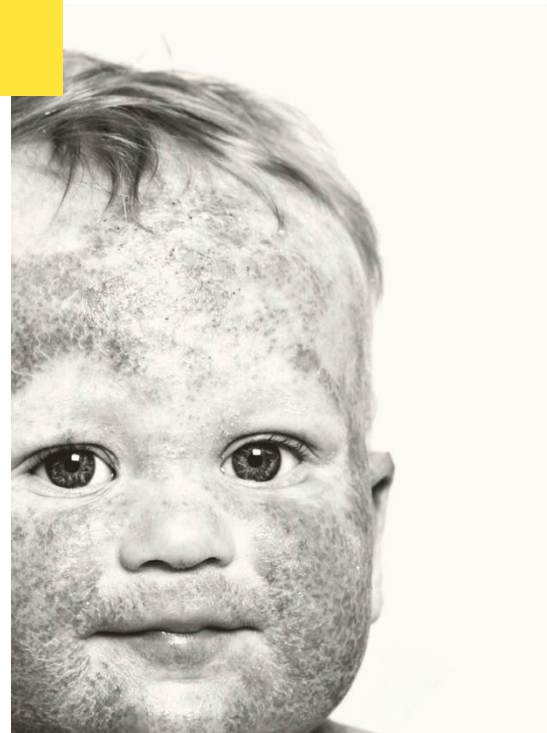
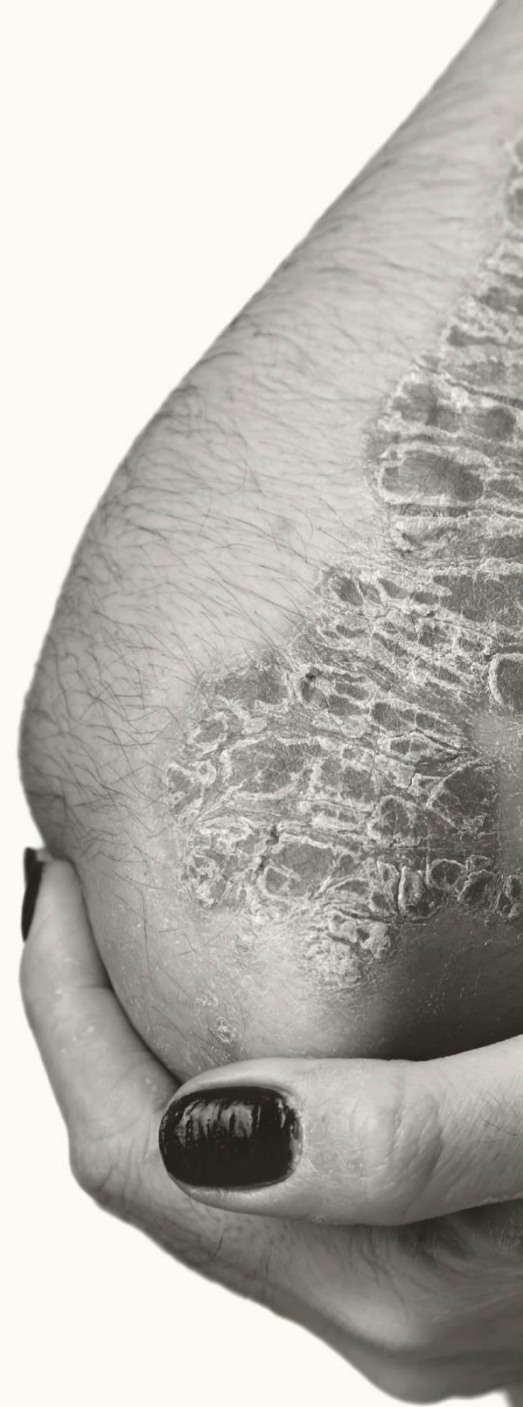


# Atopic Dermatitis Program Update

September 19, 2023



**ARCUTIS**  
BIOTHERAPEUTICS

Bioscience applied to the skin.

# Legal Disclaimers

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.

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 submissions 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 and future agreements with third parties in connection with the commercialization of our product candidates; the timing and our ability to obtain quality payer coverage; our expectations regarding our ability to obtain and maintain intellectual property protection; our dependence on third party manufacturers; the success of competing therapies that are or may become available; our ability to attract and retain key scientific or management personnel; our ability to identify additional product candidates with significant commercial potential consistent with our commercial objectives; and our estimates regarding expenses, future revenue, capital requirements and needs for additional financing.

