

VEOZAH™ (fezolinetant) U.S. COMMERCIAL UPDATE

MAY 18/19, 2023



VEOZAH™
(fezolinetant) tablets 45 mg

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION

In this material, In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this material is not intended to constitute an advertisement or medical advice.

The safety and efficacy of fezolinetant has been assessed by the FDA and approved for use in the U.S. for the treatment of moderate to severe vasomotor symptoms due to menopause. In other markets, fezolinetant is an investigational compound in clinical development. The safety and efficacy of fezolinetant is being assessed by other Regulatory Authorities. There is no guarantee it will receive regulatory approval or become commercially available in all markets.

本資料には、医薬品に関する情報が含まれています。それらの医薬品は、すべての国で発売されているとは限らず、また、国によって商標、効能・効果、用法・用量等が異なる可能性もあります。ここに記載されている内容は、株主や投資家の皆さまのための情報開示を目的としており、開発品を含むいかなる医療用医薬品の宣伝広告、医学的アドバイスを意図するものではありません。

この資料に記載されている現在の計画、予想、戦略、想定に関する記述及びその他の過去の事実ではない記述は、アステラス製薬の業績等に関する将来の見通しです。これらの記述は経営陣の現在入手可能な情報に基づく見積りや想定によるものであり、既知及び未知のリスクと不確実な要素を含んでいます。様々な要因によって、これら将来の見通しは実際の結果と大きく異なる可能性があります。その要因としては、(i) 医薬品市場における事業環境の変化及び関係法規制の改正、(ii) 為替レートの変動、(iii) 新製品発売の遅延、(iv) 新製品及び既存品の販売活動において期待した成果を得られない可能性、(v) 競争力のある新薬を継続的に生み出すことができない可能性、(vi) 第三者による知的財産の侵害等がありますが、これらに限定されるものではありません。

