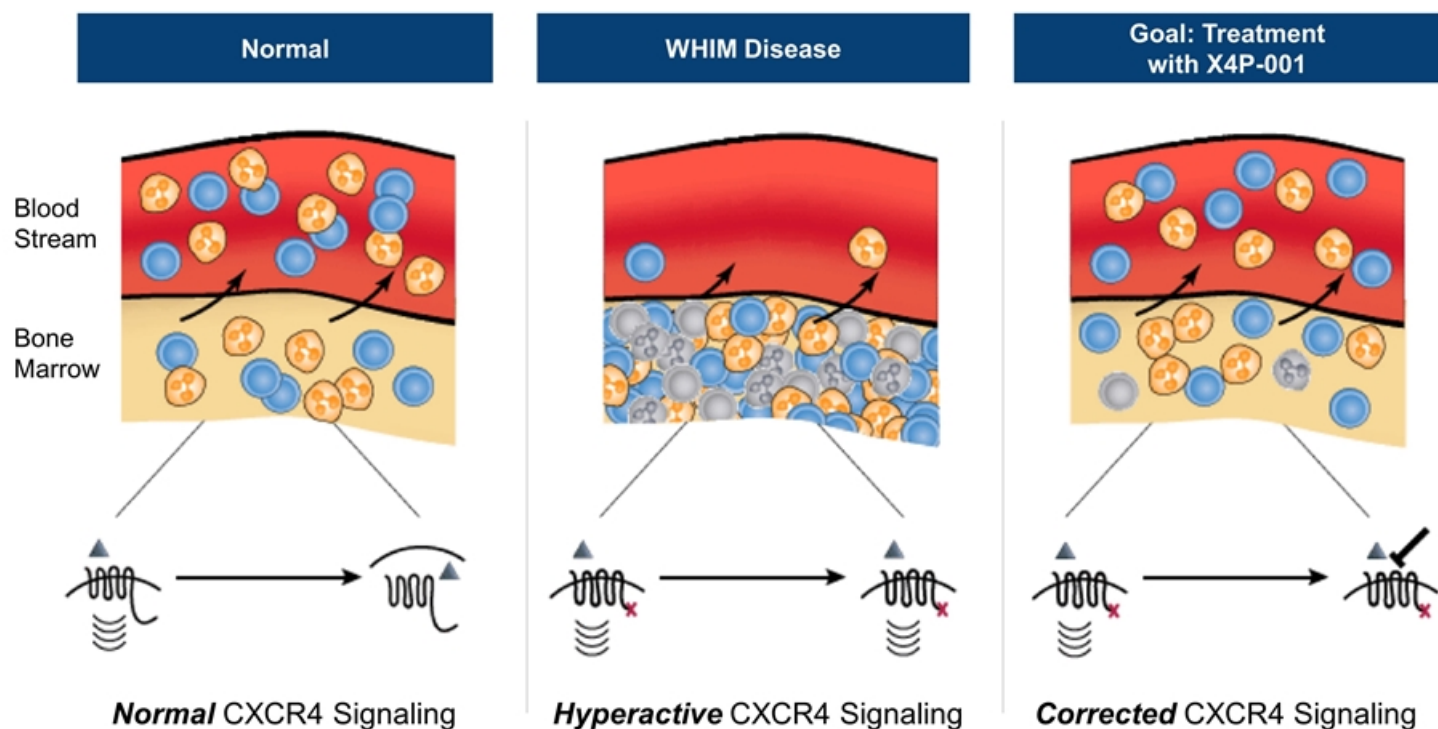
mavorixafor: Phase 3 Ready for WHIM Syndrome

- Completed open-label, dose escalation Phase 2 trial
 - Clinically meaningful improvement in neutropenia
 - Patients showed improvements in certain other signs and symptoms
 - Favorable safety profile
- Five patients continuing to receive mavorixafor in Phase 2 open-label extension (OLE) study
 - Plan to provide future updates
- Randomized, placebo controlled double blinded Phase 3 pivotal trial expected to commence in second quarter 2019
- Diagnosis confirmed genetic testing; >1000 estimated WHIM patients in US
- Orphan drug designation received in October 2018 from US FDA and submitted request to EMA in March 2019