Moreover, we operate in a very competitive and rapidly changing environment, and new risks may emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed herein may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

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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 our 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

# Speakers & Agenda



Frank Watanabe

President and CEO

## Arcutis Overview

INTEGUMENT-PED Clinical Results

INTEGUMENT-OLE Results

Contextualizing Data within AD Landscape

Q&A



# 2023: A Year of Execution



Launch of ZORYVE® (roflumilast) cream 0.3% in plaque psoriasis continues to strengthen with positive real-world experience and formulary coverage wins validating our pricing and access strategy



INTEGUMENT-PED represents fifth successful pivotal Phase 3 trial for topical roflumilast in the last 18 months

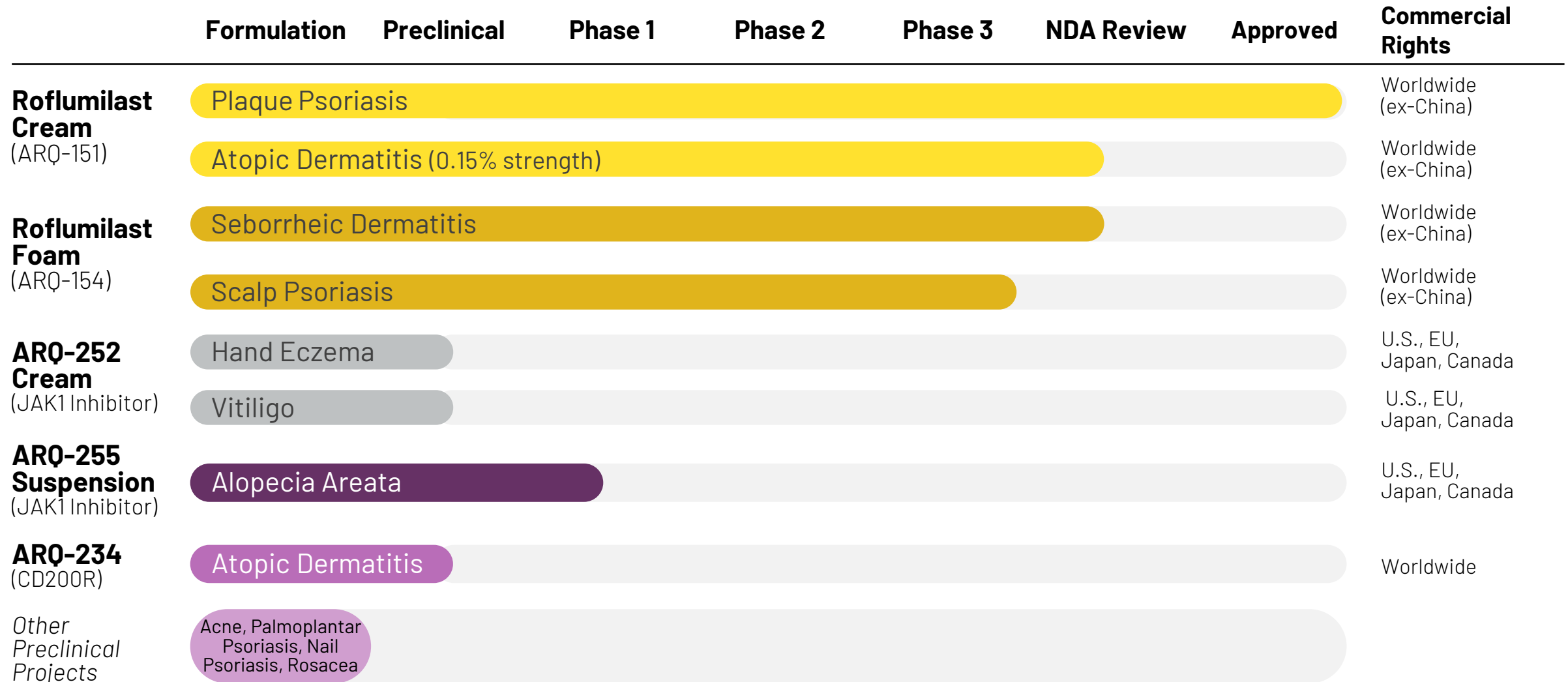


sNDA submission for roflumilast cream in atopic dermatitis in ages 6 and above sets up two potential launches in 2024



Topical roflumilast represents truly unique, de-risked 4-in-1 asset targeting a 13 million patient market in the U.S. alone

# Broad and Deep Pipeline Continues to Progress





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

	<b>Psoriasis</b>	<b>Atopic Dermatitis</b>	<b>Seborrheic Dermatitis</b>
Prevalence	~9M	~26M	~10M
Topical Rx treated in Derm Setting	<b>2.0M</b> <i>(mild-moderate-severe)</i>	<b>2.6M</b> <i>(mild-to-moderate)</i>	<b>2.2M</b> <i>(moderate-to-severe)</i>
Topically treated outside Derm	~1.2M <i>(mild-moderate-severe)</i>	~4.1M <i>(mild-to-moderate)</i>	~1.0M <i>(moderate-to-severe)</i>

**Significant incremental opportunity**

to access the millions of U.S. patients Rx treated by other specialties (e.g., PCPs or pediatricians) via potential commercial collaboration

*Rx = Prescription; PCP = primary care physician*

# Regulatory Steps for Roflumilast Cream in AD

sNDA submitted for roflumilast cream 0.15% for atopic dermatitis in individuals aged 6+ earlier this month

↳ Expect a 10-month FDA review timeline, with potential for launch in Q3 2024

Successful topline data from INTEGUMENT-PED for roflumilast cream 0.05% in 2-5 year-olds today