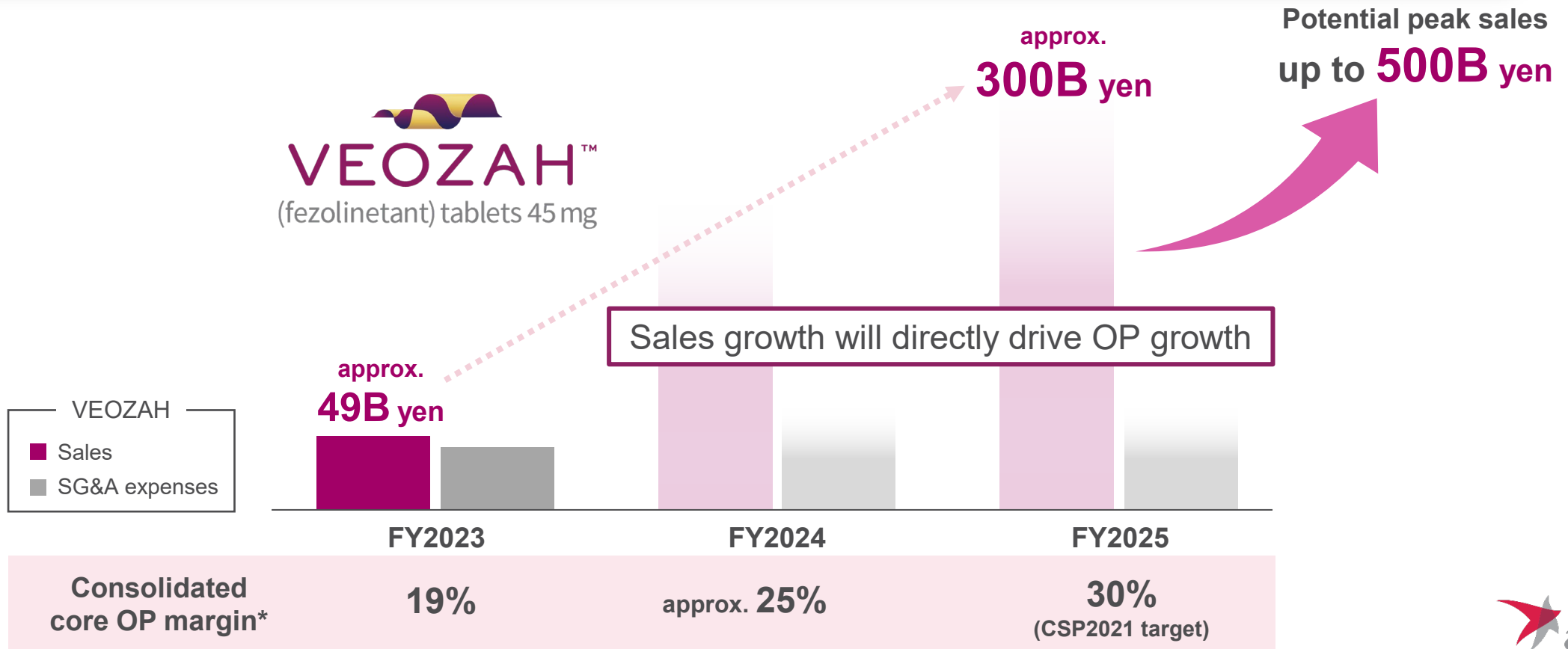
EXPECTATIONS FOR VEOZAH



NAOKI OKAMURA
PRESIDENT AND CEO

EXPECTATIONS FOR VEOZAH

- Accelerate growth through proactive investment, aiming to reach approx. 300B yen by FY2025
- Potential major growth driver to help compensate for XTANDI LOE



The figure is for illustrative purposes only and does not represent the exact values. *Impact of acquisition of Iveric Bio is not incorporated.
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VMS AWARENESS & EDUCATION



MARK REISENAUER
U.S. COMMERCIAL PRESIDENT



VMS AWARENESS ACTIVITIES REINFORCE INTEREST AND DESIRE FOR INFORMATION



HCPs



Patients



245,000+
reached

58+ million
ages 35-64 reached



267,000 visitors
to KnowVMS.com

2.9 million visitors
to WhatsVMS.com



82% increase in awareness
of the mechanism of VMS
from 22% to 40% in about a year

83% increase in awareness
of the term VMS
from 11% to 21% in 3 months



57% perceive VMS
as worthy of HCP attention

64% recognize VMS
as a medical condition



“WHAT’S VMS” TURNED UP THE HEAT AROUND WOMEN’S HEALTH AT THE SUPER BOWL



338%

increase in traffic to WhatsVMS.com compared to the previous 30-day average

2x 10x 6x

Increase in average time on WhatsVMS.com

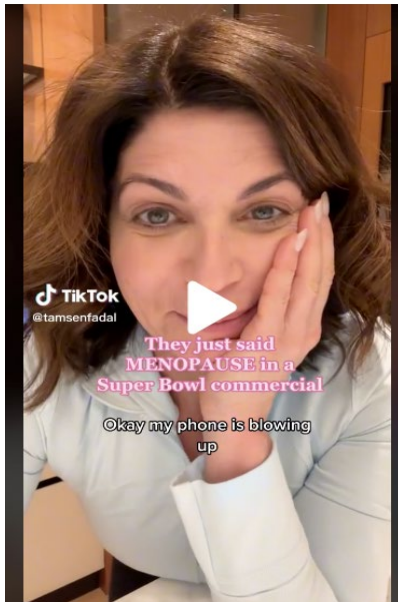
Increase in daily CRM sign-ups

Increase in quiz completions



309M+

media and social media impressions



Forbes

Super Bowl Commercials 2023 Deliver On Humor But Tackle New Topics: Sobriety, Menopause, And Christianity



Irene Preklet
@IreneCityNews

What a menopause commercial after the #SuperBowl2023 coin toss! Nice to see, because hot flashes suck!! Clearly they know a lot of women watch the game.



