

Bioscience applied to the skin.



#### **ZORYVE**<sup>®</sup> (roflumilast) Topical Foam, 0.3% FDA Approval Call December 18<sup>th</sup>, 2023

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This presentation and the accompanying oral presentation contain "forward-looking" statements that are based on our management's beliefs and assumptions and on information currently available to management. Forward-looking statements include all statements other than statements of historical fact contained in this presentation, including information concerning our current and future financial performance, business plans and objectives, current and future clinical and preclinical development activities, current and future commercialization activities (including payer coverage), timing and success of our ongoing and planned clinical trials and related data, the timing of announcements, updates and results of our clinical trials and related data, timing of submissions and our ability to obtain and maintain regulatory approval, the potential therapeutic benefits and economic value of our product candidates, competitive position, industry environment, and potential market opportunities.

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### Today's Speakers



Frank Watanabe President & CEO



#### **Patrick Burnett, MD, PhD, FAAD** Chief Medical Officer



**Todd Edwards** Chief Commercial Officer



#### Speakers & Agenda



Frank Watanabe

President and CEO

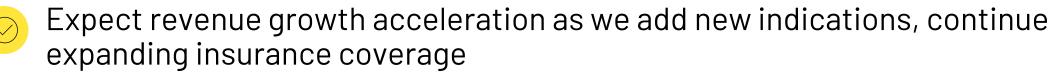
#### **Arcutis Overview**

ZORYVE Foam - Differentiated Clinical Profile Commercial Execution Conclusions Q&A



## Laying the Groundwork for Long-Term Growth

- $\bigcirc$
- FDA approval of ZORYVE<sup>®</sup> (roflumilast) topical foam, 0.3% in seborrheic dermatitis is second product approved in less than 18 months
- ⊘ ZORYVE® (roflumilast) cream 0.3% launch in plaque psoriasis gaining momentum
- FDA accepted sNDA and assigned PDUFA target date of July 7<sup>th</sup>, 2024 for roflumilast cream 0.15% in atopic dermatitis in adults and children down to age 6
- Additional indications and coverage may propel ~10X expansion in patient opportunity
- Strengthened capital position with Q3 capital raise and Huadong out-license

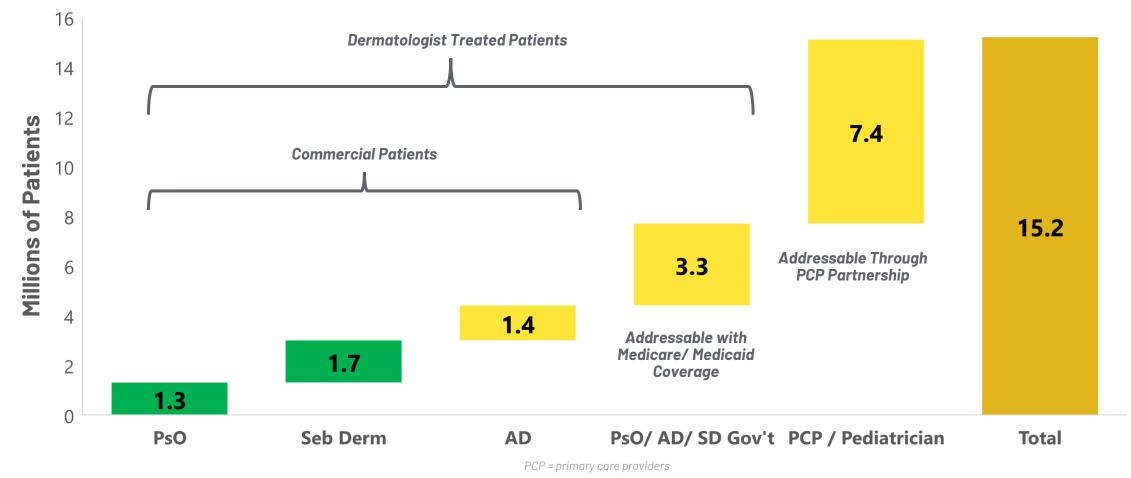


TRx = total prescriptions; GTN = gross-to-net; sNDA = supplemental New Drug Application