↳ Expect to submit sNDA for 2-5 year-olds after potential approval of atopic dermatitis indication for ages 6+



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MD, PhD, FAAD

Chief Medical Officer

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# Roflumilast Cream Has Shown Optimal Profile for AD

## **Rapid and robust efficacy across multiple endpoints**

- Efficacy comparable with current standard-of-care
- Improvement as early as 1 week
- Rapid improvement in itch, as early as 24 hours after first application

## **Favorable safety and tolerability**

- Especially important in AD due to high prevalence in children
- Can be used on any area of the body, including sensitive areas (e.g., face, eyelids, groin)
- Formulation doesn't disrupt the skin barrier and doesn't contain sensitizing or irritating ingredients

## **Profile supports long-term use: chronic medication for a chronic disease**

- Efficacy continues to increase post initial 4-week period
- Able to use less frequent maintenance dosing to maintain response

## **Efficacy and safety/tolerability consistent across ages**

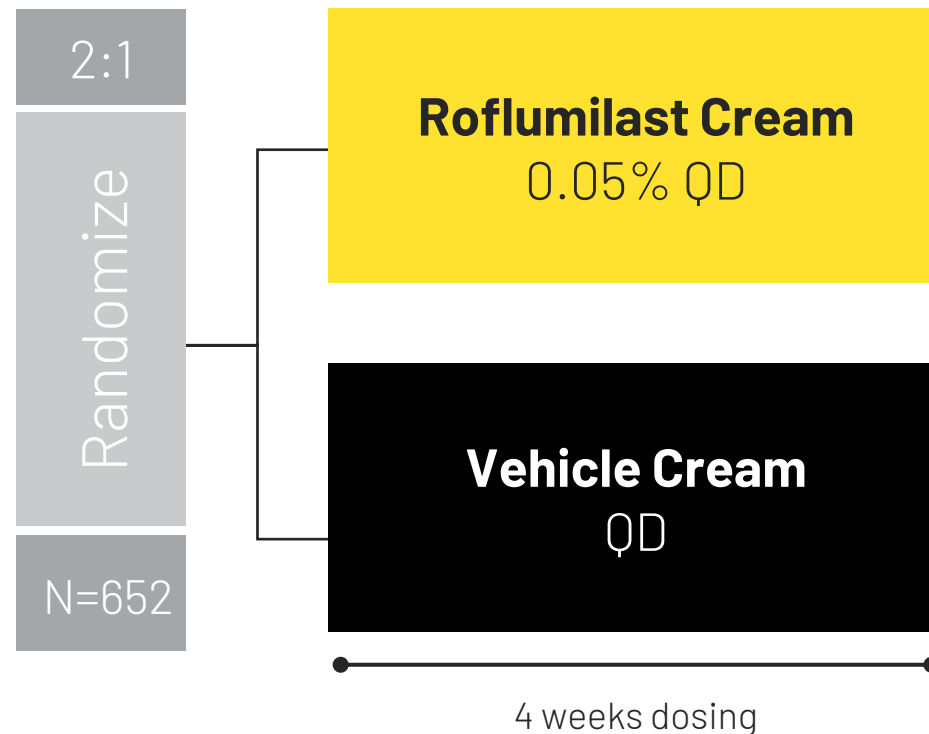
- INTEGUMENT-PED data release today includes patients down to the age of 2

# INTEGUMENT-PED Phase 3 Atopic Dermatitis Study

Parallel group, Double-blind, Vehicle-controlled, Multicenter Study

## Eligibility

- Diagnosis of mild or moderate AD (vIGA = 2 or 3)
- Age 2-5
- BSA  $\geq 3\%$
- EASI Score  $\geq 5$



## Endpoints

### Primary

- vIGA-AD success at Week 4

### Secondary

- EASI-75 at Week 4
- vIGA-AD success at Week 2, Week 1
- vIGA = Clear (0) or Almost Clear (1) at Week 4, Week 2, and Week 1

### Safety and tolerability

vIGA = Validated Investigator's Global Assessment; vIGA-AD Success = Clear or Almost Clear with at least a 2-grade improvement from baseline; BSA = body surface area; EASI = eczema area severity index; QD = once a day dosing