Astellas turns up the heat with Super Bowl spot

Ad Age

ASTELLAS TO AIR ITS FIRST SUPER BOWL SPOT



PATIENT & HCP PERSPECTIVES

Projection Only

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VEOZAH COMMERCIALIZATION

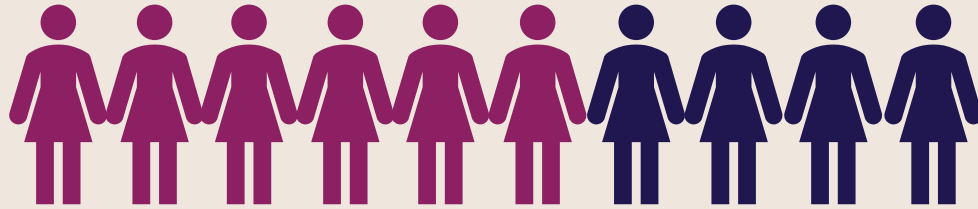


MARK REISENAUER
U.S. COMMERCIAL PRESIDENT



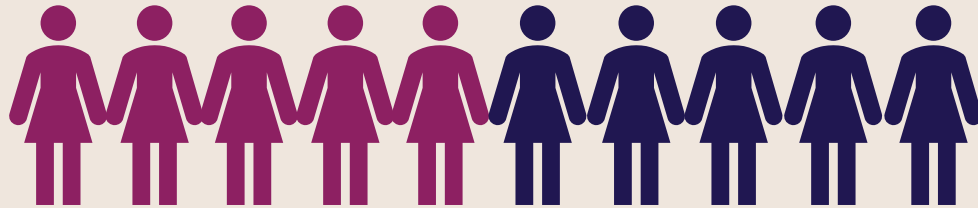
MARKET RESEARCH VALIDATES DEMAND

>60%



Patients will not take hormone therapy for personal or medical reasons

~50%



Patients with moderate to severe VMS due to menopause are willing to use and/or ask physician

~40%



Physicians likely to prescribe

Source: Astellas sponsored primary market research (2019, 2021 & 2023)

SUCCESSFULLY LAUNCHING IN THE U.S.



“Decades of limited treatment options created a gaping ‘unmet need’, making Veozah...both groundbreaking and long overdue.”

The New York Times

Dr. Lauren Streicher
Medical Director, Northwestern
Medicine Center for Menopause

