# SCYNEXIS

# BREXAFEMME® Ibrexafungerp tablet, 150 mg

# for the Treatment of VVC

**Commercial Update Call** 

June 29, 2021

US-BREX-2100003

### **Forward-Looking Statements**

Certain statements regarding SCYNEXIS, Inc. (the "Company") made in this presentation constitute forward-looking statements, including, but not limited to, statements regarding our business strategies and goals, plans and prospects, market size, adoption rate, potential revenue, clinical validity and utility, growth opportunities, future products and product pipeline. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from our expectations. These risks and uncertainties include, but are not limited, to: BREXAFEMME may not be accepted by physicians and patients at the rate SCYNEXIS expects; risks inherent in SCYNEXIS' ability to successfully develop and obtain FDA approval for ibrexafungerp for additional indications; unexpected delays may occur in the timing of acceptance by the FDA of an NDA submission; the expected costs of commercializing BREXAFEMME or of clinical studies and when they might begin or be concluded; SCYNEXIS' need for additional capital resources; and SCYNEXIS' reliance on third parties to conduct SCYNEXIS' clinical studies and commercialize its products. The use of words such as "anticipates," "expects," "intends," "plans," "could," "should," "would," "may," "will," "believes," "estimates," "potential," or "continue" and variations or similar expressions are intended to identify forward-looking statements, but not all forward-looking statements may be so identified. These statements are based upon the current expectations and beliefs of management and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks and uncertainties include, but are not limited to, risks and uncertainties discussed in the Company's most recent reports filed with the Securities and Exchange Commission ("SEC"), including under the caption "Risk Factors" in the Company's annual report on Form 10-K for the year ended December 31, 2020 and in the Company's subsequent guarterly reports on Form 10-Q, which factors are incorporated herein by reference. Readers are cautioned not to place undue reliance on any of these forward-looking statements. The Company undertakes no obligation to update any of these forward-looking statements to reflect events or circumstances after the date of this presentation, or to reflect actual outcomes.

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# Agenda

12:00	12:10	12:30	1:00	1:10	1:30
Introduction	VVC Treatment Landscape	Commercial Update	Financial Update	Q&A Session	Closing Remarks
<b>Dr. Marco Taglietti</b> CEO	KOL: Dr. Michael Krychman	<b>Christine Coyne</b> Chief Commercial Officer	<b>Eric Francois</b> Chief Financial Officer	Open to all	<b>Dr. Marco Taglietti</b> CEO



# Introduction

Dr. Marco Taglietti, President and Chief Executive Officer



# Now APPROVED!

### BREXAFEMME<sup>®</sup> (ibrexafungerp 150 mg tablets)



The **5** Reasons **Why** 

we expect BREXAFEMME will be a **Success** 



### **Medical Need**

- VVC is a problem
- It is common and it is serious
- It affects multiple dimensions of well-being
- If improperly treated, it can result in long-term problems for the patient



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Reason 1

# **Disruptive Innovative Solution**

- First new oral class in VVC in over 25 years
- Different mechanism of action
- Favorable attributes
- One-day dose regimen
- Let's stop relying just on azoles!



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#### Reason 3

### We are the Loudest and Only Voice in VVC

- No other antifungals are being promoted in the VVC space
- No one else is engaging with patients
- Generics are not promoted
- HCPs and patients are eager to try something new