# Summary of Baseline Disease Characteristics for INTEGUMENT-PED

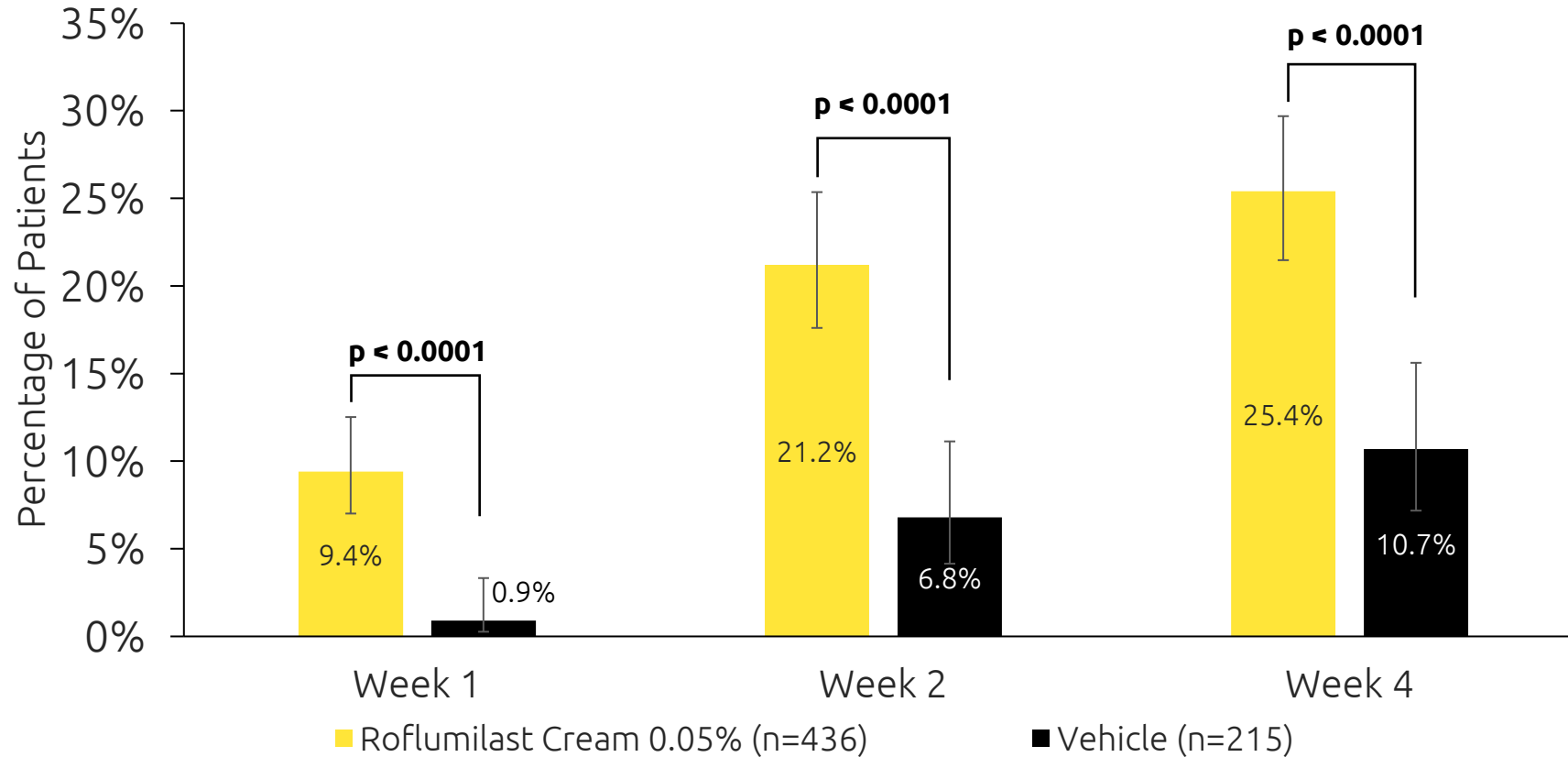
<b>Subjects (%)</b>	<b>Roflumilast 0.05%</b> (n=436)	<b>Vehicle</b> (n=215)	<b>Overall</b> (n=651)
Baseline vIGA-AD, n (%)			
2 (mild)	99 (22.7%)	43 (20.0%)	142 (21.8%)
3 (moderate)	337 (77.3%)	172 (80.0%)	509 (78.2%)
% BSA			
Mean (standard deviation)	22.5 (16.4)	21.2 (15.6)	22.1 (16.2)
Median	17.3	16.5	17.0
Average weekly baseline WI-NRS $\geq 4$ , n (%)	347 (79.6%)	160 (74.4%)	507 (77.9%)