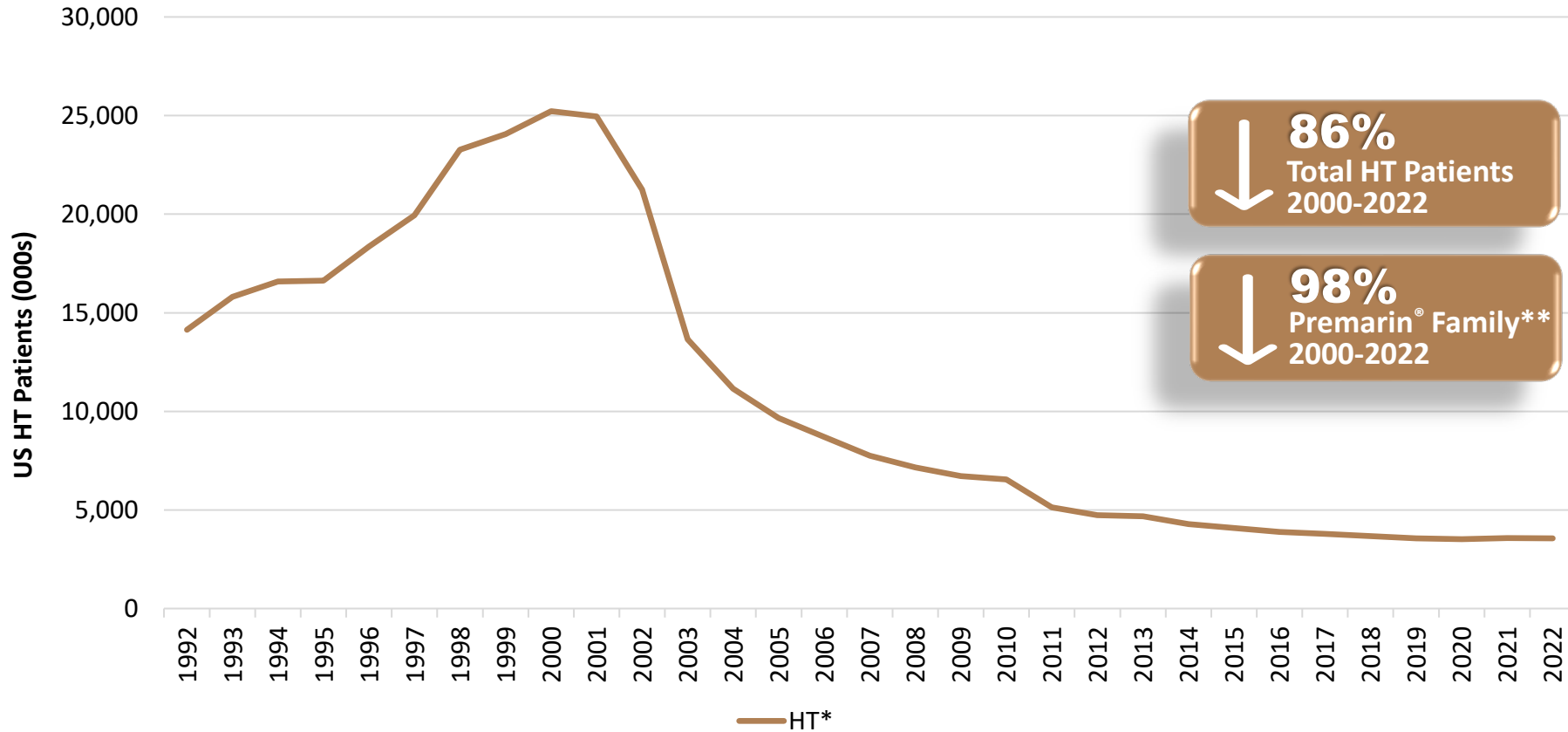


<p>750+ News Stories</p>	<p>35+ Ex-US News Stories</p>	<p>150+ Social Media Posts</p>
<p>FDA approves first-of-its-kind drug to treat hot flashes</p>	<p>FDA Approves First Nonhormonal Drug to Ease Menopause Hot Flashes</p>	<p>Astellas wins FDA approval of hot flashes drug Veozah</p>



PATIENT TREATMENT PATTERNS INDICATE MILLIONS OF WOMEN IN U.S. NEED HELP WITH VMS DUE TO MENOPAUSE

U.S. Estimated HT Patients***



↓ **86%**
Total HT Patients
2000-2022

↓ **98%**
Premarin® Family**
2000-2022

Currently Available Treatment Options for VMS

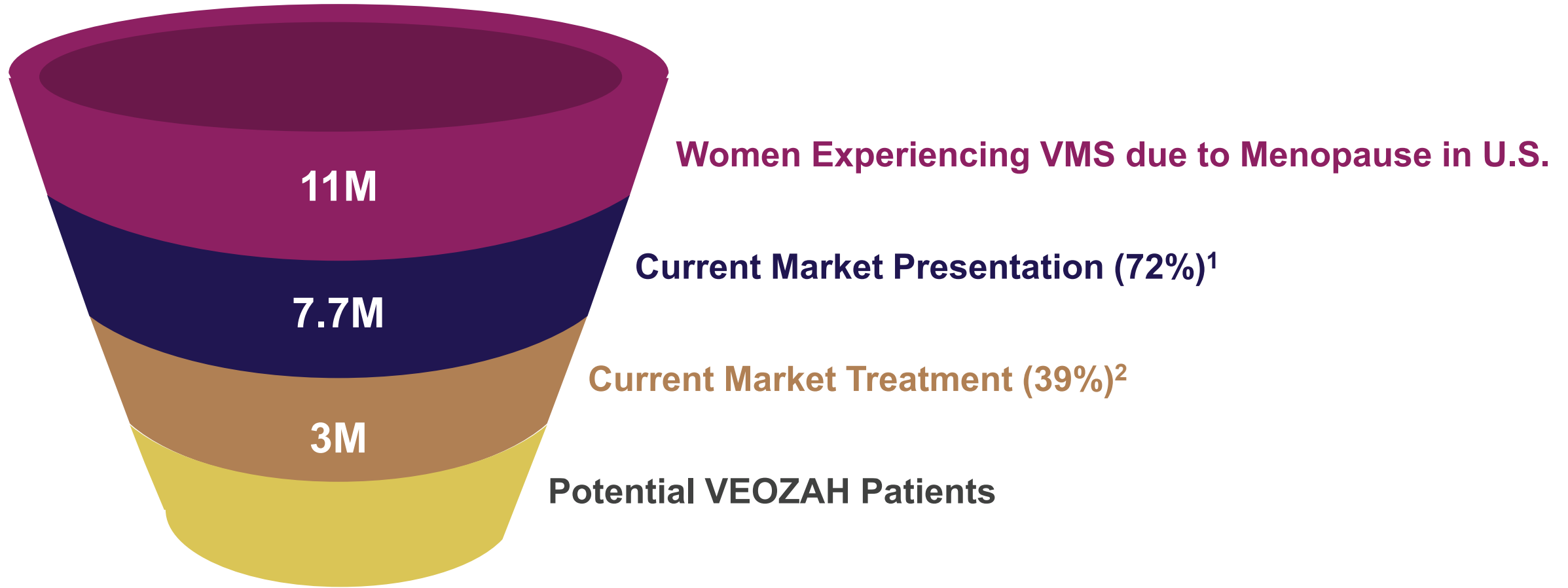
Hormonal treatment

Nonhormonal therapy

- SSRIs / SNRIs
- Clonidine
- Gabapentin
- Over-the-counter medicines
- Herbal medicines

