#### INTEGUMENT -1 & -2 Phase 3 Atopic Dermatitis Topline Data Presentation

December 12, 2022



Bioscience applied to the skin.





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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 commercialization activities, 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, our ability to obtain and maintain regulatory approvals, the potential therapeutic benefits and economic value of our product candidates, competitive position, industry environment, and potential market opportunities.

Forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors including, but not limited to, those related to the success, cost and timing of our product candidate development activities and ongoing and planned clinical trials; our plans to develop and commercialize targeted therapeutics, including our lead product candidates roflumilast cream and roflumilast foam; the progress of patient enrollment and dosing in our clinical trials; the ability of our product candidates to achieve applicable endpoints in the clinical trials; the safety profile of our product candidates; the potential for data from our clinical trials to support a marketing application, as well as the timing of these events; our ability to obtain funding for our operations, development and commercialization of our product candidates; the timing of and our ability to obtain and maintain regulatory approvals; the rate and degree of market acceptance and clinical utility of our product candidates; the size and growth potential of the markets for our product candidates, and our ability to serve those markets; our commercialization, marketing and manufacturing capabilities and strategy; current

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For further information with respect to Arcutis, we refer you to our most recent annual report on Form 10-K, as amended, and in our two most recent quarterly report on Form 10-Q, filed with the SEC. In addition, we are subject to the information and reporting requirements of the Securities Exchange Act of 1934 and, accordingly, we file periodic reports, current reports, proxy statements and other information with the SEC. These periodic reports, current reports, proxy statements and other information are available for review at the SEC's website at http://www.sec.gov.

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### Today's Speakers



Frank Watanabe President & CEO



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



#### Lawrence Eichenfield, MD

Chief of Pediatric & Adolescent Dermatology at Rady Children's Hospital; Professor of Dermatology & Pediatrics at UC San Diego School of Medicine



Ken Lock Chief Commercial Officer



#### Speakers & Agenda



Frank Watanabe President and CEO

#### **Arcutis Overview**

Clinical Results Clinically Contextualizing Results Commercial Opportunity Q&A



## 2022: A Transformational Year for Arcutis



Topical roflumilast offers a differentiated clinical profile, with positive efficacy results in three distinct disease areas, each with >2 million topically treated patients today in U.S. Dermatology offices



Continued clinical trial execution with topline success in three pivotal Phase 3 development programs



We are very excited about the clinical profile and the significant opportunity for roflumilast cream in atopic dermatitis



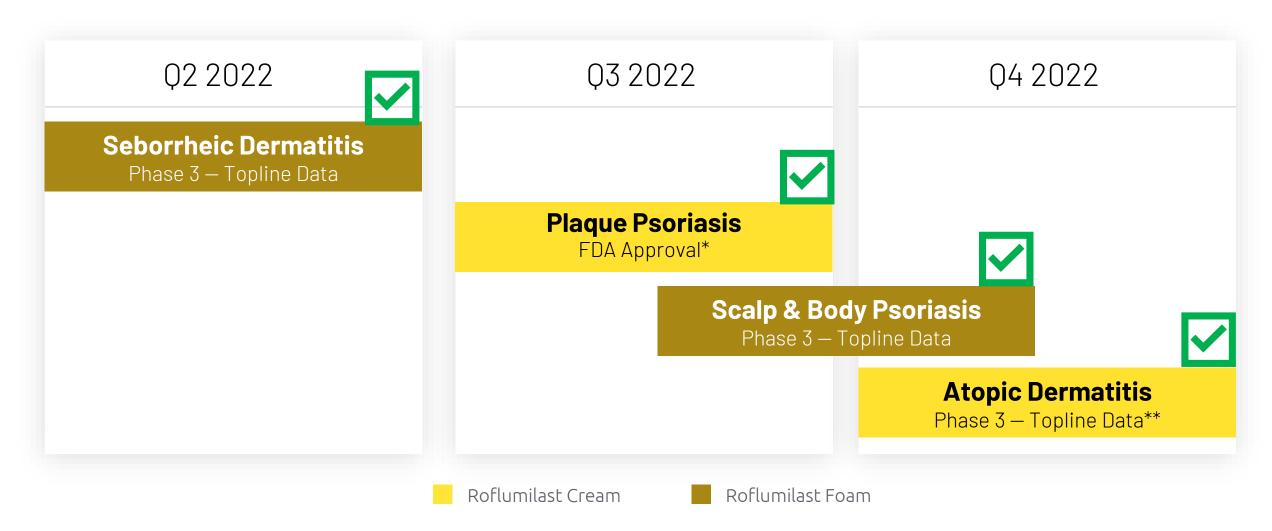
Launch of ZORYVE® (roflumilast) cream 0.3% in plaque psoriasis continues to build with early formulary coverage wins validating our pricing and access strategy