*Intent to Treat Population*

# Rapid, Robust Efficacy on IGA Success Observed, Consistent with INTEGUMENT-1 & -2

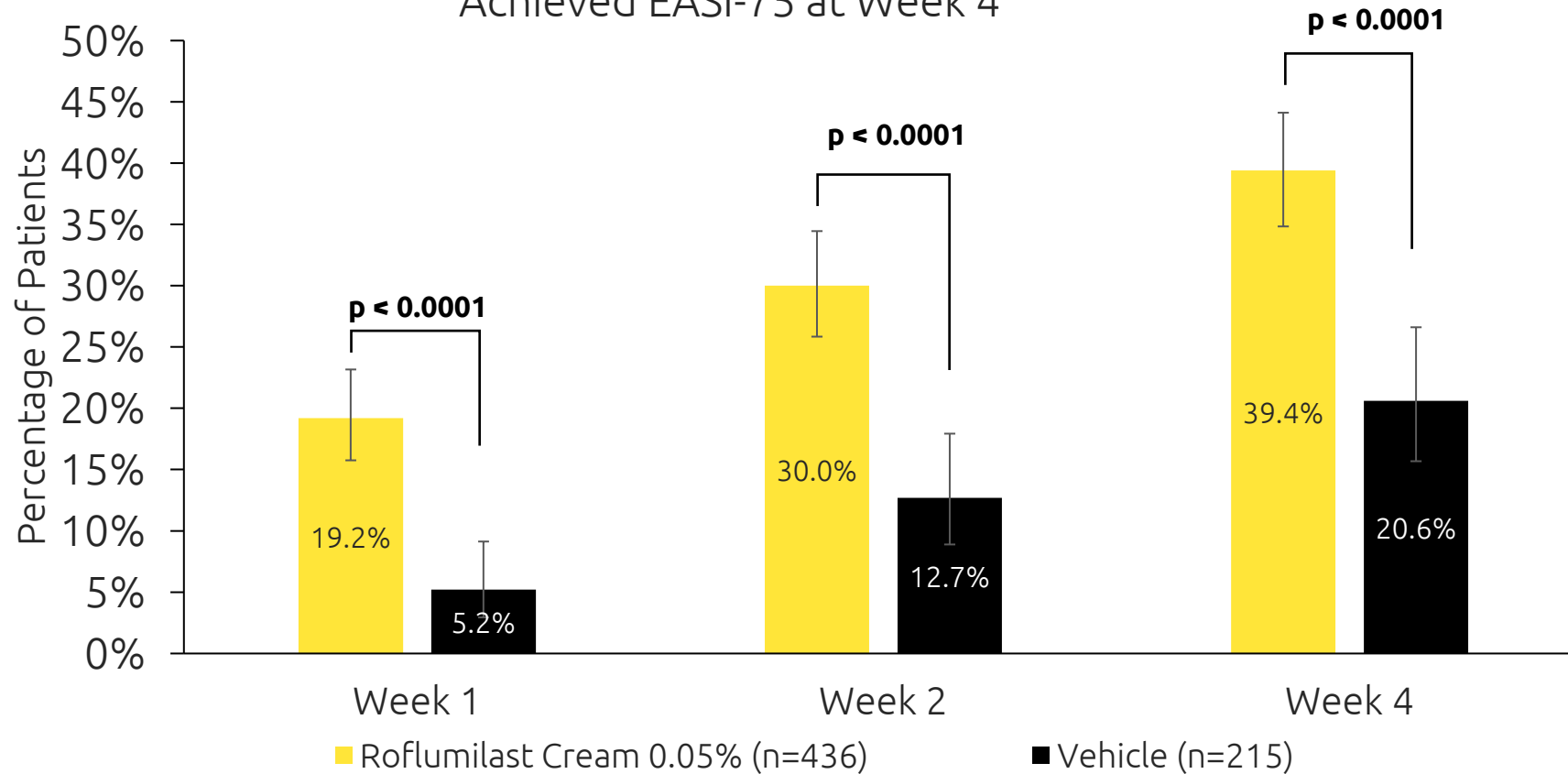
**~25% of Patients**

Achieved vIGA-AD Success at Week 4



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

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

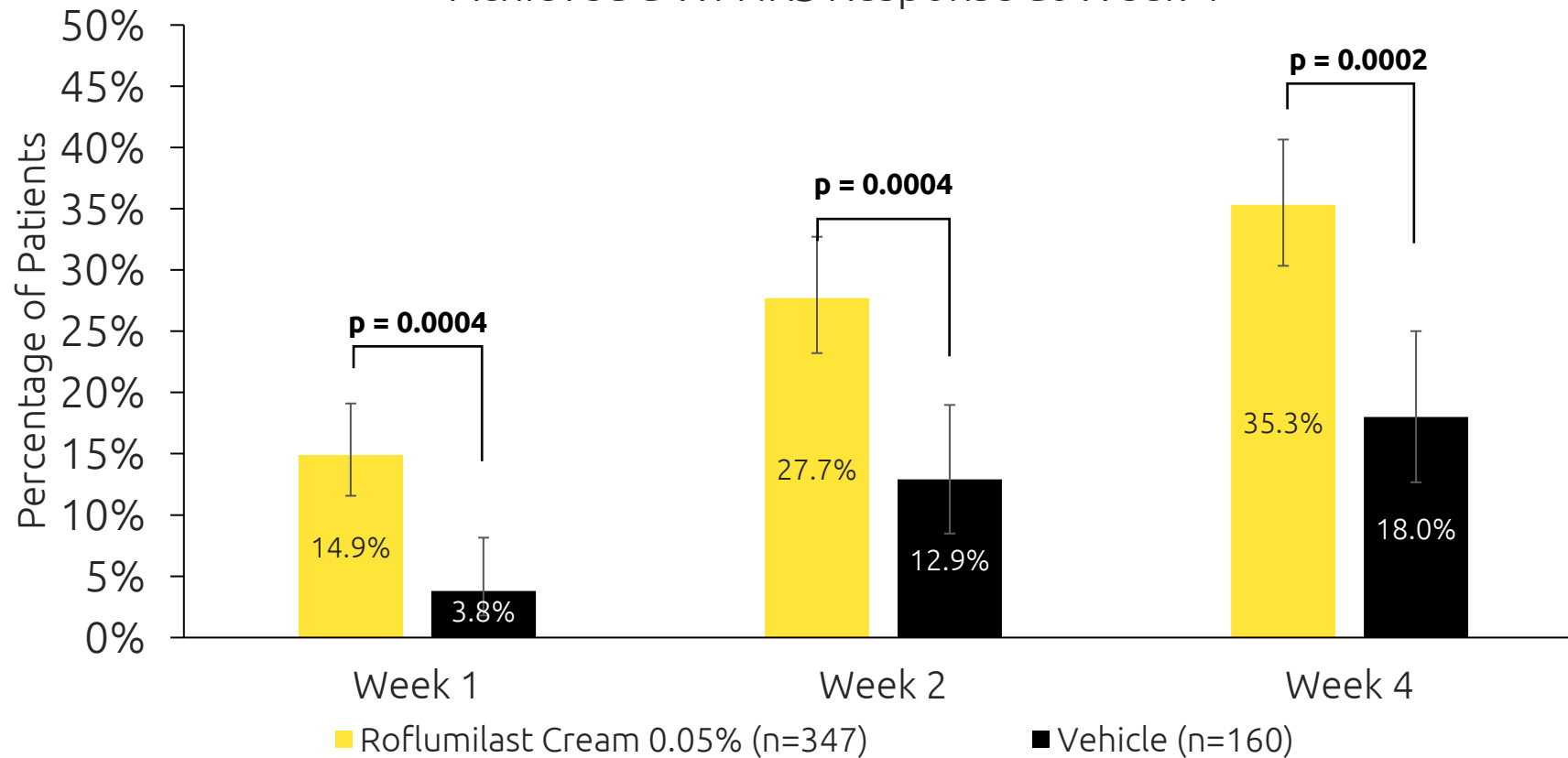


EASI-75 = 75% improvement from baseline

# Rapid Itch Response in Phase 3

**~35% of Patients**

Achieved a WI-NRS Response at Week 4



WI-NRS: Worst Itch Numeric Rating Scale; WI-NRS response = 4 point reduction in WI-NRS in patients with WI-NRS  $\geq 4$  at baseline; P values are nominal



# Roflumilast Cream Well-Tolerated in 2-5 Year Olds

<b>Subjects (%)</b>	<b>Roflumilast 0.05%</b> (n=437)	<b>Vehicle</b> (n=215)	<b>Overall</b> (n=652)
Subjects with any TEAE	130 (29.7%)	47 (21.9%)	177 (27.1%)
Subjects with any Treatment-Related TEAE	15 (3.4%)	6 (2.8%)	21 (3.2%)
Subjects with any SAE	1 (0.2%)	0	1 (0.2%)
Treatment-related SAE	0	0	0
Subjects who discontinued Study due to AE	5 (1.1%)	4 (1.9%)	9 (1.4%)

*Safety population; AE: adverse event; SAE: serious adverse event; TEAE: treatment-emergent adverse event*

# Most Common Treatment-Emergent Adverse Events ( $\geq 2.0\%$ in Any Group)

<b>Preferred Term</b>	<b>Roflumilast 0.05%</b> (n=437)	<b>Vehicle</b> (n=215)	<b>Overall</b> (n=652)
Upper respiratory tract infection	18 (4.1%)	3 (1.4%)	21 (3.2%)
Pyrexia	12 (2.7%)	6 (2.8%)	18 (2.8%)
Diarrhea	11 (2.5%)	1 (0.5%)	12 (1.8%)
Vomiting	9 (2.1%)	0	9 (1.4%)
Dermatitis atopic	2 (0.5%)	5 (2.3%)	7 (1.1%)

