



**ARCUTIS**  
BIOTHERAPEUTICS

# Corporate Overview

August 2021

# 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, 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 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 ARQ-151 and ARQ-154; 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; future agreements with third parties in connection with the commercialization of our product candidates; 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.

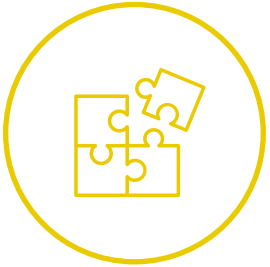
Moreover, we operate in a very competitive and rapidly changing environment, and new risks may emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, 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. Further information on these and other factors that could affect these forward-looking statements is contained in our our Form 10-K filed with U.S. Securities and Exchange Commission (SEC) on February 16, 2021, and other reports filed with the SEC from time to time. You should not rely upon forward-looking statements as predictions of future events. Although our management believes that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances described in the forward-looking statements will be achieved or occur. We undertake no obligation to publicly update any forward-looking statements, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. Neither we nor any other person makes any representation as to the accuracy or completeness of such data or undertakes any obligation to update such data after the date of this presentation. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

# Arcutis Drivers of Value

- Focus on large dermatology markets with significant unmet medical needs
- Late-stage pipeline of differentiated products with significant near-term potential
- Topical roflumilast could become first-line therapy and transform treatment paradigm
- Leading dermatology development engine
- Experienced commercial team prepared to effectively launch our products

# Our Strategy to Build the Preeminent Immuno- Dermatology Company



Filling the **innovation gap** in the dermatology drug sector



Elevating the standard of care to **simplify disease management** and **eliminate the need to compromise** between drug efficacy and safety/tolerability



Developing potential **best-in-class** and innovative topical dermatology therapies against **validated biological targets**



Led by a **world-class leadership team** (>50 FDA-approved products)



Rapidly advancing an **innovative pipeline** with **strong IP** protection for clinical assets

# Broad and Deep Pipeline

## Multiple “Pipeline in a Molecule” Opportunities

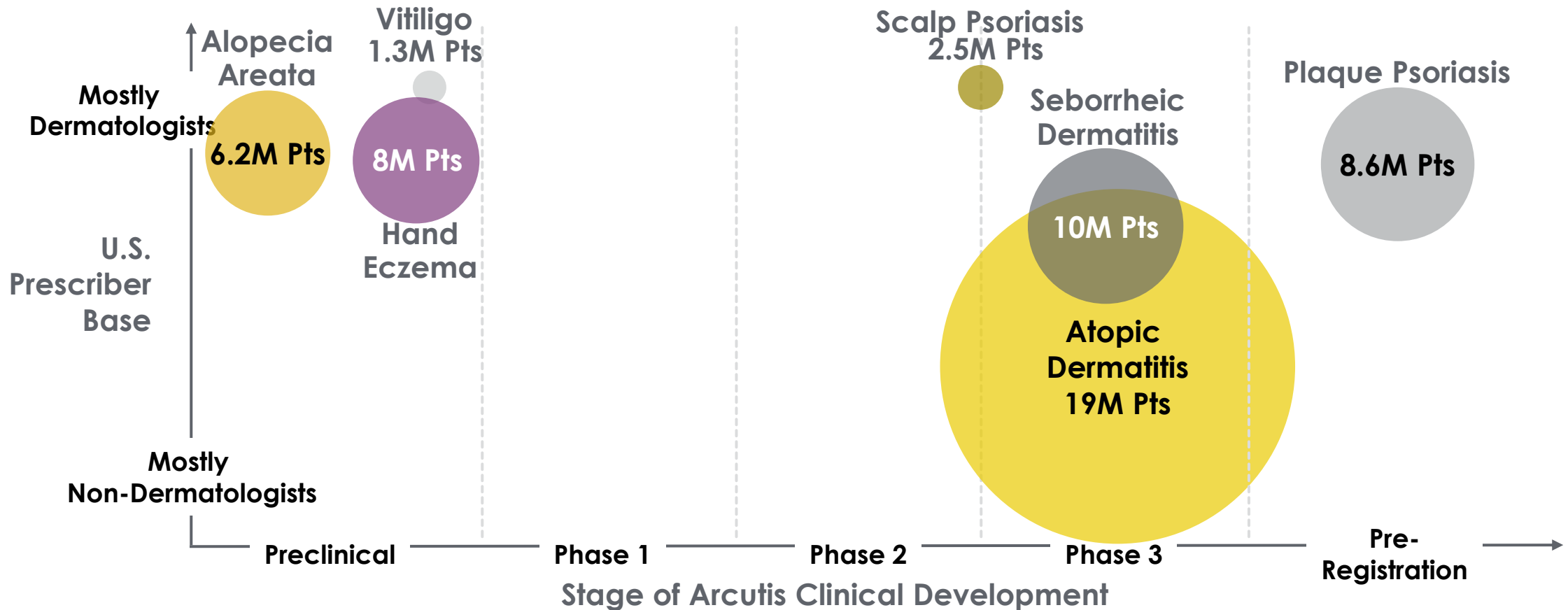
	Preclinical	Phase 1	Phase 2	Phase 3	Pre-registration	Commercial Rights
<b>Topical Roflumilast Cream</b> (ARQ-151)	Plaque Psoriasis					Worldwide
	Atopic Dermatitis					Worldwide
<b>Topical Roflumilast Foam</b> (ARQ-154)	Seborrheic Dermatitis					Worldwide
	Scalp Psoriasis					Worldwide
<b>ARQ-252 Cream</b> (JAK1 Inhibitor)	Hand Eczema					U.S., EU, Japan, Canada
	Vitiligo					U.S., EU, Japan, Canada
<b>ARQ-255 Suspension</b> (JAK1 Inhibitor)	Alopecia Areata					U.S., EU, Japan, Canada

# Steady Flow of Significant Clinical Catalysts



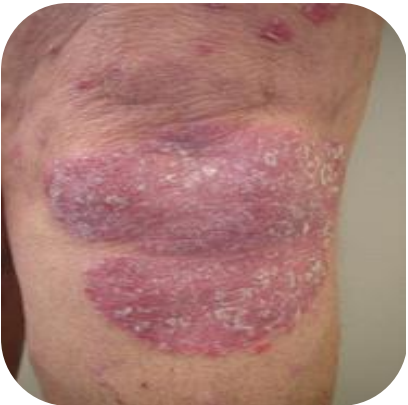
# Our Product Candidates Target Large Markets<sup>1</sup>