Designed Phase 3 trial to leverage key learnings from Phase 2

WHIM: Genetic Mutations in CXCR4 Create Abnormal Trafficking of White Blood Cells (WBCs)



WHIM Phase 2 Study: Assess Neutrophil Counts Biomarker “Time Above Threshold” Metric

Intra-Patient Dose Escalation

- Open label
- 50 mg to 400 mg once daily (QD)
- n = 8 patients

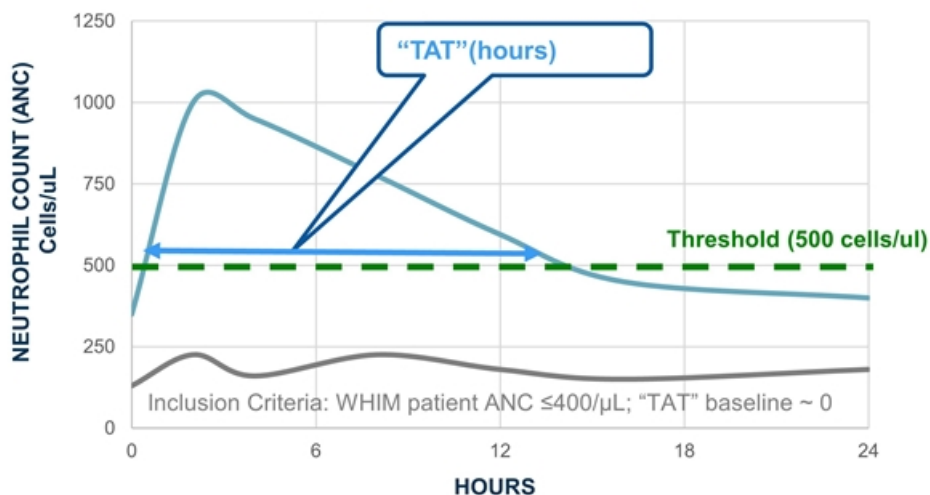
Inclusion

- Neutrophil count: ANC $\leq 400/\mu\text{L}$ and/or
- Lymphocyte count: ALC $\leq 650/\mu\text{L}$ or both

Endpoints & Assessments

- Safety (infections, warts), pharmacokinetics (PK) / pharmacodynamics (PD)
- **Biomarker:** 24-hr Blood Counts of Neutrophils– Time (hrs) Above Threshold

**Objective: Increase Daily Neutrophil Counts (ANC) Above Threshold As Measured Over 24 hours:
Time Above Threshold (“TAT”)**