### Broad and Deep Pipeline Continues to Progress

	Formulation	Preclinical	Phase 1	Phase 2	Phase 3	NDA Review	Approved	Commercial Rights
<b>ZORYVE</b> (roflumilast cream)	Plaque Psoria	asis						Worldwide
	Atopic Derm	atitis (0.15% str	ength)					Worldwide
<b>Roflumilast Foam</b> (ARQ-154)	Seborrheic D	)ermatitis						Worldwide
	Scalp Psoria	sis						Worldwide
<b>ARQ-252</b> Cream (JAK1 Inhibitor)	Hand Eczema	а						U.S., EU, Japan, Canada
	Vitiligo							U.S., EU, Japan, Canada
<b>ARQ-255</b> Suspension (JAK1 Inhibitor)	Alopecia Are	ata						U.S., EU, Japan, Canada
<b>ARQ-234</b> (CD200R)	Atopic Derm	atitis						Worldwide
Other Preclinical Projects	Acne, Palmoplantar Psoriasis, Nail Psoriasis, Rosacea							

### Arcutis Continues to Execute Without Fail



\*Approved by the FDA for topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older; \*\* Phase 3 topline for INTEGUMENT-1 and -2 with 0.15% strength; INTEGUMENT-PED expected in 2023



#### Topical Roflumilast Opportunity: ~7 million Dermatologist-Treated Patients in the U.S. Alone

Prevalence	<b>Psoriasis</b> ~9M	Atopic Dermatitis ~26M	Seborrheic Dermatitis ~10M	Significant incremental opportunity	
Topical Rx treated in Derm Setting	<b>2.0M</b> (mild-moderate-severe)	<b>2.6M</b> (mild-to-moderate)	<b>2.2M</b> (moderate-to-severe)	to access the millions of U.S. patients Rx treated by other specialties (e.g., PCPs or pediatricians) via partnership	
Topically treated outside Derm	<b>~1.2M</b> (mild-moderate-severe)	<b>∼4.1M</b> (mild-to-moderate)	<b>~1.0M</b> (moderate-to-severe)		