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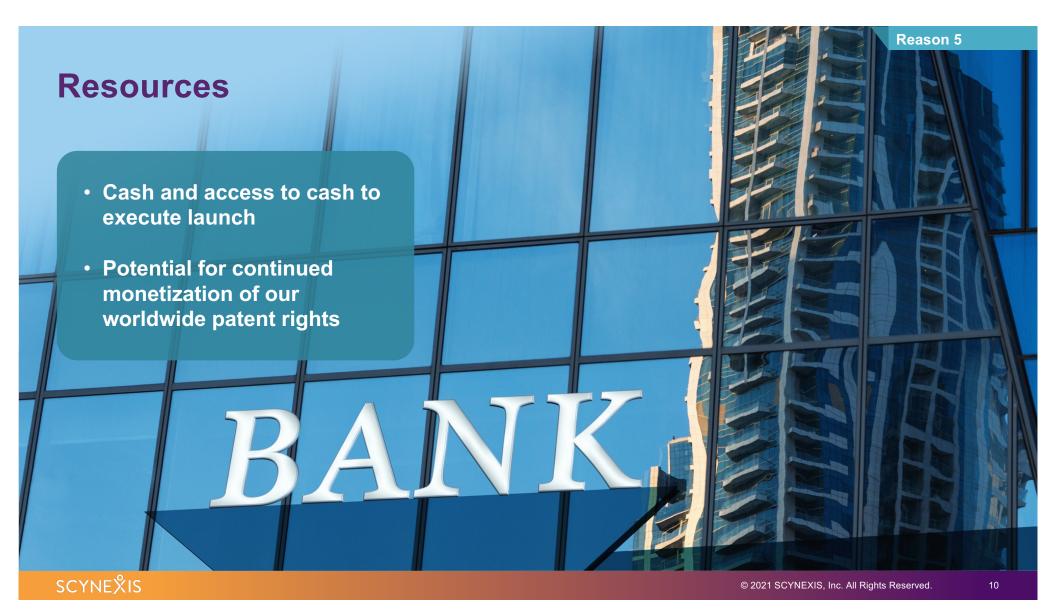
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- SCYNEXIS' track record in strong execution
- Experienced team in place
- Partnership with Amplity







# VVC is Only the Beginning

- Treatment of VVC is the first of several indications planned for ibrexafungerp
- Solution for community AND
   hospital fungal infections
- At least 14 years of patent protection to build a longlasting anti-fungal franchise





# Vulvovaginal Candidiasis from a Provider Perspective

#### Michael Krychman, MD

Health Science Clinical Professor at the University of California Irvine, Division of Gynecological Oncology

Relevant Disclosure: Consultant for SCYNEXIS



# Bio: Michael Krychman, MD





# Vulvovaginal Candidiasis Background

75% of all women experience at least one episode of VVC during their lifetime<sup>1</sup>
45% of women will have 2–5 episodes of VVC<sup>2</sup>
10 million office visits per year for vaginal symptoms<sup>3</sup>
20–25% for Candida infections<sup>3</sup>
VVC caused by multiple Candida species

Candida albicans, Candida glabrata

Azoles Had been the only treatments FDA approved for VVC<sup>2</sup>

Majority of women prefer oral therapy to topical<sup>4</sup>



References: 1. Azie N, et al. Expert Opin Investig Drugs. 2020;29(9):893-900. 2. CDC. STD Treatment Guidelines 2015. 3. Anderson MR. JAMA. 2004;291(11):1368-1379. 4. Sobel JD. Women's Health, (1) 2: 253-261.



# VVC Physical Signs and Symptoms

#### Typical Signs<sup>1,2</sup>

- Perineal edema (swelling)
- Vulvovaginal erythema (redness)
- Fissures
- Excoriations (abrasions from scratching)
- · Abnormal vaginal discharge

#### Typical Symptoms<sup>1,3</sup>

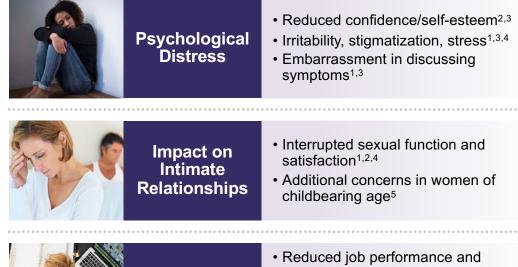
- Pruritus (itchy skin)
- Irritation
- Burning
- Soreness
- Dyspareunia (painful intercourse)
- Dysuria (painful urination)

These Signs and Symptoms Are Nonspecific, Making It Difficult to Differentiate from Other Causes of Vaginitis, Leading to Potential Subsequent Suboptimal Care<sup>2,3</sup>

1. Sobel JD. Am J Obstet Gynecol. 2016;214(1):15-21. 2. Marot-Leblond A, et al. J Clin Microbiol. 2009;47(12):3821-3825. 3. Gonçalves B, et al. Crit Rev Microbiol. 2016;42:905-927.