Prevalent U.S. Patient (Pts) Populations



1. Source: company estimates

# Significant Unmet Need in Plaque Psoriasis



- > 90% of U.S. patients treated with topical drugs
- Existing topical therapies have numerous shortcomings
  - Physicians and patients forced to trade-off between efficacy and safety/tolerability
- Ideal topical: efficacy of high potency steroids, ability to use chronically, and ability to use on all body areas



# Roflumilast May Address Unmet Needs in Plaque Psoriasis

- Efficacy:
  - Symptomatic improvements similar to steroid/vitamin D combination, exceeding high-potency steroids or Otezla<sup>®</sup>
  - Improvement on intertriginous plaques
  - Impact on itch associated with psoriasis
  - Rapid onset
  - Well tolerated
- Simple, easy-to-use, once-a-day cream or foam

IGA = Investigator's Global Assessment (IGA) Scale

# DERMIS-1/2 Phase 3 Plaque Psoriasis Studies

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

## Eligibility

- Diagnosis of at least mild plaque psoriasis
- Age 2+
- 2-20% BSA



**Roflumilast Cream  
0.3% QD**

**Vehicle  
QD**

**8 weeks dosing**

## Endpoints

### Primary

- IGA success at week 8

### Secondary

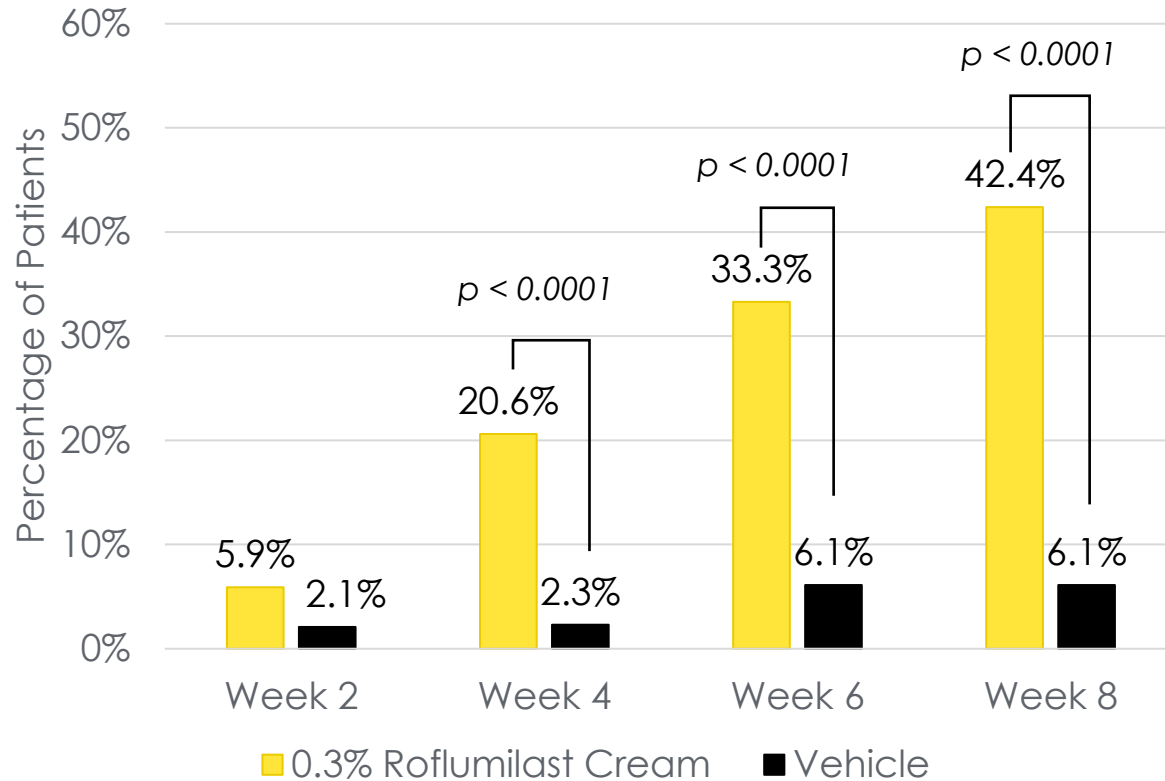
- PASI-50 and PASI-75
- Intertriginous-IGA (I-IGA) Success
- WI-NRS (itch)
- Psoriasis Symptom Diary (PSD)

### Safety and tolerability

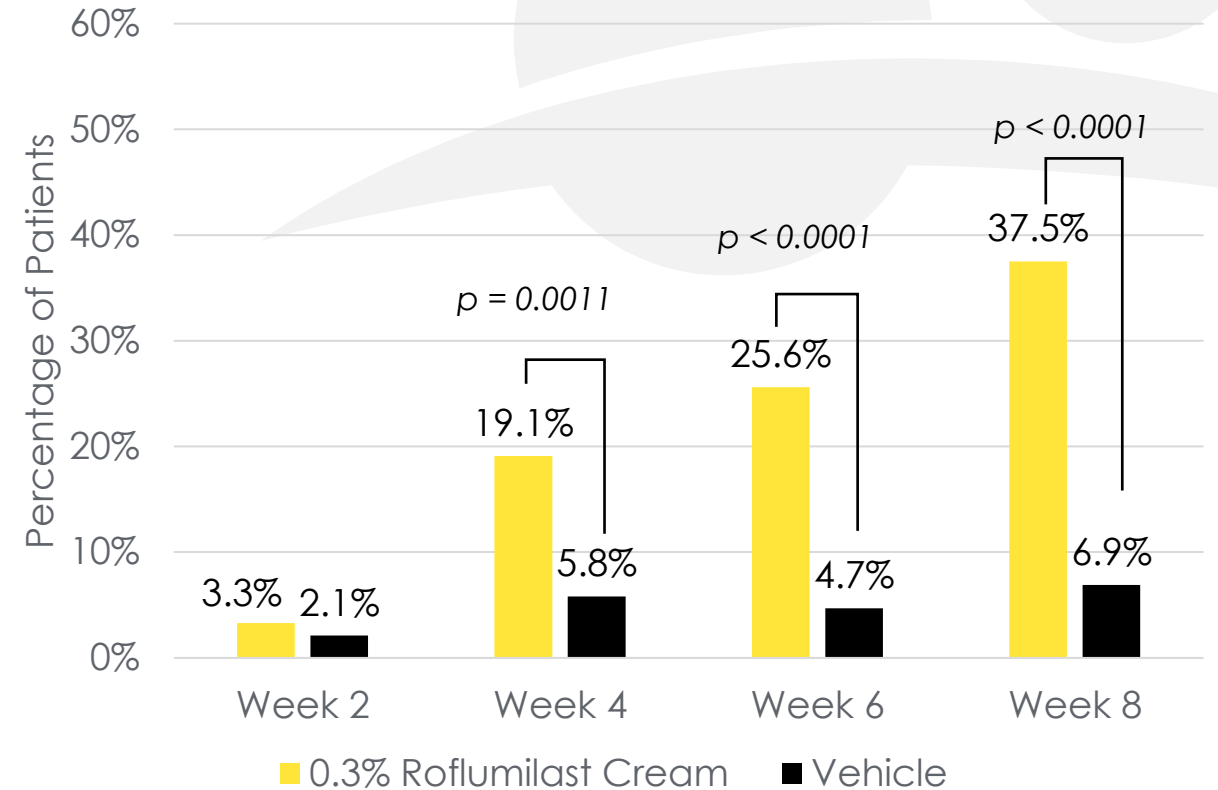
IGA Success & I-IGA Success = Clear or Almost Clear with at least a 2-grade improvement from baseline