Rx = Prescription; PCP = primary care physician

#### Speakers & Agenda



Patrick Burnett, MD, PhD, FAAD Chief Medical Officer

#### Arcutis Overview

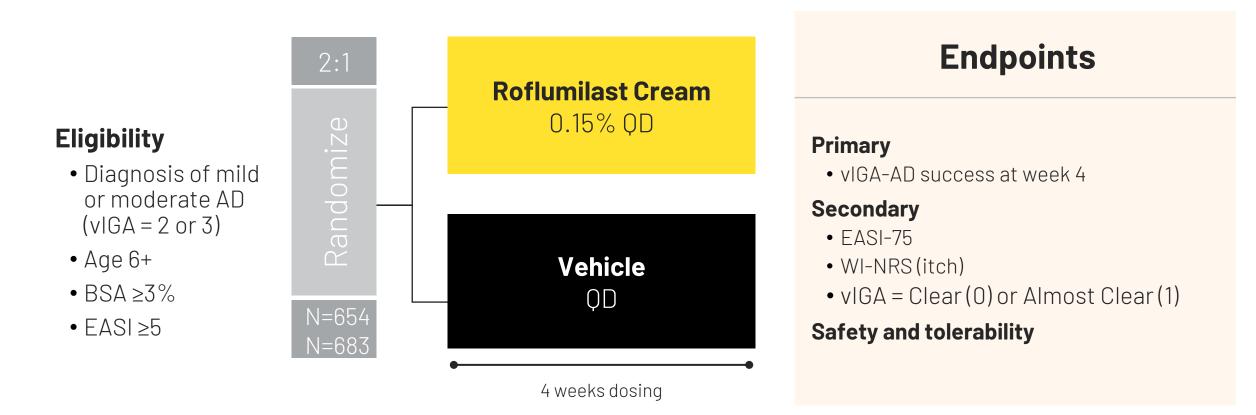
#### **Clinical Results**

Clinically Contextualizing Results Commercial Opportunity Q&A



## INTEGUMENT-1& -2 Phase 3 Atopic Derm Studies

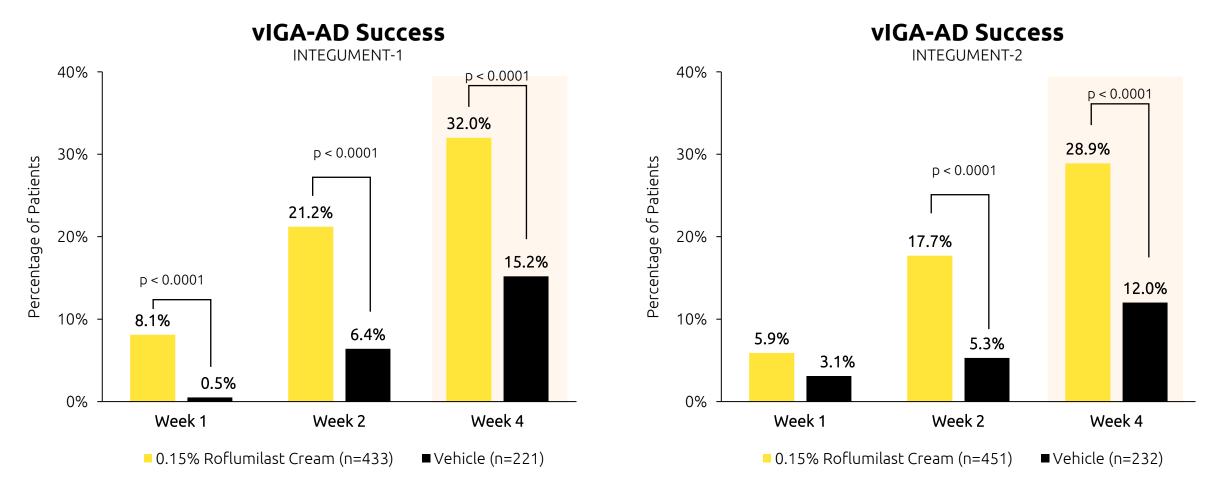
Randomized, Double-blind, Vehicle-controlled, Multicenter Studies (Two identical, parallel Phase 3 studies)



vIGA- Success = Clear or Almost Clear with at least a 2-grade improvement from baseline; BSA = body surface area; EASI = eczema area severity index; WI-NRS: Worst Itch Numeric Rating Scale; QD = once a day dosing