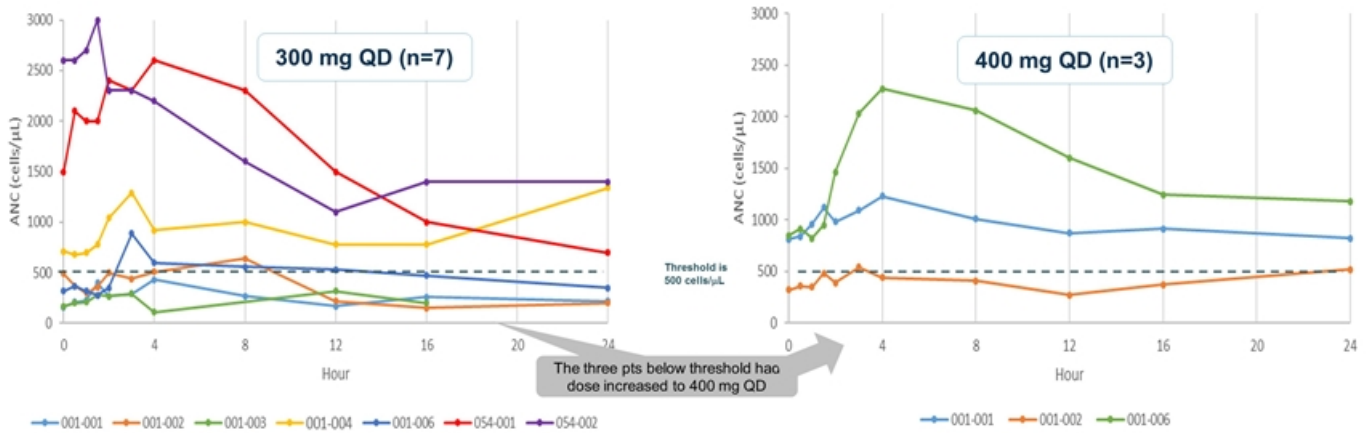


0 hours < TAT < 24 hours
baseline maximum
Treatment Goal

Phase 2: Achieved Maximum TAT In Most Patients

Neutrophil and Lymphocytes Mobilized; Pan-Leukopenia Addressed

Patients Started with an ANC of 50 – 200 cells/ μ L Prior to Treatment



Assessments		Result
Neutrophil Counts > Threshold	✓	5 of 7 patients (71%): maximum TAT
Lymphocyte Counts > Threshold	✓	6 of 7 patients (85%): maximum TAT
Safety	✓	Acceptable; no Grade 3/4

400 mg QD: Phase 3 Pivotal Trial for Patients > 12 years of age

Dramatic Reduction in Wart Burden Through 55 Weeks

Reductions in Infections Rate Compared to Historical Rates

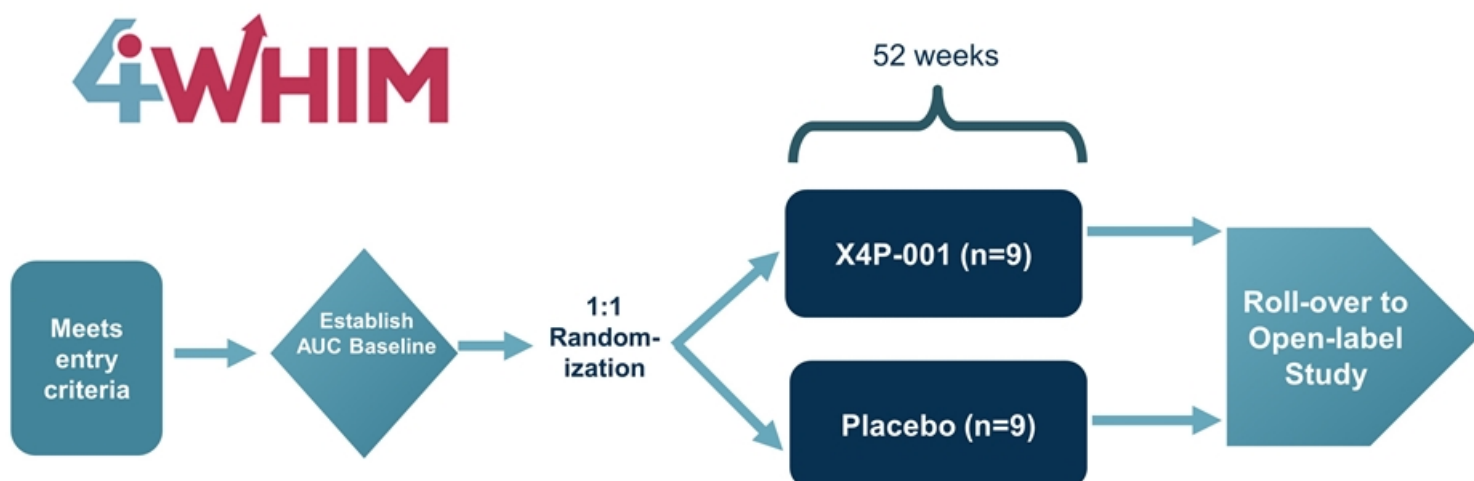


Infection Rates

- Minimal infections in three patients dosed for over 9-months (0.08 infections/pt/month)¹
- Historical infection rates reported in WHIM (0.37 infections/pt/month)²