# Robust Efficacy on IGA Success in Both Phase 3 Studies

## IGA Success (DERMIS-1)



## IGA Success (DERMIS-2)



IGA Success = Clear or Almost Clear with at least a 2-grade improvement from baseline  
ITT Population

# DERMIS-1/2 Efficacy

Vehicle

Topical Roflumilast 0.3%

Baseline

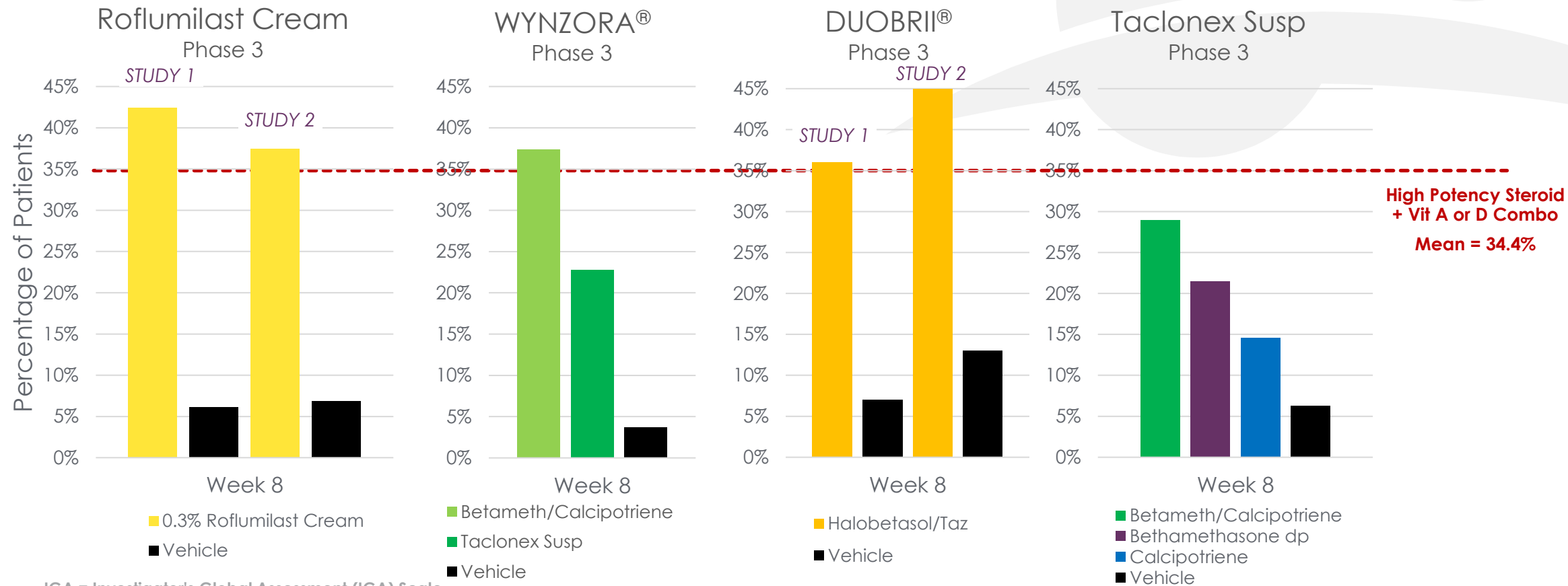


Week 8 of Treatment



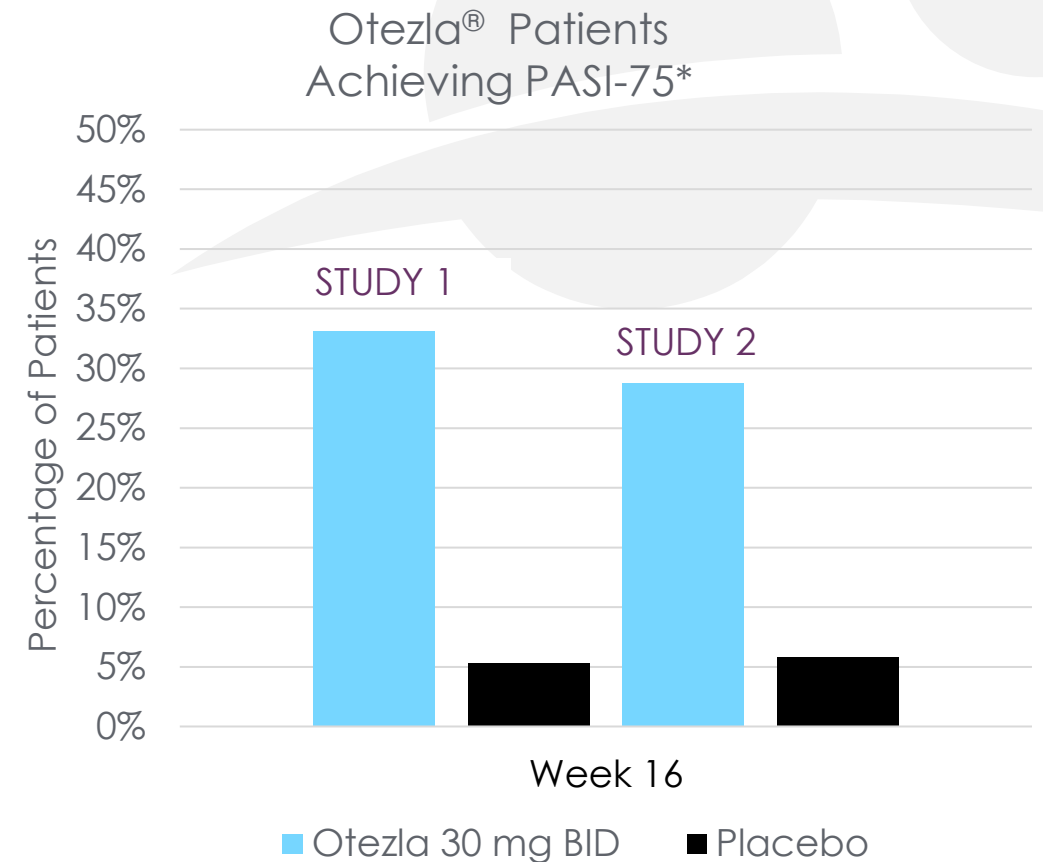
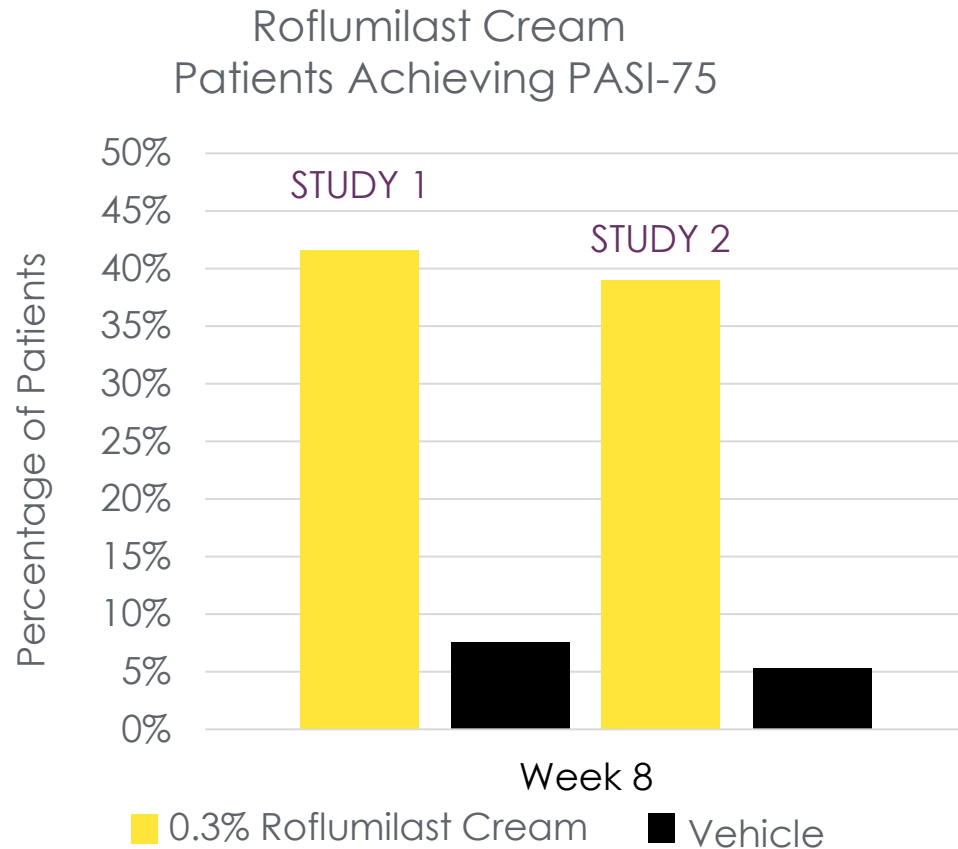
# IGA Success at 8 Weeks Comparable to Combo of High-potency Steroids & Vitamin D / Tazarotene

## Comparison of IGA Success Rates Across Separate Topical Psoriasis Clinical Trials



# PASI-75 at 8 Weeks Surpasses Otezla® 16-Week Data

## Comparison of PASI-75 Across Separate Psoriasis Clinical Trials



PASI-75 =  $\geq 75\%$  PASI improvement from baseline ITT Population

Note: The results of this retrospective post-hoc cross-trial comparison may not be directly comparable, as they are not from a single head-to-head clinical trial.

\*Otezla® trials were in moderate-to-severe patients



# Long-Term Data Supports Chronic Use in Plaque Psoriasis

- 73.5% of patients completed 52-64 weeks of treatment
  - Only 0.9% discontinued due to lack of efficacy
  - Only 3.9% discontinued due to any adverse event
- Efficacy over 52-64 weeks comparable to DERMIS-1/-2  
8-week efficacy

# Roflumilast May Address Unmet Needs in Many Other Inflammatory Skin Diseases

- Dermatologists and patients need topical therapies that:
  - Provide efficacy as good as or better than current standard-of-care
  - Do not pose worrisome safety or tolerability issues
  - Don't force trade-offs in efficacy and safety
  - Available in patient-friendly formulations that support adherence