Source: IQVIA NPA / Market Definition: *HRT – ATC3 G03C Estrogen (Oral), G03F Estrogen Progestogens Combination (Oral); **Premarin® Family – Premarin®, Prempro®; ***Patient estimate = Total Days of Therapy/182 days

FORECAST FLOW



Sources: 1. U.S. Quant Patient Screener. U.S. Quant Patient Survey. ClearView Analysis. 2. U.S. Quant Physician and Patient Survey. ClearView Analysis

POTENTIAL EARLY ADOPTERS



2+ million
motivated
& proactive patients¹



97,000
pioneering &
early adopting HCPs^{2,3}

What They Believe

- Symptoms are bothersome
- VMS occur frequently and can be severe
- Frustrated and angry

- Patients with VMS are in distress
- Job is to solve patient's problems
- Appreciate impact of VMS on QOL and actively treating

What They Will Do

- Will ask an HCP about a treatment
- More likely to have tried treatment
- More proactive about their health

- Listens well to patient complaints and sympathizes
- More likely to adopt new health products
- Takes action to solve problem

HCP: healthcare professional

Sources: 1. U.S. Consumer Tactical Segmentation (919 U.S. VMS Consumers). 2. U.S. HCP Tactical Segmentation (500 U.S. HCPs). 3. SHA U.S. Claims Analysis. April 2023.

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CATEGORY PERSISTENCE



VMS are the **most common symptoms** of menopause for which women seek treatment¹



Symptoms persist for a **median of 7.4 years**²



Patients are **highly compliant and persistent**³
- 80% persistence at 1 year } for nonhormone therapy
- 70% persistence at 2 years }

Sources:

1. Williams RE, Kalilani L, DiBenedetti DB, Zhou X, Fehnel SE, Clark RV. Healthcare seeking and treatment for menopausal symptoms in the United States. *Maturitas*. 2007;58:348-58.
2. Avis NE, Crawford SL, Greendale G, Bromberger JT, Everson-Rose SA, Gold EB, et al. Duration of menopausal vasomotor symptoms over the menopause transition. *JAMA Intern Med*. 2015;175:531-9.
3. SHA Open Claims Full Deliverable 1/1/2014 – 12/31/2018

MAXIMIZING THE VALUE OF VEOZAH: LEVERAGING PROVEN EXPERTISE

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Successfully launching products with novel MOAs



Establishing market leadership with therapies predominately prescribed to women by Ob-Gyns



Creating strong relationships in the women's health space



Experienced, knowledgeable and agile sales force

 **Myrbetriq**[™]
mirabegron

 **VESicare**[®]
(solifenacin succinate)
5 mg, 10 mg tablets

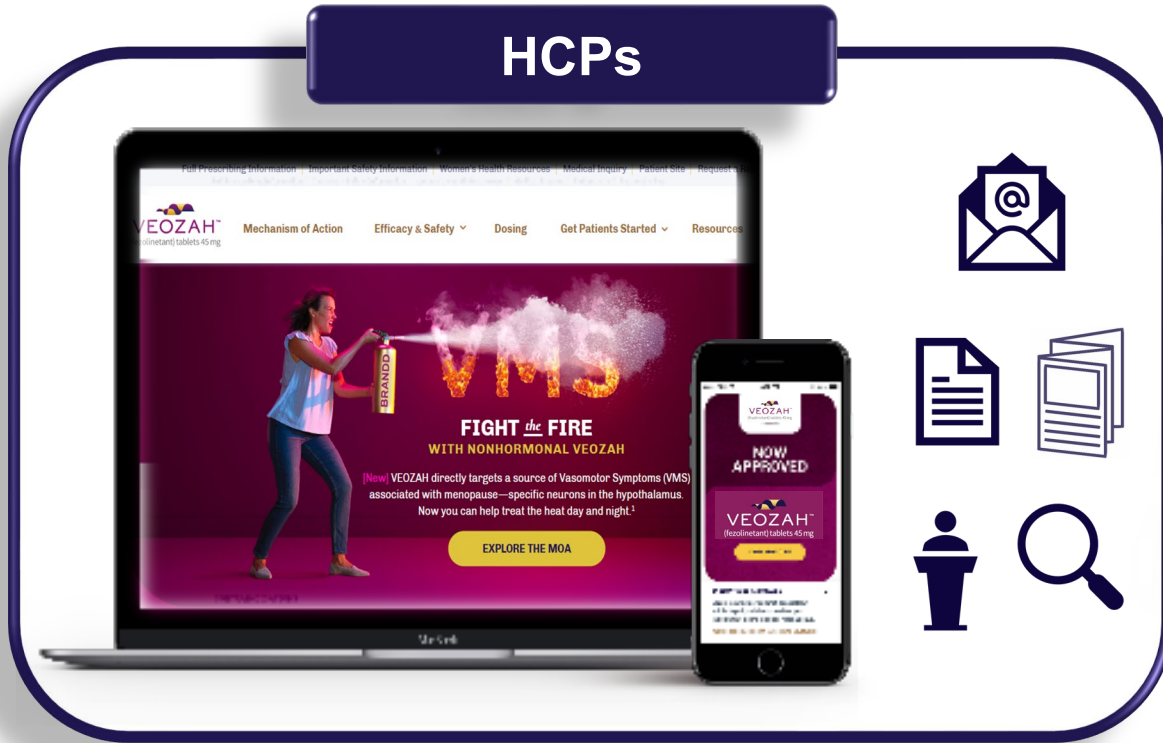
MOA: mechanism of action, Ob-Gyn: obstetrician-gynecologist