1. Dale et al, ASH, 2019; 2. McDermott, et a. Blood, 2014.

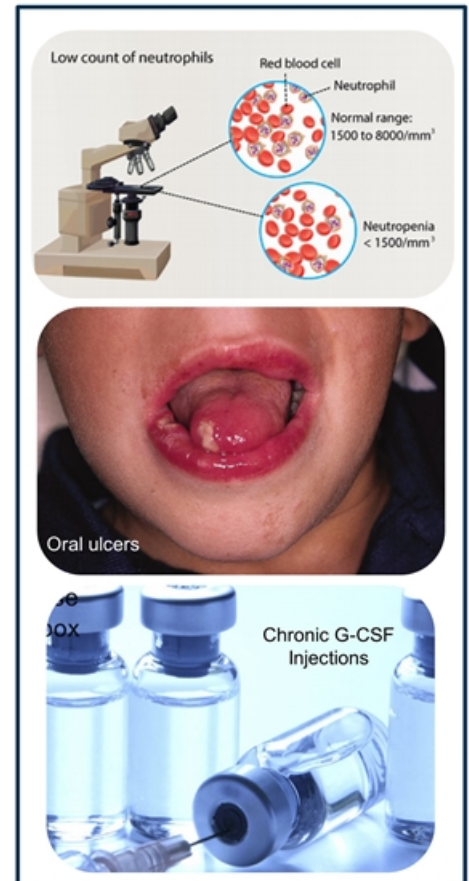
Phase 3 Trial in WHIM Syndrome – Expected 2Q19 Initiation



- 400 mg QD dosing in patients 12 years of age or higher
- Primary endpoint: biomarker of neutrophil count time above threshold ('TAT') where the threshold is defined as 500 cells/uL
- Secondary endpoints include infection rates and wart burden assessments

Primary Immunodeficiency Label Expansion : Phase I Trial in Severe Congenital Neutropenia

- Rare blood disorder
- Characterized by abnormally low levels of certain white blood cells (neutrophils $<1,500$ cell/ul)¹
 - From birth, fevers, severe bacterial infections (at times life-threatening), pneumonias, oral ulcers, premature tooth loss
 - Treatment options: antibiotics and G-CSF
- Prevalence estimated 2,000-3,000 patients (US & EU)²
- Genetic drivers:
 - May be inherited as either an autosomal dominant or an autosomal recessive genetic trait
 - Many cases of SCN are the result of spontaneous, random mutations
- Phase 1 trial planned for 2019
 - Designed to determine the genetic profile of adult SCN patients and assess/correlate their pharmacodynamic response to mavorixafor



1. <https://rarediseases.org/rare-diseases/severe-chronic-neutropenia/> 2. https://www.orpha.net/consor/cgi-bin/OC_Exp.php?Ing=en&Expert=42738

CXCR4 in Cancer: Waldenström's Macroglobulinemia (WM)

- Rare Form of Non-Hodgkin's Lymphoma
- Estimated prevalence of >13,000 in US and EU¹
 - Annual incidence: 1000-1500 in US²; ~1,800 in EU³
- Signs and Symptoms
 - Elevated IgM and other blood-markers
 - Hepatomegaly, splenomegaly, skin purpura
- ~8-year survival rate post-diagnosis
- Current Treatment
 - Imbruvica (\$136,000 per year)
 - Chemo and Rituxan in certain lines/settings
- Mechanism: Genetic Drivers in WM
 - >90% have mutations in MYD88 gene
 - **30-40% have WHIM-like mutations in CXCR4 gene**



Sources ¹Prevalence estimate mathematically as incidence x median Survival X 50% (1/2 living and 1/2 dead at 8 years); Incidence derived mathematically as Prevalence/ 8 years
²Sekhar J, et al., Waldenström macroglobulinemia: a Surveillance, Epidemiology, and End Results database review from 1988 to 2005. Leuk Lymphoma 2012;53(8):1625-1626
³<https://www.cdc.gov/nczod/dpdx/waldenstrom-macroglobulinemia/> (prevalence estimated at 1/102,220 for EU)

CXCR4^{WHIM} R/R Waldenström's: Poor Clinical Outcomes vs. Wild-type Phase 1/2 Study Targets CXCR4-Mutant Population

- Very Good Partial Response (VGPR) Rates: 9.5% vs. 44.4% for wild-type; no Complete Responses (CRs) in either¹
- Median time to major response of 6 months vs. 2 months for wild-type¹
- Median Progression Free Survival (mPFS) for CXCR4^{WHIM} is less than half that of mPFS for wild-type²
- ~4-fold likelihood ibrutinib discontinuation in CXCR4^{WHIM} WM³