*Safety population*

# Rapid Response to Treatment with Roflumilast Cream

Baseline  
vIGA-AD = 3

Week 1  
vIGA-AD = 1

Week 4  
vIGA-AD = 1



*Individual results may vary*

# Rapid Response to Treatment with Roflumilast Cream

Baseline  
vIGA-AD = 3

Week 1  
vIGA-AD = 1

Week 4  
vIGA-AD = 1



*Individual results may vary*

# Speakers & Agenda



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MD, PhD, FAAD

Chief Medical Officer

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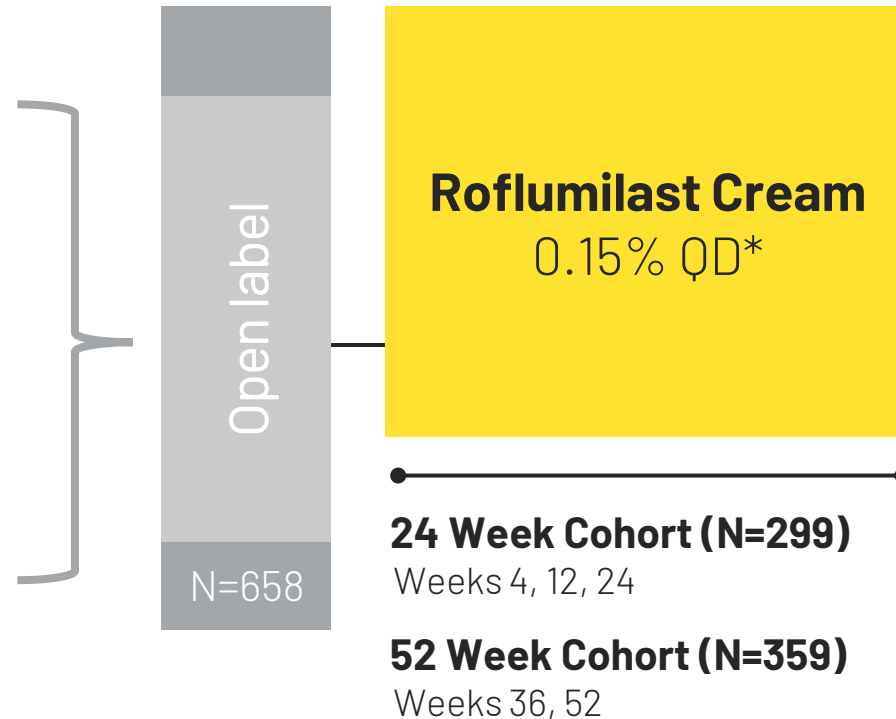
# INTEGUMENT-OLE Phase 3 Atopic Dermatitis Study

Open Label, Long-Term, Multicenter Study

## Subjects Included in Interim Analysis

Subjects who completed INTEGUMENT-1 or -2. At parent study baseline:

- Diagnosis of mild or moderate AD (vIGA = 2 or 3)
- Aged  $\geq 6$
- BSA  $\geq 3\%$
- EASI Score  $\geq 5$



**\*Starting at OLE Week 4, subjects with vIGA-AD=0 switch to twice-weekly maintenance dosing**

## Endpoints

### Primary

- Occurrence of AEs
- Occurrence of SAEs

### Secondary

- vIGA-AD Success
- EASI-75
- WI-NRS

### Safety and tolerability

# Long-Term Safety and Tolerability Profile Consistent with INTEGUMENT-1 & -2 in AD

<b>Subjects (%)</b>	<b>Overall (n=657)</b>
Subjects with any TEAE	241 (36.7%)
Subjects with any Treatment-Related TEAE	31 (4.7%)
Subjects with any SAE	8 (1.2%)
Treatment-related SAE	0
Subjects who discontinued Study due to AE	21 (3.2%)

## Most Common TEAEs by Preferred Term (≥ 2% overall)

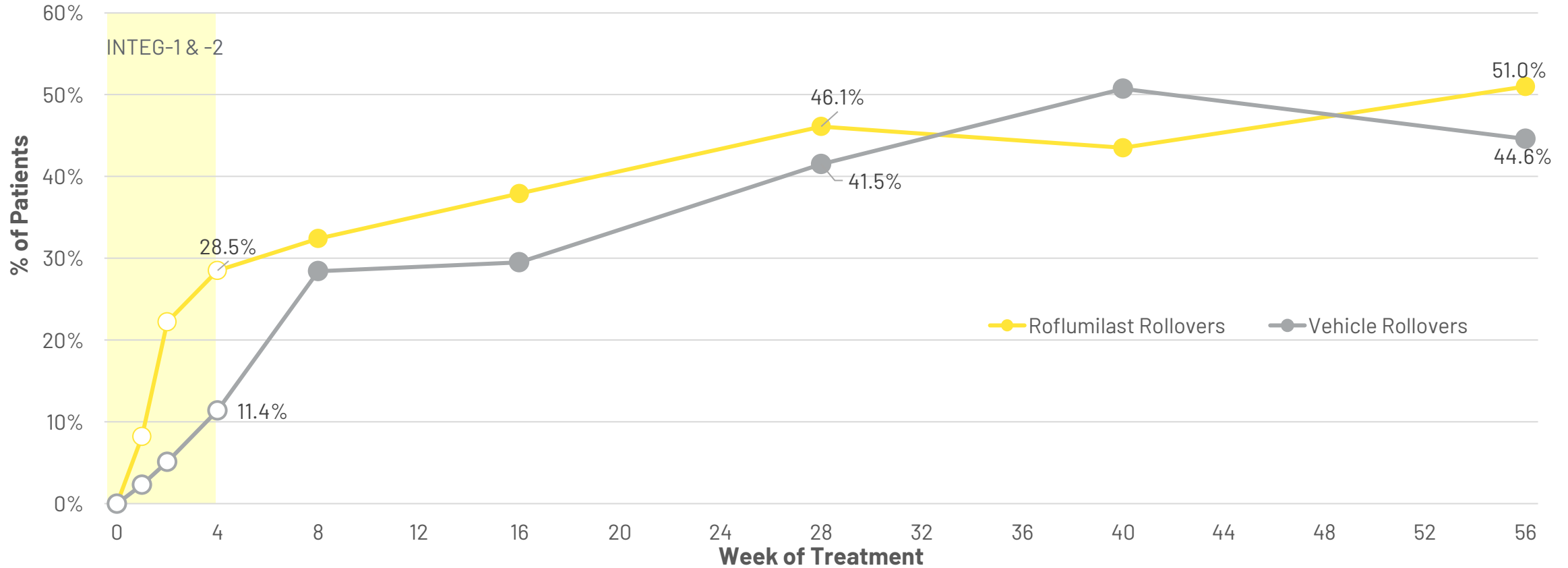
<b>Subjects, n (%)</b> Preferred Term	<b>Roflumilast cream 0.15%</b> (N=657)
COVID-19	30 (4.6%)
Upper respiratory tract infection	21 (3.2%)
Nasopharyngitis	20 (3.0%)
Headache	18 (2.7%)