# Significant Unmet Needs in Treatment of Atopic Dermatitis (AD)

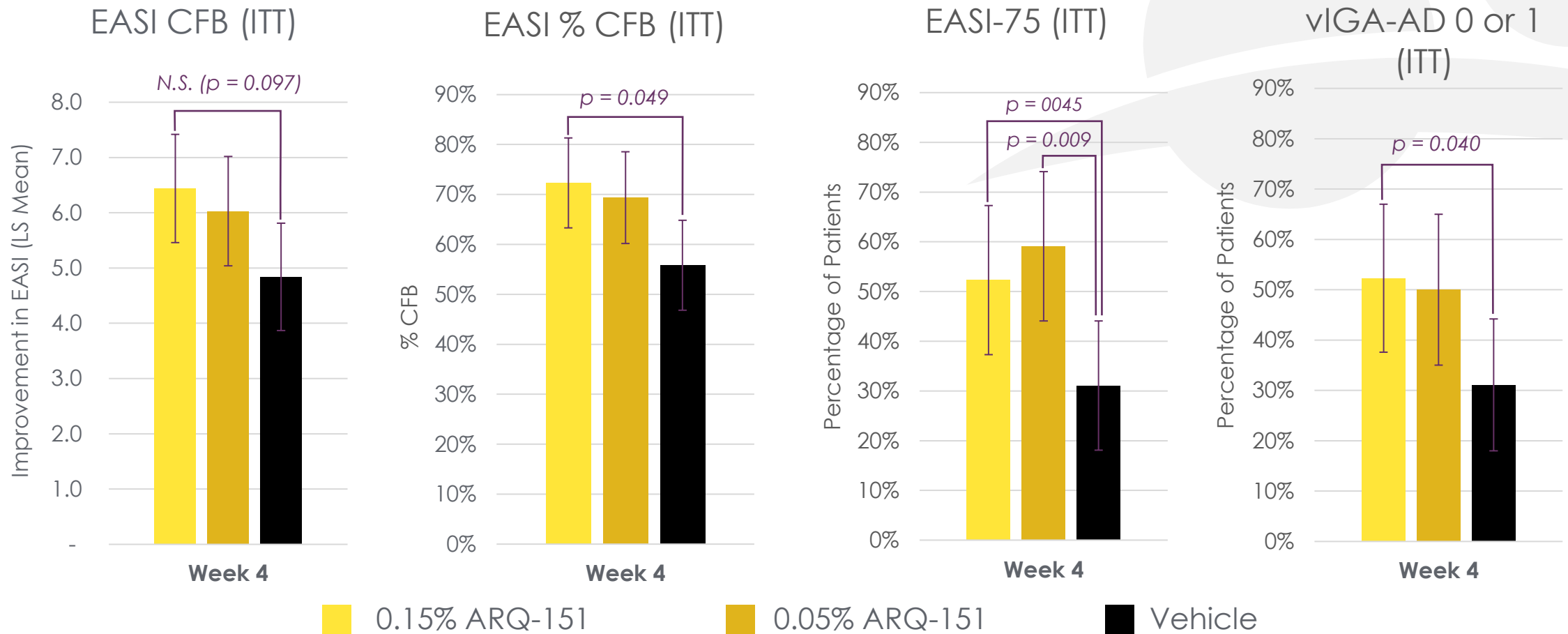


- At least 60% of AD patients are children
  - 15-20% of all children in U.S. affected
- Topicals dominate treatment
  - Low- to mid-strength steroids most commonly used
  - Calcineurin inhibitors can be used for maintenance therapy
  - Side effect concerns with both steroids and calcineurin inhibitors
  - Eucrisa® causes frequent burning at application site
- For moderate-to-severe disease, first biologic (Dupixent®) has a high response rate but use is very limited
- Ideal topical: equal or better efficacy without safety concerns or tolerability issues of current topicals

# Topical Roflumilast May Address Unmet Needs in Atopic Dermatitis

- Proof-of-concept in treating atopic dermatitis across multiple endpoints
- Efficacy similar to topical JAK inhibitors or mid-potency steroids
- Well tolerated
- Simple, easy-to-use, once-a-day cream
- Commenced Phase 3 trials in atopic dermatitis in January 2021

# Consistent Evidence of Efficacy in Atopic Dermatitis Across Endpoints



N.S. = not significant

# Roflumilast Cream 0.15% Atopic Dermatitis

## Phase 1 Study

Topical Roflumilast 0.15%

Baseline



Week 2 of Treatment



Baseline

Week 4 of Treatment

## Phase 2 Study

Vehicle

Topical Roflumilast 0.15%

IGA = 3



IGA = 3



IGA = 3



IGA = 2



# Significant Unmet Needs in Seborrheic Dermatitis (Seb Derm)

- Common, chronic inflammatory skin disease
- Itchy red patches covered by greasy, flaking scales on the scalp, face, and chest
- Topicals dominate treatment but pose challenges
  - Steroids effective but pose safety issues, especially with chronic use
  - Topical antifungals offer only modest efficacy
  - Proximity to eyes / thin skin on face exacerbates safety concerns
  - Treatment requires special formulation
- Ideal topical: more effective, ability to use chronically, safe on face/near eyes, hair-friendly formulation