Response Profile in R/R WM			
	MYD88 ^{Mut} CXCR4 ^{WT}	MYD88 ^{Mut} CXCR4 ^{Mut}	P-value
N=	36	21	
ORR	100%	85.7%	0.005
Major (>PR)	97.2%	66.6%	<0.001
VGPR	44.4%	9.5%	0.007
Time to Minor Response (mos.)	1.0	1.0	0.10
Time to Major response (mos.)	2.0	6.0	0.05

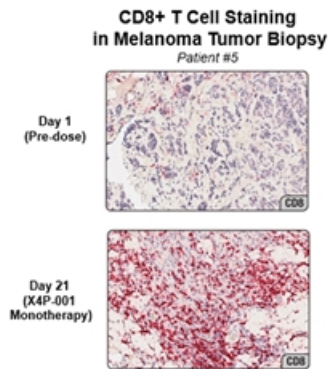
1. Table Recreated from: Treon et al, EHA 2018

Planned Waldenström's Trial: Double-Mutant R/R WMs

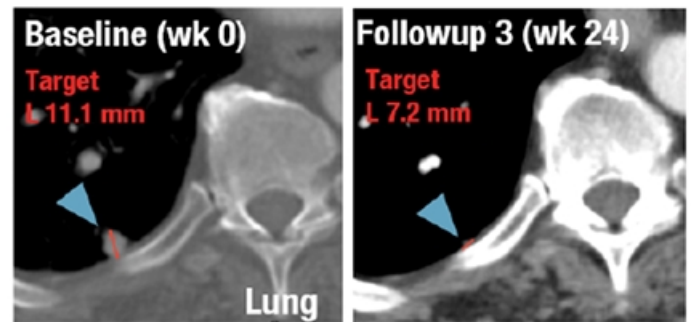
- Inclusion: Patients with MYD88 + CXCR4 mutations who have failed prior Rx
- Design: Multinational Phase 1/2 of mavorixafor in combination with ibrutinib
 - 3X3 dose escalation in combination; then expansion
 - Endpoints: safety, PK/PD, VGPR and CR rates, other
- Expected to commence in 2019