## VVC Negatively Affects Several Aspects of a Patient's Well-Being<sup>1</sup>



#### VVC Is Associated With a Significant Economic Burden



- Up to **\$14.4B** annually in high-income countries<sup>1</sup>
- \$4.7B in the United States<sup>2</sup>
- ~33 work hours lost per year<sup>1,3</sup>

Due to the widespread availability and use of OTC antifungals to treat VVC symptoms, the true economic impact of VVC is not well-defined<sup>1,4</sup>

#### OTC=over-the-counter.

References 1. Denning DW, et al. *Lancet Infect Dis.* 2018:e339-e347. 2. Denning DW, et al. *Lancet Infect Dis.* 2018:e339-e347 [supplementary appendix]. 3. Aballéa S, et al. *Health Qual Life Outcomes.* 2013;11:169. doi:10.1186/1477-7525-11-169. 4. Sobel JD. *Am J Obstet Gynecol.* 2016;214(1):15-21.



- Reduced job performan employment<sup>1,3</sup>
  - Lower ability to perform daily activities<sup>1,2</sup>
     Reduced appagement with their
  - Reduced engagement with their environment<sup>1,3</sup>

References: 1. Fukazawa EI, et al. Arch Gynecol Obstet. 2019;300(3):647-650. 2. Denning DW, et al. Lancet Infect Dis. 2018;18(11):e339-e347. doi:10.1016/S1473-3099(18)30103-8. 3. Adolfsson A, et al. Adv Sexual Med. 2017;7:1-19. doi:10.4236/asm.2017.71001. 4. Moshfeghy Z, et al. J Turk Ger Gynecol Assoc. 2020;21(2):90-96. 5. Zeng X, et al. Biomed Res Int. 2018;2018:9703754. doi:10.1155/2018/9703754.

Impact on

Productivity



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### Previously Only One Class of Medications Was FDA Approved for VVC<sup>1</sup>

Number of Drug Classes Indicated for Medical Conditions<sup>1-4</sup>



# Current Treatment Recommendations Issued by the CDC for the Treatment of Uncomplicated VVC Include Only the Azole Drug Class<sup>1</sup>

CDC = Centers for Disease Control and Prevention; UTI = urinary tract infection.

References: 1. Centers for Disease Control and Prevention. 2015 sexually transmitted diseases treatment guidelines. https://www.cdc.gov/std/tg2015/candidiasis.htm. Accessed February 4, 2021. 2. Gupta K, et al. Clin Infect Dis. 2011;52(5):e103-20. doi:10.1093/cid/ciq257. 3. American Heart Association. Know diabetes by Heart<sup>TM</sup>. https://knowdiabetesbyheart.org/wp-content/uploads/2020/04/ KDBH\_UnderstandingMeds\_bookletFinal.pdf. Accessed February 4, 2021. 4. American Heart Association. Types of blood pressure medications. https://knowdiabetesbyheart.org/wp-content/uploads/2020/ 04/KDBH\_UnderstandingMeds\_bookletFinal.pdf. Accessed February 4, 2021.



# Guidelines for Treatment of Uncomplicated & Complicated **VVC** – Prescription Regimens

Treatment Options for Uncomplicated and Complicated VVC Are the Same, the Only Difference is in the Duration of Use

Uncomplicated		Complicated* / Severe <sup>1-3</sup>	
Intravaginal Agen	nts <sup>1,2*†</sup>		
Butoconazole	2% cream 5 g intravaginally in a single application or	<b>Topical azole (Butoconazole or Terconazole)</b> for 10–14 days* or 7–14 days <sup>†</sup> or 5–7 days <sup>‡</sup> or	
	0.4% cream 5 g intravaginally daily for 7 days or		
Terconazole	0.8% cream 5 g intravaginally daily for 3 days or	Fluconazole 150 mg orally every 72 hours x	
	80 mg vaginal suppository, once daily for 3 days	2–3 doses* <sup>†‡</sup>	
Oral Agents <sup>1-3*†‡</sup>		*la chudeo De sumant M/O es Courses Curanteres es Nevelhicens es adidiceia	
Fluconazole	150 mg in a single dose	*Includes Recurrent VVC or Severe Symptoms or Nonalbicans candidiasis Women with diabetes, immunocompromising conditions (e.g., HIV infection), debilitation, or immunosuppressive therapy (e.g., corticosteroids)	

<sup>\*</sup> ACOG recommendation. <sup>†</sup>CDC recommendation. <sup>‡</sup>IDSA recommendation.