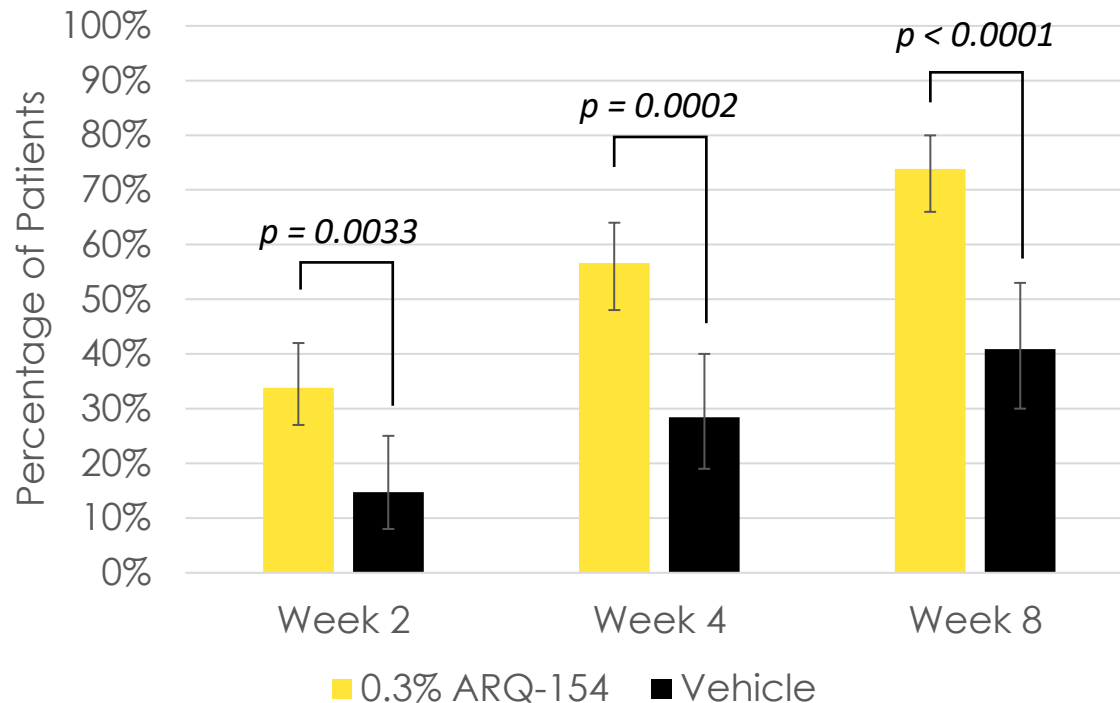


# Topical Roflumilast May Address Unmet Needs in Seborrheic Dermatitis

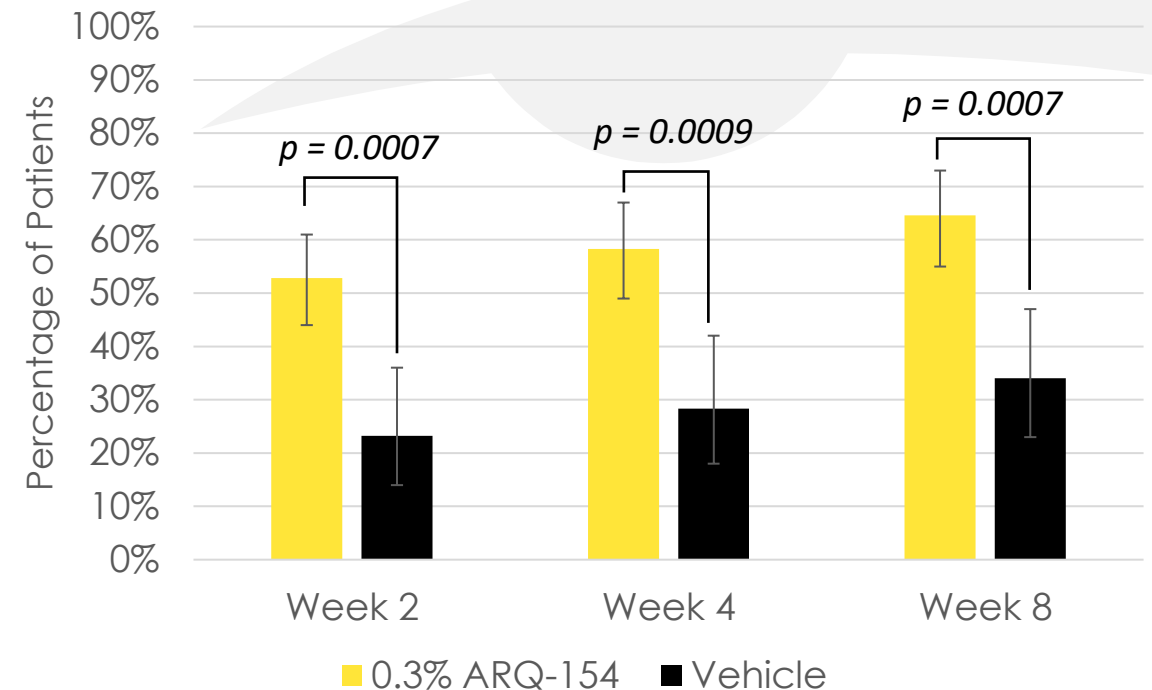
- Efficacy:
  - Symptomatic improvements potentially better than current standard-of-care
  - Rapid and robust impact on itch
  - As early as week 2 – rapid onset
- Well tolerated
- Safe for use near eyes / on thin facial skin
- Simple, easy-to-use, once-a-day foam suitable for scalp

# Rapid and Robust Efficacy on Key Seborrheic Dermatitis Efficacy Measures

74% of Patients Achieved IGA Success at Week 8



65% of Patients Achieved a WI-NRS Response at Week 8



IGA Success = Clear or Almost Clear with at least a 2-grade improvement from baseline

WI-NRS response = 4 point reduction in WI-NRS in patients with WI-NRS  $\geq 4$  at baseline

# Topical Roflumilast May Address Unmet Needs in Scalp Psoriasis

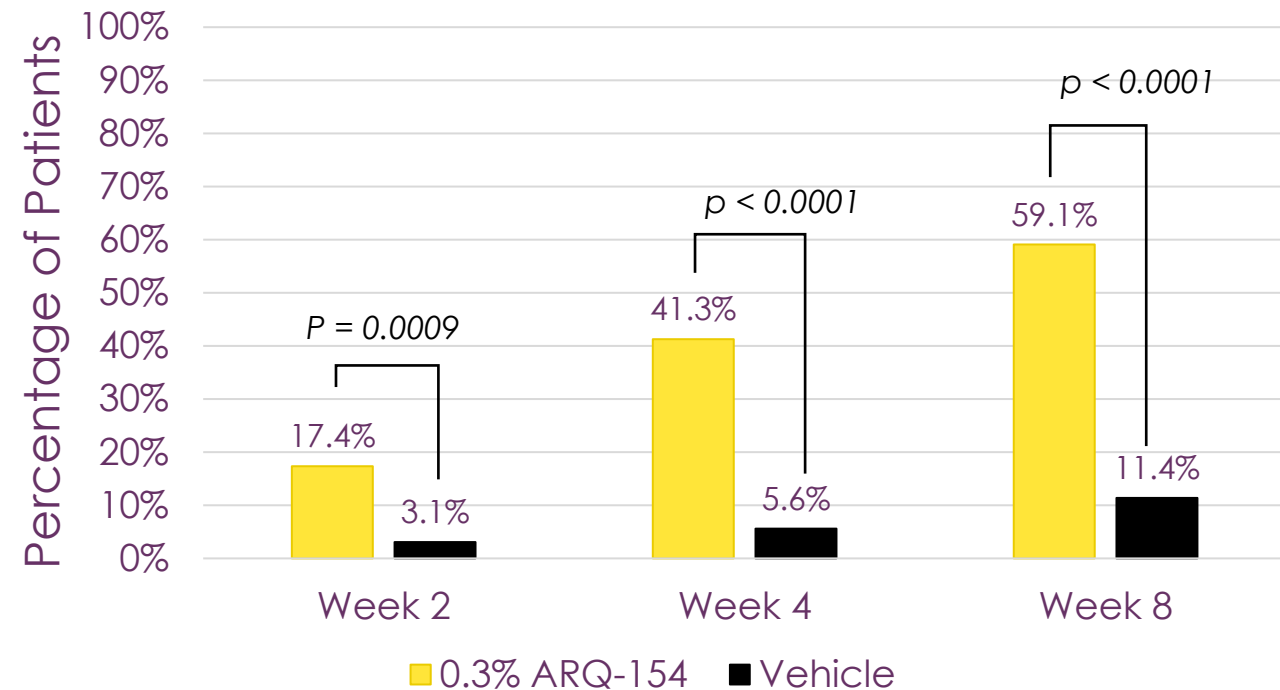


- Scalp psoriasis
  - Affects over 2.5 million U.S. patients
  - Difficult to treat because of drug access into hair-bearing regions
  - Significant unmet need for effective treatment safe for chronic use
- Roflumilast foam ideal for scalp psoriasis
  - Suitable for chronic use
  - Foam is ideal for hair-bearing areas such as scalp, where cream, lotion, or ointment is not suitable
  - Unlike most other options, single treatment for all areas of the body
  - Safe to use near the eyes