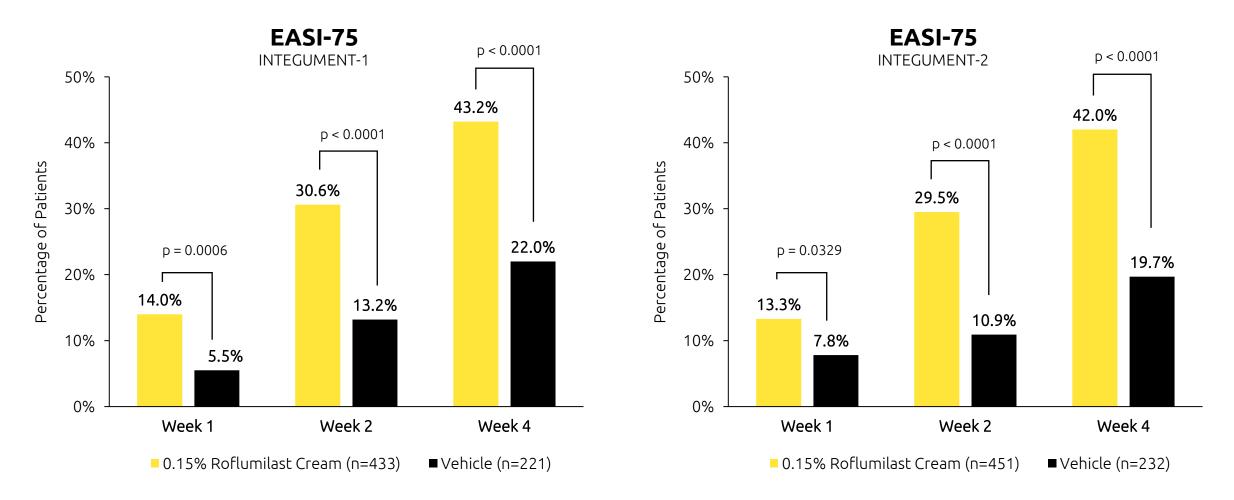
#### Rapid, Robust Efficacy on IGA Success Observed in Both Phase 3 Atopic Dermatitis Trials



vIGA = Validated Investigator's Global Assessment; IGA Success = Clear or Almost Clear with at least a 2-grade improvement from baseline; ITT Population Statistical analysis based on multiple imputation



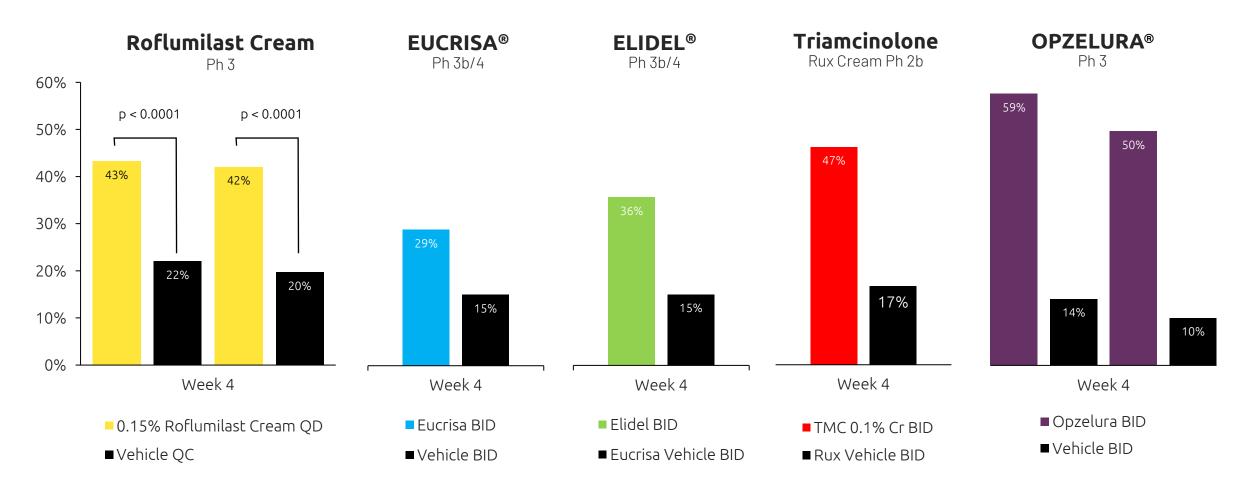
#### Over 40% of Patients Achieved EASI-75 at Week 4



EASI -75 = 75% improvement from baseline



# Roflumilast Cream vs. Current Approved Treatments in Atopic Dermatitis [EASI-75 Responders]



Note: The results of this retrospective post-hoc cross-trial comparison may not be directly comparable. Differences exist between trial designs and subject characteristics, and caution should be exercised when comparing data across unrelated studies. QD = once a day dosing; BID = twice a day dosing; EUCRISA = crisaborole; ELIDEL = pimecrolimus; OPZELURA = ruxolitinib cream