IO Strategy: Goal of Leveraging Biological Expertise Via Partnering

Completed Trials Demonstrate Single Agent Activity & Proof of Mechanism



✓ Phase 1b In Treatment Naïve Melanoma



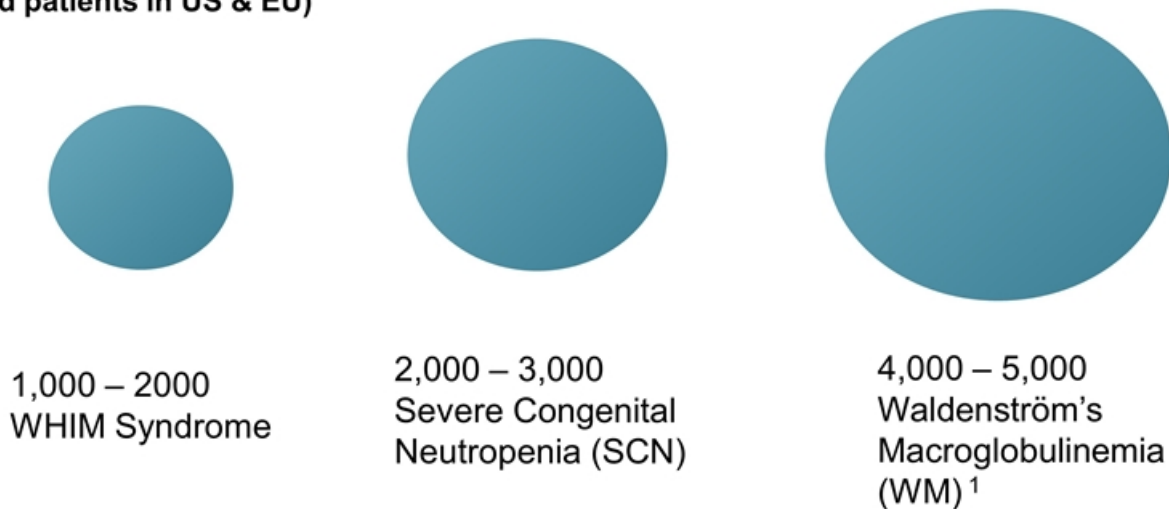
✓ Phase 1b In Progressing RCC w/Opdivo

On-Going Phase 2a ccRCC Trial: Mavorixafor + Axitinib

- 65-patients; multi-national, fully enrolled
- Assessment: mPFS
 - Benchmark to beat: 4.8 months mPFS with axitinib in patients with immediate prior TKI
- Data expected: 2H 2019
- Strategy: Identify strategic collaborators to advance in IO; keying off data readout

Epidemiology Suggests Significant Market Opportunity

Clinical Epidemiology (Estimated patients in US & EU)



*Partnering with World Class Organizations to
Increase Awareness in Primary Immunodeficiencies*



1. Represents CXCR4-mutant patients; 30% to 40% of total WM estimate of 13,000 patients

Significant Progress Expected 2019 to 2021

Target Date	Milestones
2H19	Phase 2a ccRCC PFS data readout
Mid 2019	EMA Orphan Drug Designation for WHIM
4Q19-1Q20	WHIM patient identification update
2019	Commence Phase I trial in SCN
2019	Commence Phase 1/2 in Waldenstrom's
1H20	New pipeline molecules: 002 and 003 INDs
Mid 2020	Phase 1 Trial in SCN: topline results
Mid 2020	WHIM Phase 2 OLE – Updates
2H 2020	Phase 1/2 in Waldenstrom's– Safety, Dose and Activity
2020	WHIM Ex-Vivo Fitness Study Results
2021	Phase 3 Trial in WHIM – topline results



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April 2019



X4 Pharmaceuticals Provides Business and Clinical Development Update

- *Expects to commence the global Phase 3 pivotal trial of mavorixafor for the treatment of patients with Warts, Hypogammaglobulinemia, Infections and Myelokathexis (WHIM) syndrome in second quarter 2019 having finalized the protocol based on FDA guidance*
- *Receives World Health Organization (WHO) approval for mavorixafor as recommended International Non-proprietary Name (INN) for X4P-001*

Cambridge, MA – April 1, 2019 – X4 Pharmaceuticals, Inc. (Nasdaq: XFOR), a clinical-stage biopharmaceutical company focused on the development of novel therapeutics for the treatment of rare diseases, today provided a business and clinical development update.

“This has been a transformative period for X4 with our listing on Nasdaq, finalization of our Phase 3 clinical protocol in WHIM syndrome and the recent approval from the WHO for the use of mavorixafor as our lead candidate name for X4P-001,” said Paula Ragan, Ph.D., President and Chief Executive Officer of X4 Pharmaceuticals. “We look forward to advancing our rare disease pipeline throughout the year with plans to commence a global Phase 3 pivotal trial in WHIM, initiate a Phase 1 trial in severe congenital neutropenia and a Phase 1/2 trial in Waldenström macroglobulinemia, and to disclose data from our ongoing Phase 2a trial in clear cell renal cell carcinoma at a medical meeting later this year.”

Business Update

In March 2019, X4 Pharmaceuticals commenced trading on the Nasdaq Capital Market under the symbol “XFOR.”

In March 2019, X4 submitted its orphan drug designation request to the European Medicines Agency (EMA) for mavorixafor for the treatment of WHIM syndrome. In October 2018, X4 received orphan drug designation from the FDA for the treatment of WHIM syndrome.

X4 also recently received approval from the World Health Organization (“WHO”) for mavorixafor as the recommended International Non-proprietary Name (“INN”) for the company’s lead drug candidate, X4P-001. Mavorixafor is a first-in-class, oral, allosteric antagonist of the chemokine receptor CXCR4 with a demonstrated 23-hour half-life and bioavailability profile that support once-daily oral dosing.