**No New Safety Signals Observed Up to 56 Weeks of Treatment**



# Durable & Improving Response on IGA Success Over Time

## vIGA-AD Success

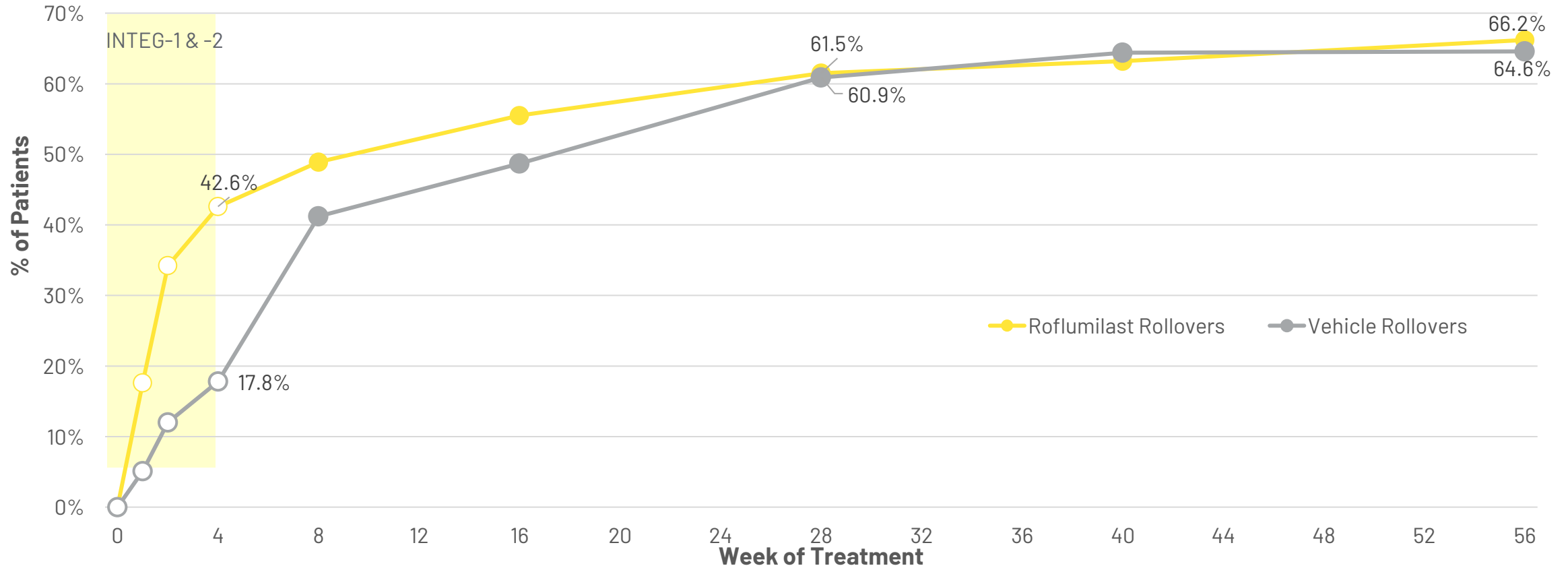


vIGA-AD success = achievement of IGA=0/1 plus 2-grade improvement from Parent Study Baseline, Observed cases.

At Week 4, Roflumilast Rollovers = n of 439, Vehicle Rollovers = n of 219. At Week 28, Roflumilast Rollovers = n of 319, Vehicle Rollovers = n of 159. At Week 56, Roflumilast Rollovers = n of 145, Vehicle Rollovers = n of 65.

# Durable & Improving Response on EASI-75

## EASI-75



75% EASI improvement from Parent Study Baseline, Observed Cases.

At Week 4, Roflumilast Rollovers = n of 439, Vehicle Rollovers = n of 219. At Week 28, Roflumilast Rollovers = n of 325, Vehicle Rollovers = n of 161. At Week 56, Roflumilast Rollovers = n of 145, Vehicle Rollovers = n of 65.

# First Large Study to Demonstrate Maintenance Dosing

- Starting at Week 4 of INTEGUMENT-OLE, participants who achieved vIGA-AD score of clear (0) switched to twice weekly maintenance dosing
- Disease control was defined by maintaining twice weekly dosing with vIGA-AD score of clear (0) or almost clear (1)
- Participants were to resume once-daily dosing if signs or symptoms were not adequately controlled, or if they reached if vIGA-AD of mild (2)



**> 2/3** of these participants remained on twice weekly schedule for **> 50%** their time in study

# 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

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