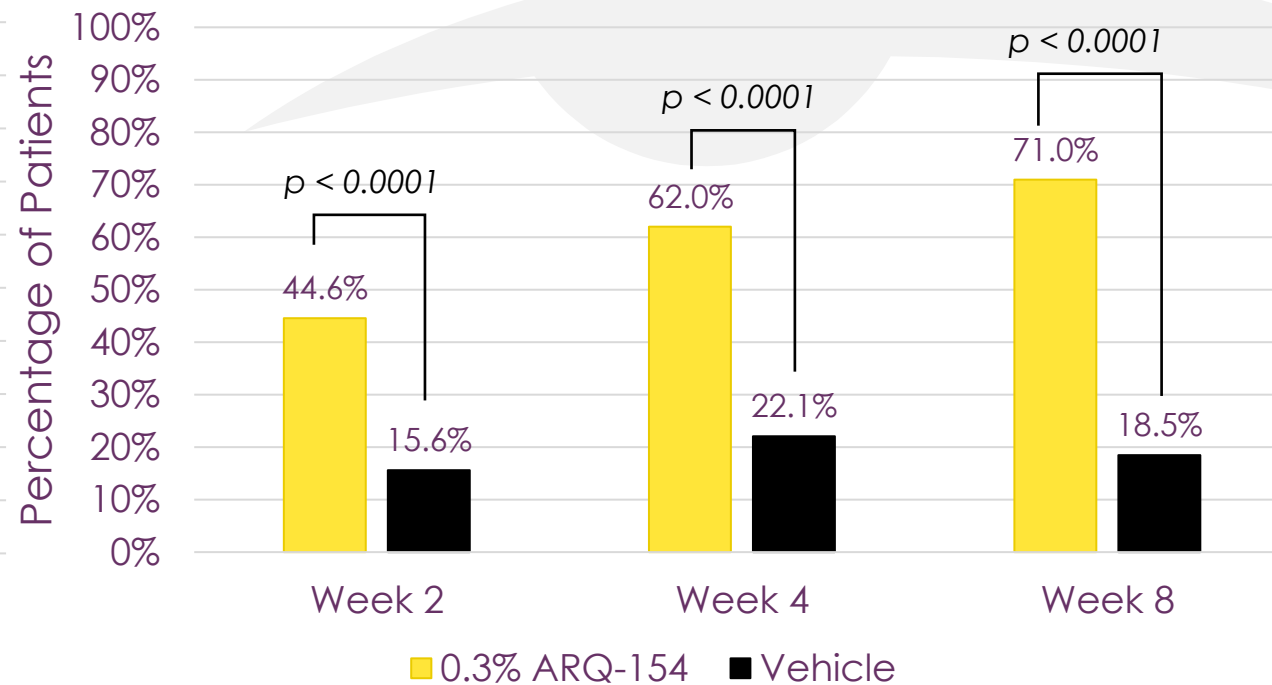


# Rapid and Robust Efficacy on Key Scalp PsO Efficacy Measures

~ 60% of Patients Achieved S-IGA Success at Week 8

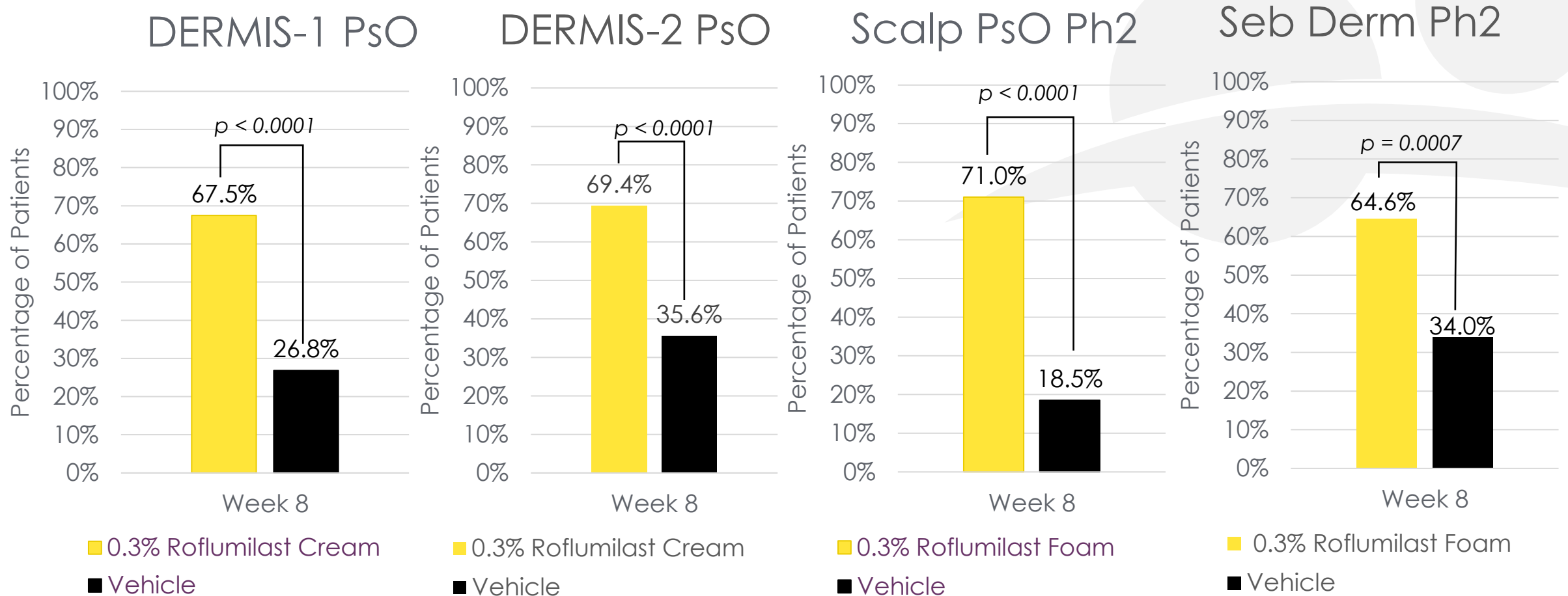


>70% of Patients Achieved a SI-NRS 4-pt Response at Week 8



**40.3% of patients on active achieved body IGA (B-IGA) success at week 8 versus 6.8% on vehicle**

# Rapid, Robust, and Consistent Effect on Itch Across Diseases



WI-NRS response = 4 point reduction in WI-NRS in patients with WI-NRS  $\geq 4$  at baseline