<sup>3.</sup> Pappas PG, et al. Clin Infect Dis. 2016;62(4):e1-e50. doi:10.1093/cid/civ933.



References: 1. American College of Obstetricians and Gynecologists. Vaginitis in nonpregnant patients. ACOG Practice Bulletin No. 215. Obstet Gynecol. 2020;135(1):e1-e17.

<sup>2.</sup> Centers for Disease Control and Prevention. 2015 sexually transmitted diseases treatment guidelines. https://www.cdc.gov/std/tg2015/candidiasis.htm. Accessed February 4, 2021.

### Limitations of Fluconazole Treatment in VVC

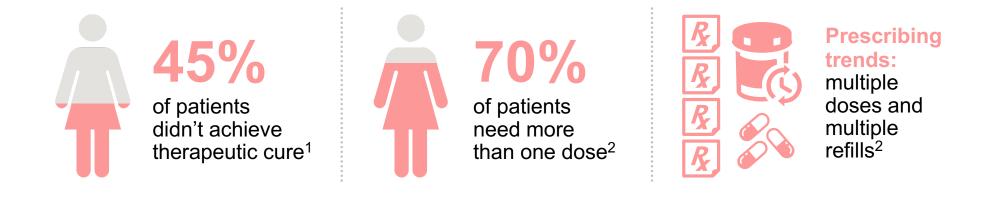
- Introduced in 1994 with single dose for VVC
- Fungistatic doesn't eradicate all Candida
- Only one oral therapy available, until now, for treatment of VVC, no other options
  - Women have a strong preference for oral therapy
  - Vaginal creams cause burning, irritation and leakage
- Resistance to Candida spp. is growing





# Limitations of Fluconazole Treatment in VVC (cont'd)

• Single-dose not effective in majority patients

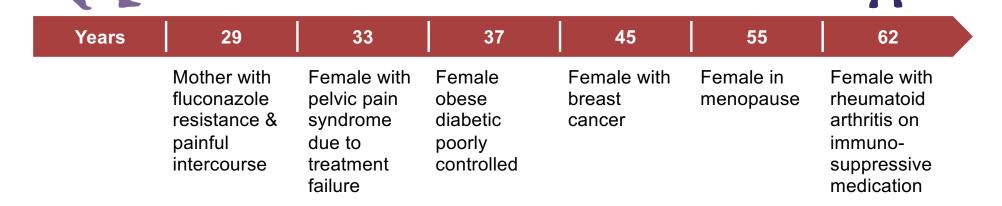


Previously, Patients Who Failed Fluconazole Had No Other Oral Alternatives... Only More Fluconazole

1. fluconazole prescribing information, 2. SCYNEXIS Proprietary Analysis of IBM Fluconazole 150mg Claim Data



### Real World Patient Cases – VVC Can Affect Women Over Their Lifetime



Many Women Want a NEW One-Day Oral Option



# Why BREXAFEMME<sup>®</sup>?

The first-ever oral alternative to fluconazole	Efficacy in <b>uncomplicated</b> and complicated VVC patients
Approximately <b>45%</b> of patients fail fluconazole <sup>2</sup>	
	Sustained Outcomes at <b>25</b> days <sup>1</sup>
Novel Mechanism of Action	
<ul> <li>Fungicidal<sup>1</sup> – Kills Candida spp.</li> </ul>	Simplifying course of care for patient
Activity against multiple species of Candida <sup>1</sup>	<ul><li>and healthcare professional</li><li>Patient friendly, less frustration and anxi</li></ul>

Patient friendly, less frustration and anxiety

BREXAFEMME<sup>®</sup> is indicated for the treatment of post-menarchal females with VVC BREXAFEMME® is contraindicated in pregnancy, the most frequent adverse events are gastrointestinal in nature