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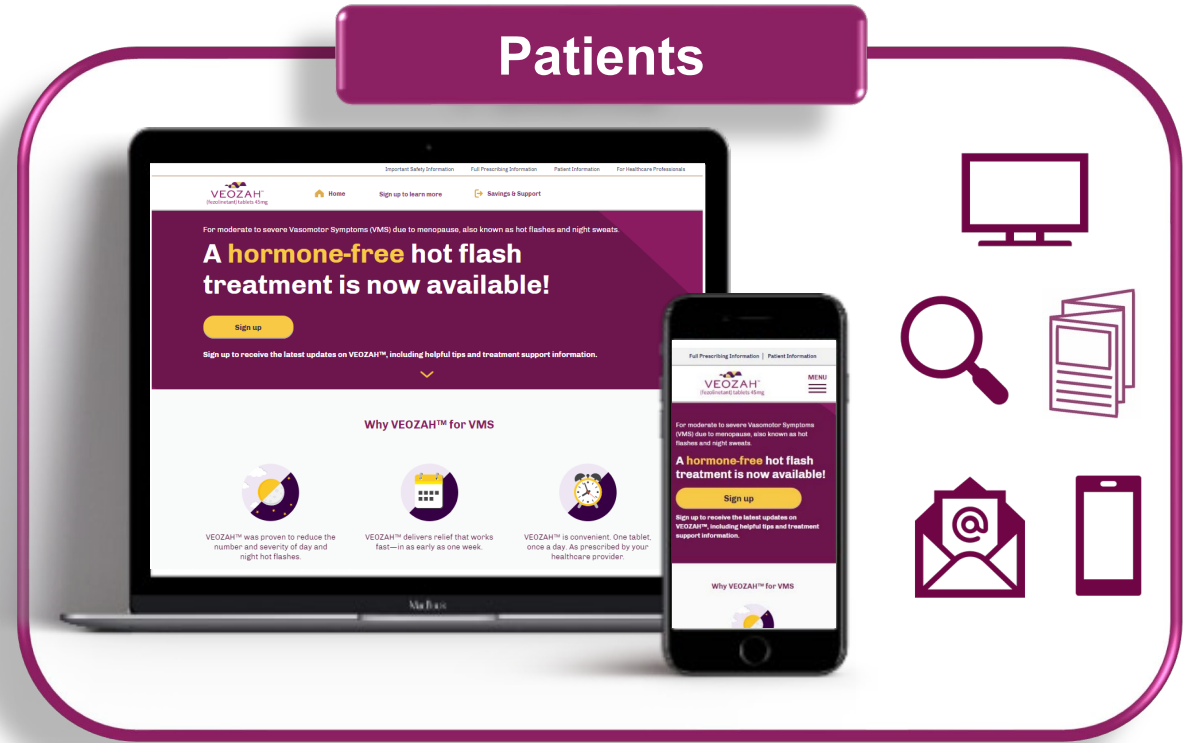
MAXIMIZING THE VALUE OF VEOZAH: BRAND AWARENESS

HCPs



The HCPs section features a laptop and a smartphone displaying the VEOZAH website. The laptop screen shows a woman fighting a fire with a fire extinguisher, with the text "FIGHT the FIRE WITH NONHORMONAL VEOZAH" and "FIGHT the FIRE WITH NONHORMONAL VEOZAH". The smartphone displays "NOW APPROVED VEOZAH (fezolinetant) tablets 45mg". To the right of the devices are icons representing an email, documents, a person at a podium, and a magnifying glass.