#### Topical Roflumilast: Total Patient Opportunity Potential to Grow ~10X

Total U.S. Topical Roflumilast Addressable Market





### ZORYVE Foam Positioned for Success

Unparalleled efficacy in treating seborrheic dermatitis

Dramatically simplifies treatment regimen

Excellent tolerability supports long-term use

Vehicle optimized to enhance compliance

Broad, high-quality coverage at launch

Profitable prescription growth



NDC 80610-430-60

**ZZORYVE** 

Rx Only 60 gran

For Topical Use Only

#### Speakers & Agenda



Patrick Burnett, MD, PhD, FAAD

Chief Medical Officer

#### Arcutis Overview

#### **ZORYVE Foam - Differentiated Clinical Profile**

**Commercial Execution** 

Conclusions

Q&A



## Seborrheic Dermatitis Overview

- Seb Derm is a form of eczema
- Associated with itchy, red patches covered by greasy, flaking scales<sup>1</sup>
- Occurs most often in areas of the body with oil-producing (sebaceous) glands:<sup>1,2</sup>
  - > Scalp
  - Face (especially on the nose, eyebrows, eyelids, and ears)
  - Upper chest
  - > Back

#### Itch: an important driver of quality-of-life burden

1. Clark et al. Am Fam Physician. 2015;91:185-190. 2. Tucker and Masood. Seborrheic Dermatitis. StatPearls Publishing; 2020.







Presentation designed for an investor audience.

## Introducing Zoryve (Roflumilast) Topical Foam, 0.3%

Novel excipients in foam allow drug delivery without skin barrier disruption Foam formulation ideally fills need for efficacious and convenient treatment option Steroid-free, once daily foam for use on all hair and skin types for any duration ZORYVE foam effectively clears seb derm and simplifies treatment



#### ZORYVE Foam: FDA-Approved Label Supports Broad Use

#### ZORY/E® (roflumilast) topical foam, 0.3%

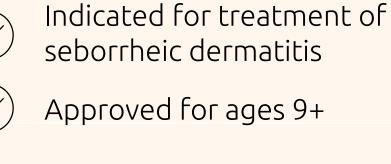
ZORYVE<sup>®</sup> (roflumilast) topical foam, 0.3% Initial U.S. Approval: 2011

----- DOSAGE AND ADMINISTRATION -----

- Apply once daily to affected areas. (2)
- For topical use only. Not for ophthalmic, oral, or intravaginal use. (2)

-----DOSAGE FORMS AND STRENGTHS ------Topical foam, 0.3%: 3 mg of roflumilast per gram in 60-gram pressurized cans. (3)

NDC 80610-430-60 ZORYVE (roflumilast) topical foam, 0.3% Rx Only | 60 gram For Topical Use Only



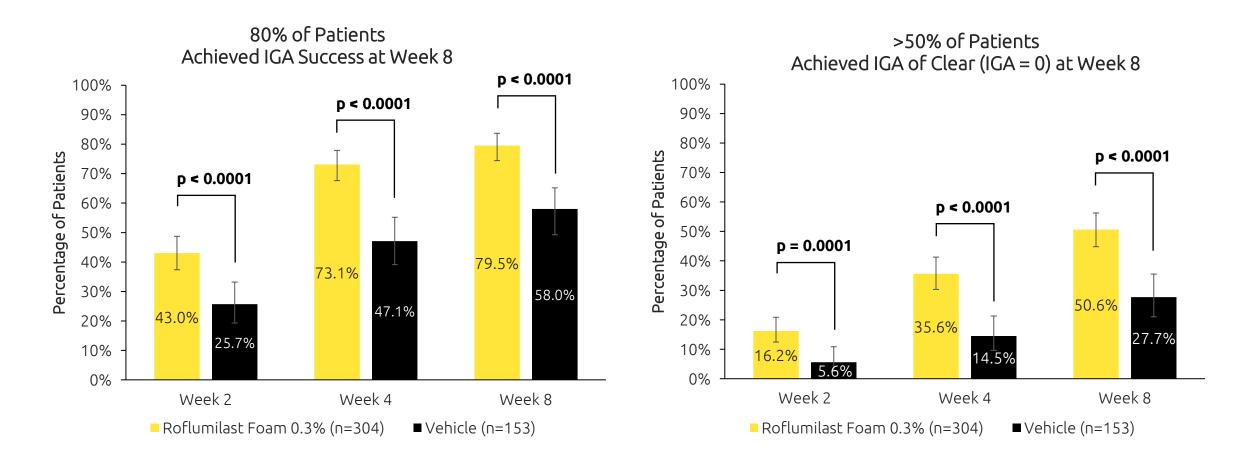
Itch improvement data included in label

Once daily use

No limitation on severity, body part, area, or duration



## ZORYVE Foam Positioned to Transform Treatment of Seborrheic Dermatitis



IGA Success = Clear or Almost Clear with at least a 2-grade improvement from baseline, Intent-to-treat population; missing scores imputed using multiple imputations