1. BREXAFEMME Prescribing Information. 2. Fluconazole Prescribing Information.



# BREXAFEMME<sup>®</sup> (ibrexafungerp tablets) Commercial Update

Christine R. Coyne, Chief Commercial Officer



# **VVC Prescription Market Historically Large and Growing** ~17M TRxs Annually 15.9M Fluconazole **1.0M** Terconazole & Other

Source: IQVIA Xponent TRx Monthly Data May 2020 - April 2021



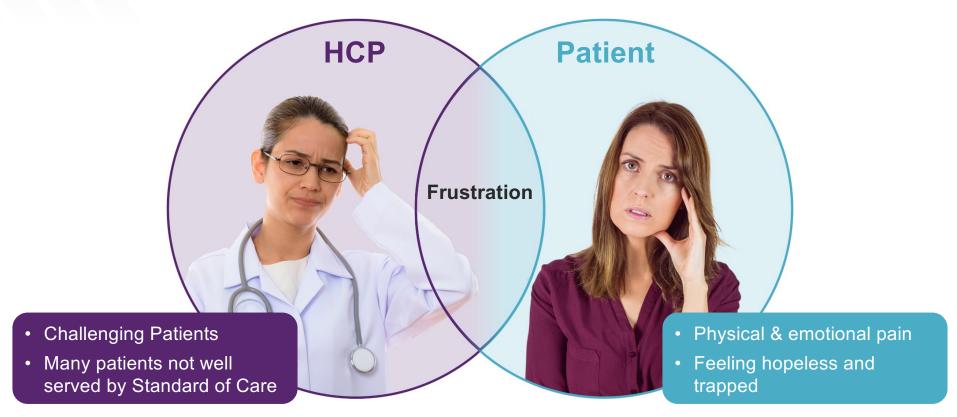
### **Most Patients Suffer from Multiple VVC Episodes**



\*Based on a study conducted in ~ 2,000 women in the United States and 5 European countries. Reference: Johnson SR, Griffiths H, Humberstone FJ et al. Attitudes and experience of women to common vaginal infections.... VVC: Vulvovaginal Candidiasis



### **Both HCPs & Patients Need New VVC Treatment Options**



Source: SCYNEXIS Market Research (data on file)



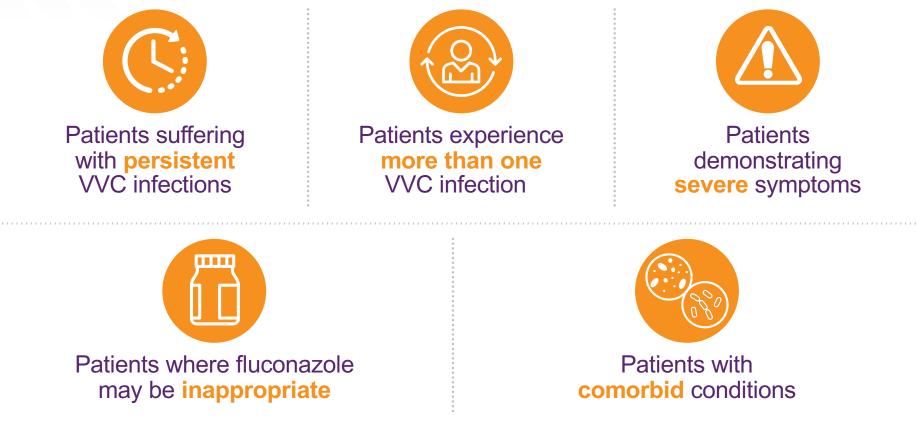
## **HCPs are Eager to Treat with BREXAFEMME®**



Source: SCYNEXIS Market Research with OBGYNs and NP/PAs (data on file)



# **HCPs Clearly See When to Use BREXAFEMME®**



Avoid use of BREXAFEMME® with strong or moderate CYP3A inducers

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#### **BREXAFEMME® – A "Modern-Day" Treatment for HCPs & Patients**

	Triterpenoid; novel class	R
NUC 75788-115-04 Pix Only 4 Tabless FOR ORAL USE ONLY USE THE THE THE THE THE THE THE THE THE TH	Fungicidal vs Candida spp.	900
BREXAFEMME* Ibrexofungerp tablets 150 mg per tablet	Half-life ~20 hours	X
Kiegs out of the reach of children. SCYNE ŘIS	Convenient 1 day dosing, with/without food	ÎEÛ