#### Robust and Rapid Itch Response Observed in Phase 3

WI-NRS Success WI-NRS Success **INTEGUMENT-2 INTEGUMENT-1** p = 0.008940% 40% p = 0.001433.6% 30.2% p = 0.0016p = 0.001530% 30% Percentage of Patients Percentage of Patients 23.8% 22.3% 20.7% 20% 20% p = 0.0020p = 0.015912.4% 11.2% 9.8% 9.5% 10% 10% 6.9% 2.3% 1.6% 0% 0% Week 1 Week 2 Week 4 Week 1 Week 2 Week 4 0.15% Roflumilast Cream (n=278) ■ Vehicle (n=135) 0.15% Roflumilast Cream (n=264) ■ Vehicle (n=136)

WI-NRS: Worst Itch Numeric Rating Scale (only measured in the 12+ year old population in the study); WI-NRS response = 4 point reduction in WI-NRS in patients with WI-NRS >= 4 at baseline



#### Roflumilast Cream Was Well-Tolerated in Phase 3

	INTEGUN	1ENT-1	INTEGUMENT-2		
Subjects (%)	<b>Roflumilast</b> 0.15% (n=433)	<b>Vehicle</b> (n=221)	Roflumilast 0.15% (n=452)	<b>Vehicle</b> (n=230)	
Subjects with any TEAE	92(21.2%)	35(15.8%)	102(22.6%)	30(13.0%)	
Subjects with any Treatment-Related TEAE	27(6.2%)	4(1.8%)	26(5.8%)	8(3.5%)	
Subjects with any SAE	4(0.9%)	0	4(0.9%)	0	
Subjects with treatment-related SAE	0	0	2(0.4%)	0	
Subjects who discontinued Study due to AE	6(1.4%)	3(1.4%)	8(1.8%)	2(0.9%)	

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



# Most Common Treatment-Emergent Adverse Events (≥1.0% in Any Group)

	INTEGUN	1ENT-1	INTEGUMENT-2		
Preferred Term	<b>Roflumilast</b> <b>0.15%</b> (n=433)	<b>Vehicle</b> (n=221)	<b>Roflumilast</b> 0.15% (n=452)	<b>Vehicle</b> (n=230)	
Headache	10(2.3%)	3(1.4%)	16(3.5%)	1(0.4%)	
Nausea	8(1.8%)	2(0.9%)	9(2.0%)	0	
Application site pain	9(2.1%)	1(0.5%)	4(0.9%)	2(0.9%)	
Nasopharyngitis	8(1.8%)	2(0.9%)	0	1(0.4%)	
COVID-19	4(0.9%)	5(2.3%)	4(0.9%)	3(1.3%)	
Diarrhea	6(1.4%)	0	7(1.5%)	2(0.9%)	
Vomiting	5(1.2%)	0	8(1.8%)	2(0.9%)	
Upper respiratory tract infection	0	1(0.5%)	5(1.1%)	1(0.4%)	



## Next Steps for Roflumilast Cream in Atopic Dermatitis

Expect to submit sNDA for atopic dermatitis using INTEGUMENT-1& -2 in the second half of 2023

Plan to seek potential approval for atopic dermatitis in individuals aged 6+ with 10-month FDA review timeline [~90% of U.S. Dermatologist-treated AD opportunity]

Topline data from INTEGUMENT-PED expected in 2023

Submit sNDA for 2-5 year olds after potential approval of 6+ atopic dermatitis indication [~10% of U.S. Derm opportunity & ~20% of broader U.S. topical AD opportunity]



#### Speakers & Agenda



Lawrence Eichenfield, MD

Chief of Pediatric & Adolescent Dermatology at Rady Children's Hospital; Professor of Dermatology & Pediatrics at UC San Diego School of Medicine Arcutis Overview Clinical Results