#### Robust Itch Response in Phase 3

>60% of Patients Achieved a WI-NRS Response at Week 8 100% p = 0.0001<sup>D</sup>ercentage of Patients 80% p = 0.000360% p = 0.000540% 62.8% 47.6% 20% 40.6% 32.7% 29.1% 15.5% 0% Week 2 Week 4 Week 8 Roflumilast Foam 0.3% (n=304) ■ Vehicle (n=153)

WI-NRS: Worst Itch Numeric Rating Scale; WI-NRS response = 4 point reduction in WI-NRS in patients with WI-NRS > 4 at baseline



### Significant and Rapid Clearance in Phase 3 Trial

**Baseline IGA=3** 



**Baseline IGA=3** 



Week 2 IGA=1



Week 2 IGA=0



Individual patient results may vary

Week 8 IGA=1



Week 8 IGA=0





Presentation designed for an investor audience.

### ZORYVE Foam Well-Tolerated in Phase 3

Outrice to (9/)	ZORYVE 0.3%	Vehicle	Overall
Subjects (%)	(n=304)	(n=153)	(n=457)
Subjects with any TEAE	70(23.0%)	33(21.6%)	103(22.5%)
Subjects with any Treatment-related TEAE	8(2.6%)	5(3.3%)	13(2.8%)
Subjects with any SAE	1(0.3%)	0	1(0.2%)
Treatment-related SAE	0	0	0
Subjects who discontinued Study Drug due to AE	2(0.7%)	3(2.0%)	5(1.1%)
Subjects who discontinued Study due to AE	2(0.7%)	3(2.0%)	5(1.1%)

AE: adverse event; SAE: serious adverse event; TEAE: treatment-emergent adverse event



## Most Common Treatment Emergent Adverse Events >1.0% in Any Group

Preferred Term	<b>ZORYVE 0.3%</b> (n=304)	<b>Vehicle</b> (n=153)	<b>Overall</b> (n=457)
COVID-19	11(3.6%)	5(3.3%)	16(3.5%)
Urinary tract infection	4(1.3%)	3(2.0%)	7(1.5%)
Nasopharyngitis	4(1.3%)	1(0.7%)	5(1.1%)
Nausea*	5(1.6%)	0	5(1.1%)
Application site pain	1(0.3%)	3(2.0%)	4(0.9%)
Sinusitis	0	2(1.3%)	2(0.4%)

\*All graded as mild



#### Speakers & Agenda



**Todd Edwards** Chief Commercial Officer

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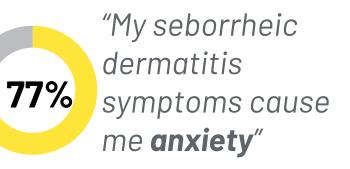
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#### Living With Seborrheic Dermatitis Significantly Impacts Multiple Areas of Life





Say living with seborrheic dermatitis **negatively impacts their social life and social interactions** 

Have ever **missed work** because of their seborrheic dermatitis symptoms

A 2022 Harris Poll nationwide survey of 300 patients with seborrheic dermatitis (16% mild, 71% moderate, 13% severe) and a survey of 601 HCPs in the dermatology community

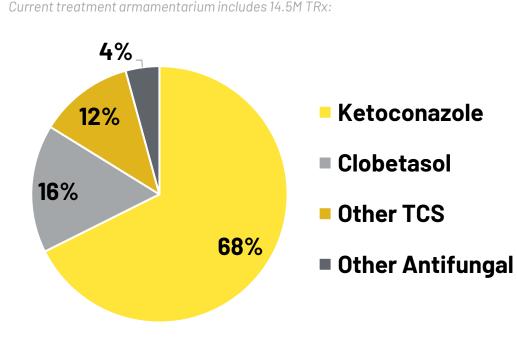


Yes

47%

# Current Standard of Care is Largely Generic Topical Steroids and Ketoconazole

Anti-fungal treatments, primarily ketoconazole | Topical steroids, primarily clobetasol 0.5%

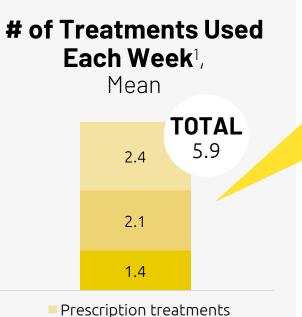


- Ketoconazole is mostly a scalp product (e.g., shampoo) used for maintenance
  - Topical steroids address inflammation and are used to manage flares
  - Patients using on average 6 different treatments weekly to manage seb derm

Data source: 2022 IQVIA Xponent data



#### Patients Dissatisfied With Complex and Onerous Treatment Regimens



OTC treatments

Alternative treatments

### **9** in **10** AGREE<sup>1</sup>

"I would be more likely to stick with a treatment plan if it meant using fewer treatments."