Safety & Efficacy	
Resolution of Signs and Symptoms	Durable and complete resolution of signs and symptoms
Activity vs. resistant & other <i>Candida</i> strains	Activity vs. resistant strains and broad-spectrum anti- <i>Candida</i> activity
Safety profile	Favorable safety profile: no evidence of QTc prolongation or hepatoxicity

BREXAFEMME<sup>®</sup> is indicated for the treatment of post-menarchal females with VVC BREXAFEMME<sup>®</sup> is contraindicated in pregnancy, the most frequent adverse events are gastrointestinal in nature

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# Well Positioned to Launch BREXAFEMME<sup>®</sup> Successfully

Early Indicators Are Positive

Strong Label

Sales Team Deployment Proceeding to Plan

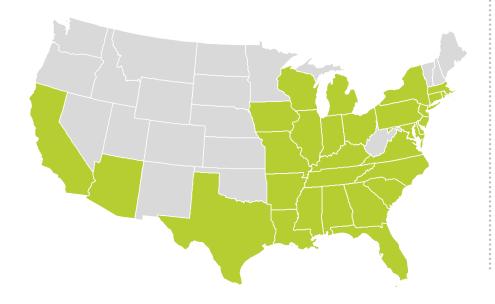
"Now Approved!" Campaign Ongoing, Transitioning to Full Branded Campaign

Payer Engagement, Pricing, and Contracting on Track

Retail Stocking, Co-Pay Card, PA Services, and Telemedicine Implementation

# Sales Team Ready to Drive Awareness and Adoption

#### VVC Market Geographically Concentrated



#### **Efficient Deployment**

- Primary call points are OBG, NP/PA, and PCP
- Sales team of 70
- Cover 89% of the market potential
- Trained for in-person and virtual sales calls
- · Sales team fully hired

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**HCP** Promotion

### **Now Approved BREXAFEMME®: Driving Awareness Pre-Launch**



#### **Digital HCP Brochure**

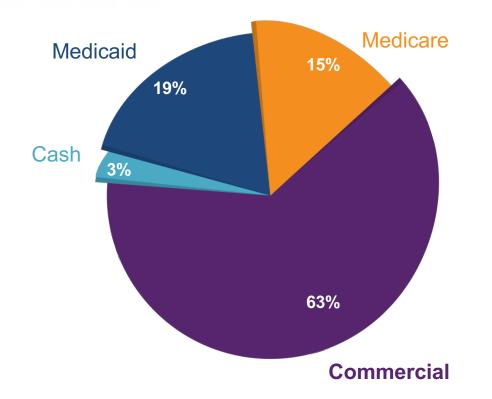
#### **Journal Ad in OBGYN News**

#### HCP Website: brexafemmeHCP.com



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### **Majority of VVC Patients Are Commercially Insured**



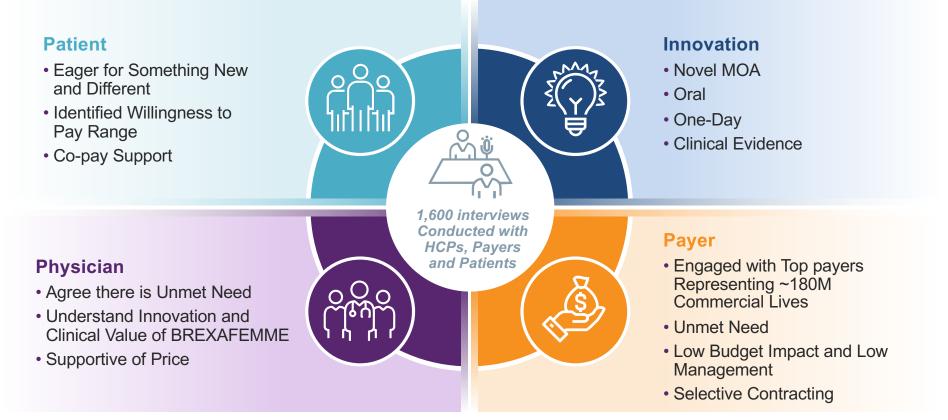
#### Payer Engagement: Strong Progress to Date