Patients



The Patients section features a laptop and a smartphone displaying the VEOZAH website. The laptop screen shows "A hormone-free hot flash treatment is now available!" and "Sign up to receive the latest updates on VEOZAH™, including helpful tips and treatment support information." The smartphone displays "A hormone-free hot flash treatment is now available!" and "Sign up to receive the latest updates on VEOZAH™, including helpful tips and treatment support information." To the right of the devices are icons representing a monitor, a magnifying glass, a stack of papers, an email, and a smartphone.

Ongoing campaign and performance evaluation will enable flexibility to maximize investment, achieve goals and meet forecasts

HCP: healthcare professional

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MAXIMIZING THE VALUE OF VEOZAH: SAFETY AND EFFICACY

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**Fewer and less
intense VMS
episodes with
VEOZAH**



**Relief that works
fast and lasts**



**Works around
the clock**



**Long-term
safety and
tolerability
characterized
across three
Phase 3 studies**

Sources:

1. Lederman S, Ottery F, Cano A et al. Fezolinetant for treatment of moderate-to-severe vasomotor symptoms associated with menopause (SKYLIGHT 1): a phase 3 randomised controlled study. *The Lancet*. March 13, 2023. doi:10.1016/S0140-6736(23)00085-5.
2. Neal-Perry G, Cano A, Lederman S, et al. Safety of fezolinetant for vasomotor symptoms associated with menopause: a randomized controlled trial. *Obstetrics & Gynecology*. March 9, 2023. doi:10.1097/AOG.0000000000005114.
3. Depypere H, Timmerman D, Donders G, et al. Treatment of menopausal vasomotor symptoms with fezolinetant, a neurokinin 3 receptor antagonist: a phase 2a trial. *J Clin Endocrinol Metab*. 2019;104:5893-5905.

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HELPING ENSURE SAFE, REAL-WORLD USE OF VEOZAH

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Baseline bloodwork to evaluate for hepatic function and injury should be performed before beginning VEOZAH



Follow-up bloodwork should be performed at 3, 6 and 9 months while taking VEOZAH and when symptoms suggest liver injury



Monitoring at the initiation of therapy will help ensure VEOZAH is administered safely in real-world use

MAXIMIZING THE VALUE OF VEOZAH: PATIENT ACCESS

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Payer Coverage

Expect VEOZAH to Achieve Widespread Coverage

Some plans take 3-6 months to review new drugs for formulary coverage

Strong Foundation to Support Formulary Decisions from Pre-Approval Information Exchange

62 completed interactions with 54 different U.S. payer accounts

Strong Value Proposition

Astellas will address the clinical and financial needs of payers in their formulary decision making process



Patient Support Programs

Patient Savings Program

(co-pay assistance) for commercially insured patients

Patient Assistance Program

for uninsured, eligible patients meeting program criteria

HUB

Navigate benefits and coverage issues[§]



Point of Sale

Engaging Wholesalers and Retailers

In pharmacies at the point of sale for patients

- Product availability – timely access from Rx written to patient possession

[§]VEOZAH Support Solutions has no control over the decisions of, and does not guarantee support from, independent third parties