#### Patients ready for new options



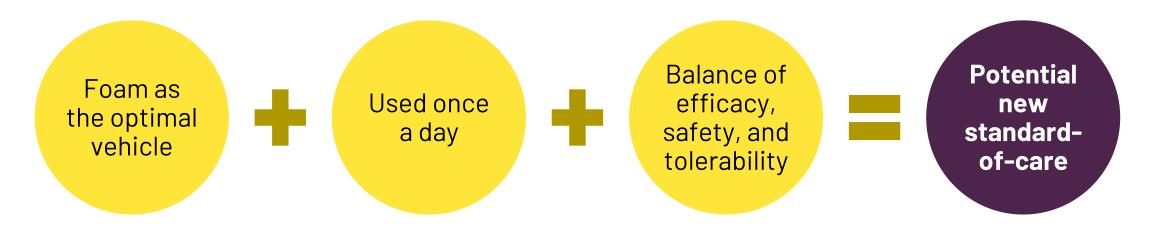
"I am interested in trying new treatment options."

<sup>1</sup>Harris Poll Seborrheic Dermatitis Survey (n>600 HCPs, n=300 patients), OTC = over the counter





# ZORYVE Offers an Unparalleled Value Proposition in Seborrheic Dermatitis



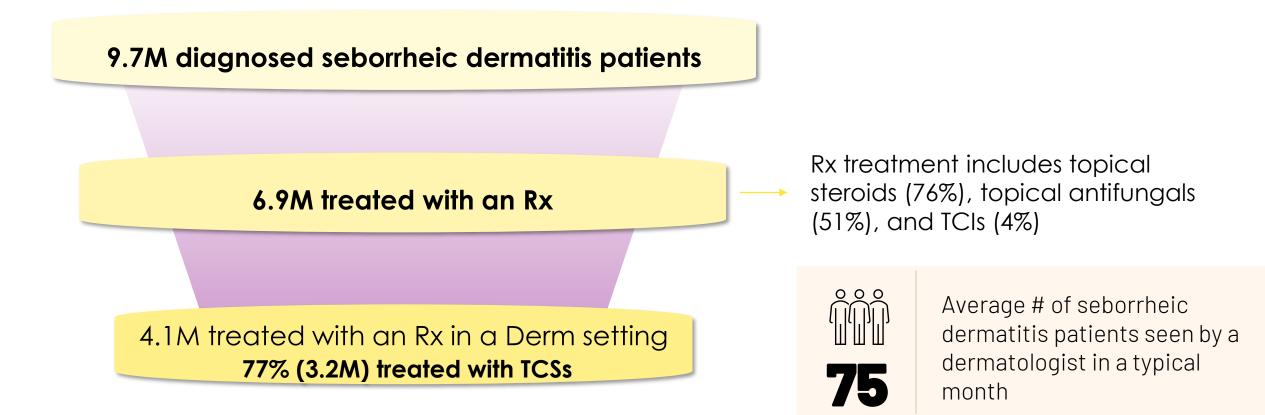
#### In STRATUM:

- 72% of patients had seborrheic dermatitis on >1 location on their body (e.g., face and scalp)
- 62% of patients had facial seborrheic dermatitis involvement with 9% eyelid involvement

One foam. Once a day. Anywhere.



## Patients Being Treated with Topical Steroids are the First Target Population for Launch



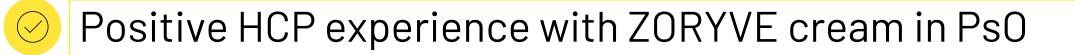
1. 2020 DRG Executive Insights; 2. Johnson MLT. National Health Survey 1978; 3. IQVIA seborrheic dermatitis LAAD Data March 2021; 4. Collective Acumen Demand Study 2019; prevalent patients uniformly available each month

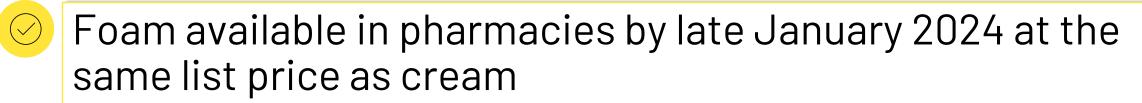


## Ready to Launch ZORYVE Foam in Seb Derm

Full field team in place and ready to begin promotion







Two national PBMs already covering foam



#### Speakers & Agenda



Frank Watanabe

President and CEO

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**Q&A** 



#### Thank You



Frank Watanabe President & CEO



**Todd Edwards** Chief Commercial Officer



**Patrick Burnett, MD, PhD, FAAD** Chief Medical Officer

Arcutis



**John Smither** Chief Financial Officer (interim)

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