#### **Clinically Contextualizing Results**

Commercial Opportunity Q&A





## Atopic Dermatitis – Disease Background



- Chronic, genetically predisposed, inflammatory skin disease
- Presents across the lifespan
  - Childhood disease common, but high prevalence throughout life (12-15% children, 7% adults)
  - Adult onset underappreciated, accounts for up to 25% of adult cases
- Altered skin barrier function and neuroimmune dysregulation
- Itch (pruritus) most burdensome symptom
- Significant unmet therapeutic needs







### Atopic Dermatitis – Clinical Presentation of Disease



## Therapeutic Considerations

- Topical corticosteroids
  - Limitation on duration of use and location
  - Risks of systemic absorption and polypharmacy
  - Topical steroid withdrawal (TSW) and flaring of disease
- Calcineurin inhibitors and crisaborole
  - Twice daily application
  - Tolerability (stinging and burning)
- Topical JAK inhibitors
  - Label- black box warning; prohibits first line use or use with biologics
  - Concern for systemic absorption and tolerability
  - Twice daily application



## Optimizing Topical AD Treatment: What do Patients Need?

- Once-a-day
- Not a steroid
- Rapid response
  - Itch and endpoints of EASI-75 and IGA
  - Itch is early indicator of clinical response
- Tolerability- may be used on all body locations and sensitive skin
- Safe for chronic use
  - Long-term disease control is the goal
- Formulation
  - Well-tolerated, without sensitizers or associated allergic contact dermatitis



#### Speakers & Agenda



Ken Lock Chief Commercial Officer Arcutis Overview Clinical Results Clinically Contextualizing Results

**Commercial Opportunity** 

Q&A



# Atopic Dermatitis: Compelling Opportunity for Roflumilast Cream



#### Very large, established market

- ~26 million individuals in U.S. affected
- ~26 million total prescriptions in U.S.<sup>1</sup> (~2x of Psoriasis)
- 12% prevalence in children<sup>2</sup> → need for safe/effective therapy



#### Significant unmet need

for safe, effective non-steroidal therapy suitable for chronic use

#### **Roflumilast Cream**

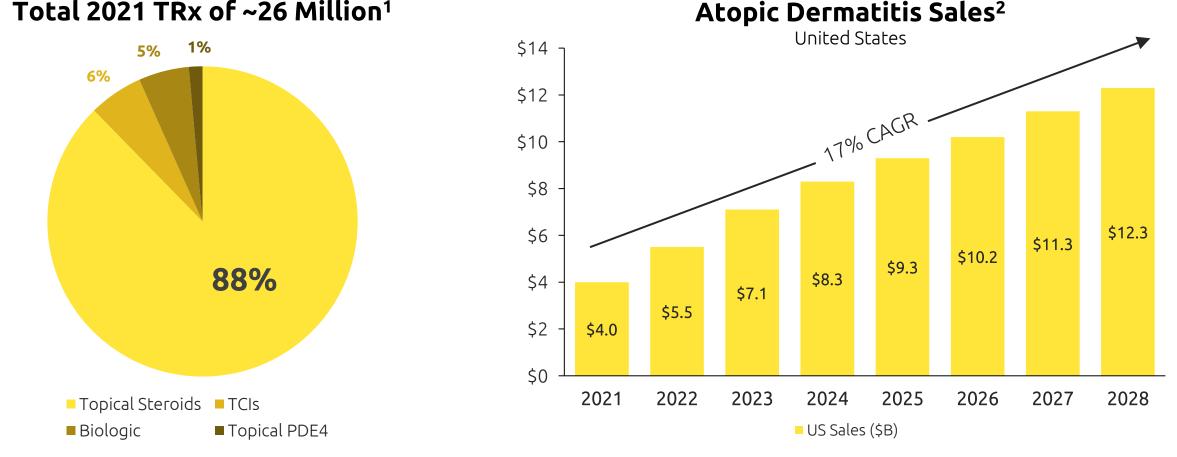
Atopic Dermatitis Profile

Closely aligned with needs of:

- 1. Physicians
- 2. Patients
- 3. Parents
- 4. Payors

<sup>1</sup>Source: IQVIA FY 2021; <sup>2</sup>Silverberg,JI, Dermatol Clin 35 (2017) 283-289

Topical Steroids Remain Standard of Care in Underserved, Rapidly Growing AD Market Segment



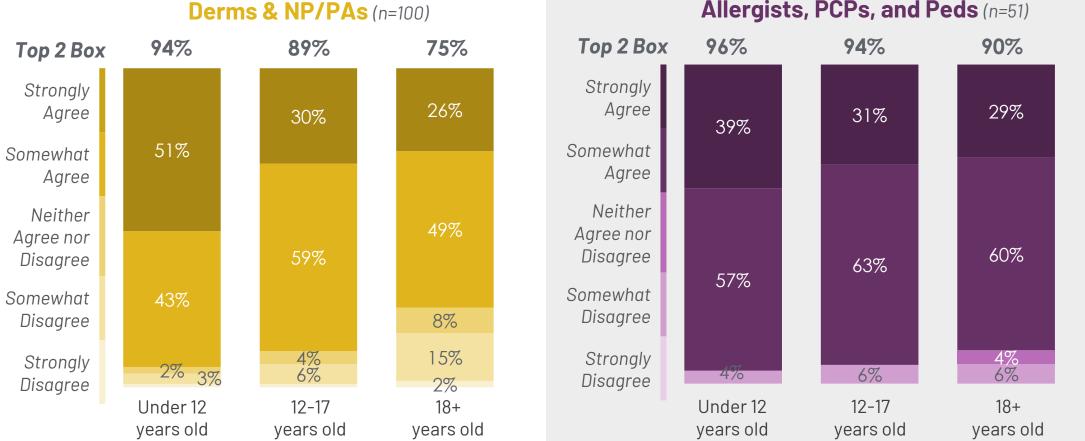
#### Total 2021 TRx of ~26 Million<sup>1</sup>

<sup>1</sup>Source: IQVIA [Biologic = Dupixent; PDE4 = Eucrisa]; TCI = topical calcineurin inhibitor

<sup>2</sup>Source: Evaluate Pharma; CAGR = compound annual growth rate

#### High Unmet Need for New Topical Therapies, Especially for Pediatric Patients

**Unmet need** with topical therapies for atopic dermatitis<sup>1</sup>



Derms & NP/PAs (n=100)

<sup>1</sup>Nov 2022 Quant Survey, The Link Group; NP = nurse practitioner; PA = physician assistant; PCP = primary care physician



## Not All PDE4 Inhibitors (PDE4i) Are Created Equal

## PDE4 inhibition is a validated mechanism in Atopic Dermatitis

- Safety profile well understood
- Chronic use

## Roflumilast cream is the next generation topical PDE4i

- 25X to 300X more potent than other approved PDE4 inhibitors<sup>2</sup>
- Formulation leverages our proprietary HydroARQ Technology<sup>TM</sup>

for treating AD<sup>1</sup>

Derms & NP/PA
Allergists, PCPs, Peds

I would be interested in a new and

**improved PDE4** inhibitor topical

<sup>1</sup>Nov 2022 Quant Survey, The Link Group [Derms & NP/PA n =100, Non-Derm n-51], those survey responses that either Strongly Agree or Somewhat Agree; <sup>2</sup>Dong C, et al. J Pharmacol Exp Ther 2016;358:413-422. NP = nurse practitioner; PA = physician assistant; PCP = primary care physician; PDE4 = phosphodiesterase-4



# The Importance of Vehicle in AD Treatment – Restoring the Skin Barrier

In AD, the skin barrier function is compromised, and moisture is lost from skin



#### Optimized vehicle formulation may promote treatment adherence and therapeutic effect

PEG = polyethylene glycol



#### Thank You



President and CEO



Frank Watanabe Lawrence Eichenfield, MD



Patrick Burnett, MD, PhD, FAAD Chief Medical Officer



Ken Lock Chief Commercial Officer

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