- "FDA Approved" Letter Sent to Payers
- Customer meetings with payers covering 70% of Commercial Lives
- 14 Payer P&T Reviews Scheduled
- Contracting Process Started for Multiple Target Accounts

Source: IQVIA Xponent Weekly Data 5/3/2019 - 4/30/2021; Rx only market



### BREXAFEMME<sup>®</sup> Value Confirmed \$475 WAC\* Supported by Key Stakeholders



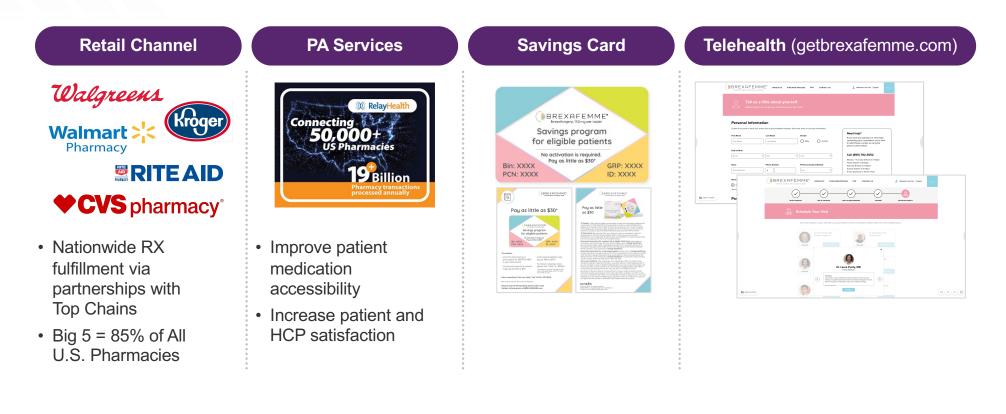
\*WAC: Wholesale Acquisition Cost

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**Price** 

Placement

# **Planned Ecosystem Supports Prescribing and Fulfillment**



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# **BREXAFEMME®** Commercialization Well On Track



• Payer P&T Reviews

# **BREXAFEMME<sup>®</sup> – the Time is Now!**

VVC prescription market large and growing

Lack of new oral treatment for more than 25 years

HCPs and patients both frustrated and eager to try newer, non-azole options

HCPs recognize the value of BREXAFEMME one-day oral dosing and novel non-azole MOA

Launch efforts on schedule

For more safety information, including full prescribing information, please visit www.brexafemme.com

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# **Financial Update**

Eric Francois, Chief Financial Officer



### **Balance Sheet is Strong**

#### Cash runway into 2023

Cash and cash equivalents of **\$92M** as of March 31, 2021; and \$30M of debt has been drawn in Q2

Access to additional \$30M of non-dilutive debt financing

Eligible to receive up to \$112M in development and commercial milestones, plus low double-digit royalties on net product sales from partner Hansoh in Greater China

Potential for additional ex-US business development opportunities

### **Strong Revenue Potential in VVC Alone**

VVC is a large addressable market and BREXAFEMME's positioning is attractive to capture a meaningful share

Based on a \$475 WAC and reasonable penetration assumptions, we anticipate a revenue opportunity in the U.S. of \$400-600M at peak

Potential upside scenarios to the base-case model

Traditional pharma gross-to-net assumptions over time with higher discounts at launch to factor-in our co-pay card program and insurance roll-up

No revenue guidance provided at this point but plan to guide for 2022

### **Preliminary Expense Considerations**

Total annual Operating Expense has historically been around \$50M, with majority dedicated to R&D

Total annual Operating Expense is expected to grow in 2021 due to increase in VVC-related SG&A costs and flatten to the new run rate in 2022

R&D expenses will continue to be opportunistically deployed towards value creating indications in the hospital setting, including the IV formulation

No expense guidance provided at this point but will be in 2022







# **Key Takeaways**



We have a differentiated product in a landscape badly lacking in innovation



We are ready for the near-term BREXAFEMME® launch and are confident in the commercial opportunity



We have adequate resources for the launch, with cash runway into 2023



We continue to maximize the full potential of ibrexafungerp for patients and shareholders