Clinical Development Update

X4 has finalized the clinical trial protocol based on guidance from the FDA for its randomized, placebo controlled double blinded Phase 3 pivotal trial of mavorixafor for the treatment of patients with WHIM syndrome and expects to commence the study in the second quarter 2019. As reviewed with the FDA, the primary endpoint will be the biomarker of neutrophil count time above threshold (“TAT”) where the threshold is defined as 500 cells/uL. The Phase 3 pivotal trial’s secondary endpoints, including infection rates and wart burden assessments, and secondary endpoint hierarchy was also reviewed with the FDA. All enrolled patients ages 12 years and older will receive 400 mg, once daily, of mavorixafor. The Phase 3 pivotal trial will enroll patients from the US and from other global sites.

X4 continues to conduct the Phase 2 open label extension study following the completion of the dose titration portion of the Phase 2 trial for the treatment of patients with WHIM syndrome in March 2018. Five patients are continuing to receive mavorixafor in the Phase 2 open-label extension study and the company plans to provide future updates on the extension study.

In March 2019, the FDA included WHIM syndrome in a guidance for industry for Severely Debilitating or Life-Threatening Hematologic Disorders. X4 has made progress in educating key stakeholders regarding the clinical impact of WHIM syndrome.

X4 is on track to commence a Phase 1 clinical trial of mavorixafor for the treatment of patients with severe congenital neutropenia (SCN) in the United States in 2019. The trial is designed to determine the genetic profile of SCN patients and assess their pharmacodynamic response to mavorixafor.

X4 also plans to commence a multi-national Phase 1/2 clinical trial of mavorixafor in combination with ibrutinib for the treatment of patients with Waldenström macroglobulinemia in 2019. The study population will focus on patients with WHIM-like mutations in CXCR4 who are known to respond poorly to standard of care.

X4 has completed enrollment in the open label Phase 2a portion of its ongoing Phase 1/2 clinical trial of mavorixafor in combination with axitinib in clear cell renal cell carcinoma (ccRCC) patients. The Company plans to unveil progression-free survival (PFS) data as part of an anticipated abstract to be submitted for presentation at a major medical conference in the second half of 2019.

About X4 Pharmaceuticals

X4 Pharmaceuticals is developing novel therapeutics designed to improve immune cell trafficking to treat rare diseases, including primary immunodeficiencies and cancer. X4's oral small molecule drug candidates antagonize the CXCR4 pathway, which plays a central role in immune surveillance. X4's most advanced product candidate, mavorixafor (X4P-001), will be commencing a global Phase 3 pivotal trial in patients with WHIM syndrome, a rare genetic, primary immunodeficiency disease, in the second quarter of 2019 and is currently also under investigation in a Phase 2a clinical trial in clear cell renal cell carcinoma. X4 was founded and is led by a team with extensive product development and commercialization expertise, including several former members of the Genzyme leadership team, and is located in Cambridge, Massachusetts. For more information, visit www.x4pharma.com.

Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statement of historical facts, included in this press release regarding our strategy, future operations, and plans are forward-looking statements. Examples of such statements include, but are not limited to, statements relating to plans for, or progress, scope, cost, duration or results or timing for the initiation, completion or availability of results of development of mavorixafor (X4P-001) or any of our other product candidates or programs, including regarding the Phase 3 clinical trial of mavorixafor for the treatment of patients with WHIM syndrome, the target indication(s) for development, the size, design, population, location, conduct, objective, duration or endpoints of any clinical trial, or the timing for initiation or completion of or reporting of results from any clinical trial, the potential benefits of mavorixafor, or any other product candidate or program or the commercial opportunity in any target indication; or the potential benefits of orphan drug designation. Actual results or events could differ materially from the plans, intentions, expectations and projections disclosed in the forward-looking statements. Various important factors could cause actual results or events to differ materially from the forward-looking statements that X4 makes, including, but not limited to, the risk that trials and studies may be delayed and may not have satisfactory outcomes, potential adverse effects arising from the testing or use of mavorixafor or other product candidates, the risk that costs required to develop mavorixafor or other product candidates or to expand our operations will be higher than anticipated and other risks described in the "Risk Factors" section of the Registration Statement on Form S-4 filed by X4 Pharmaceuticals with the SEC and declared effective by the SEC on February 14, 2019. X4 does not assume any obligation to update any forward-looking statements, except as required by law.

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