MAXIMIZING THE VALUE OF VEOZAH: PRICE

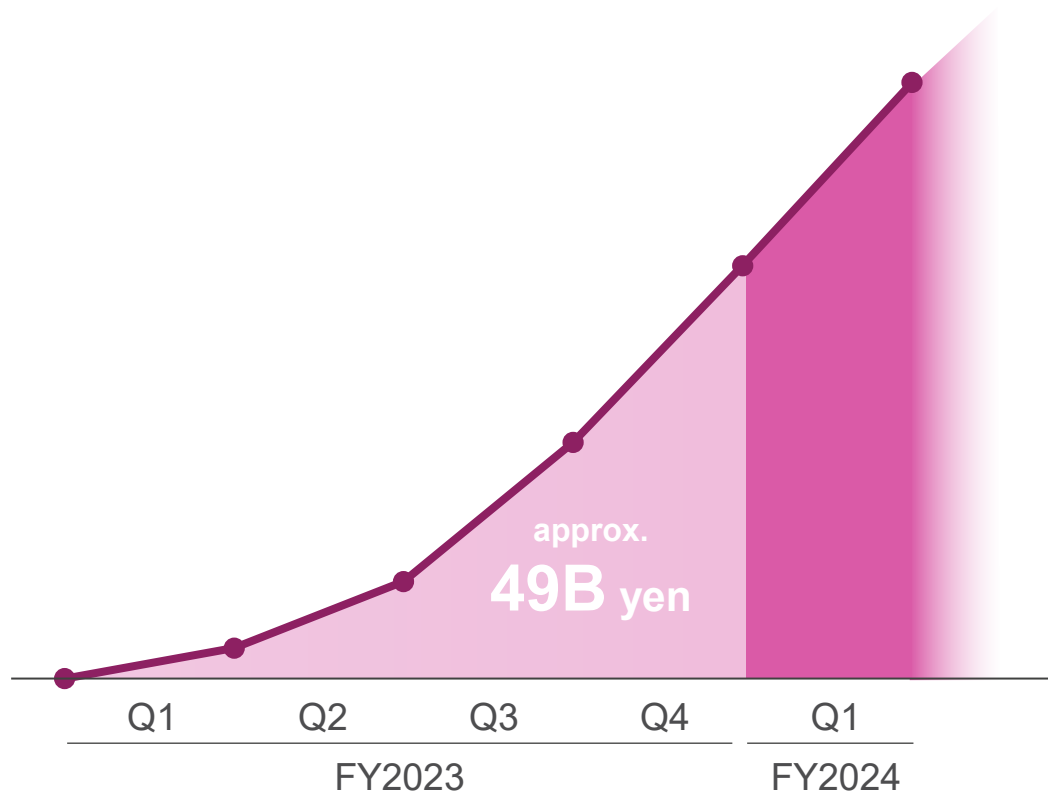


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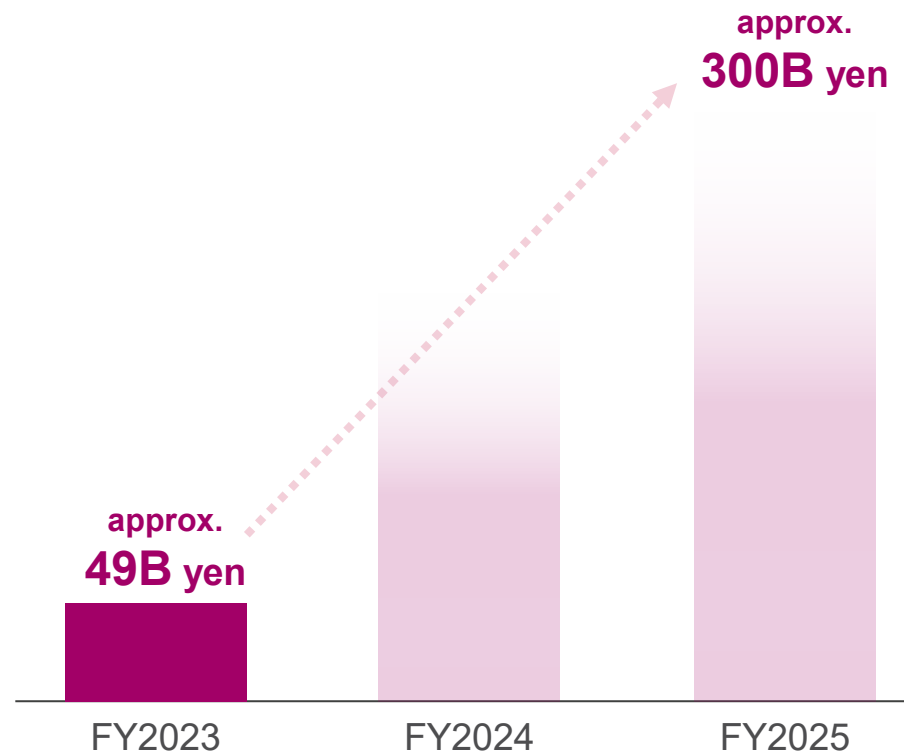
VEOZAH SALES OUTLOOK

Expect substantial uptake in latter half of FY2023 and further accelerate growth from FY2024

Quarterly Outlook



Annual Outlook



The figures are for illustrative purposes only and do not represent the exact values.

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Thank You



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