# Consistently Favorable Tolerability Profile Across Indications

*In psoriasis, AD, scalp, and seb derm programs:*

- > 2400 individuals already treated with topical roflumilast
- Treatment-related AEs rare and balanced across arms
- Discontinuations on topical roflumilast due to AEs rare
- No treatment-related SAEs on topical roflumilast
- No evidence of local tolerability issues (burning, stinging)
- Topical dosing avoids side effect profile typical of oral PDE4 inhibitors
- Supported by extensive oral roflumilast experience
  - >1M patient years of exposure

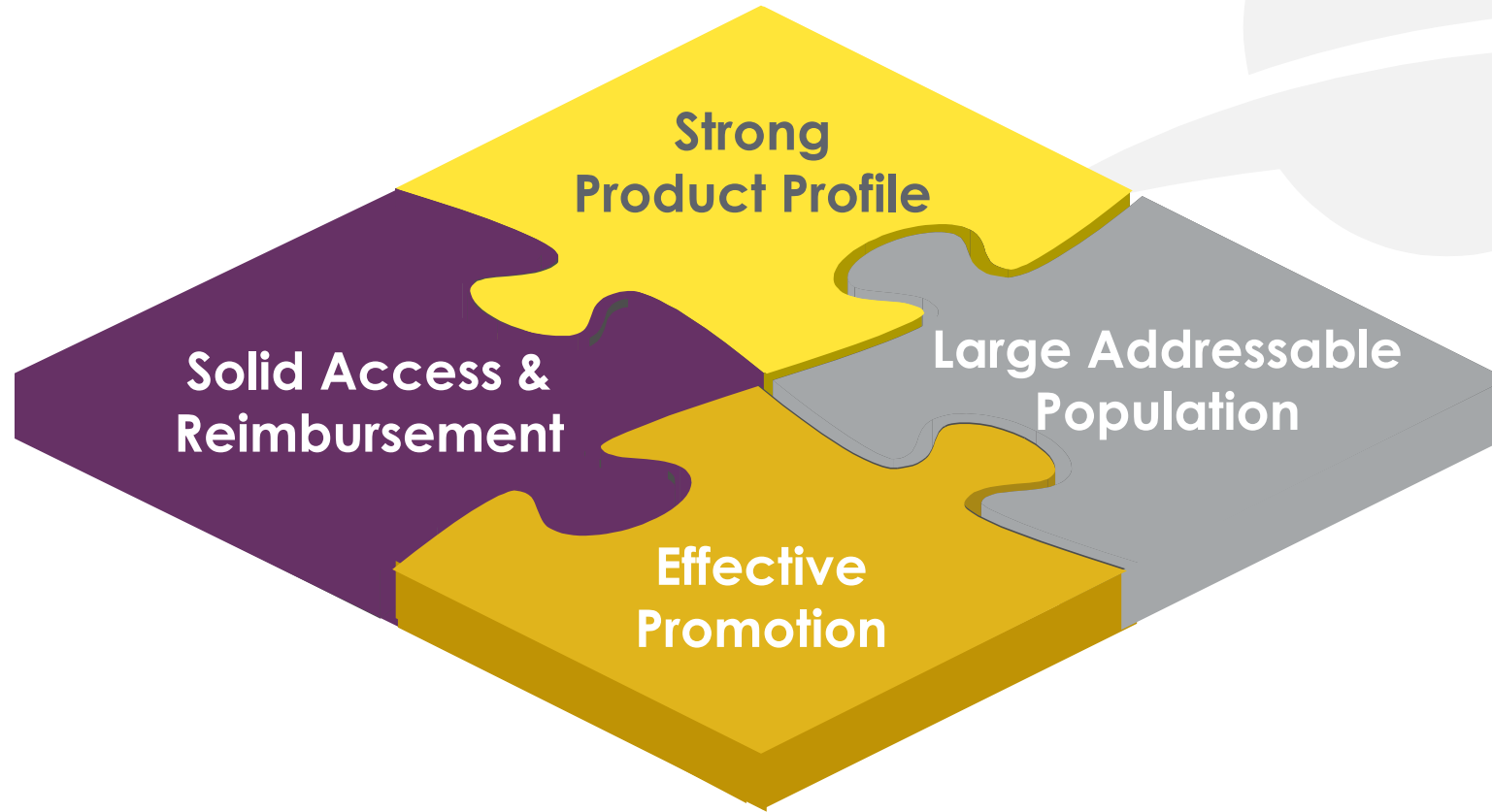
90%

of subjects  
treated with  
topical  
roflumilast  
completed  
Phase 3 studies

# Topical JAK1 Inhibition a Promising Approach to Inflammatory Dermatologic Diseases

- Topical JAK inhibitors proven effective in multiple dermatological disorders
  - But JAK inhibitors carry risk of hematological adverse events and immunosuppression
- Active ingredient in ARQ-252 is a highly potent and highly selective inhibitor of JAK1
  - Oral study shows highly potent JAK1 inhibitor with good side effect profile
- Reformulation of ARQ-252 underway to potentially deliver much more active drug to targets in the skin
- Ongoing formulation work on ARQ-255
  - A “deep penetrating” formulation of ARQ-252 for alopecia areata

# Keys to a Successful Launch



# Topical Roflumilast Positioned to Have Differentiated and Compelling Profile

- Symptomatic improvements comparable to the combo of high-potency steroids and Vitamin D / Retinoid
- Significant impact on itch
- Ability to use chronically
- Little or no application site reaction
- Convenient, easy-to-use, once-a-day cream or foam
- Ability to use everywhere, including face, scalp, and intertriginous regions
- Not expected to have boxed warning

# ~5 Million PsO, AD, Seb Derm Patients Rx Topical Treated by Dermatologists in U.S.

U.S. Patient Populations (Millions)

	Psoriasis	Atopic Dermatitis	Seborrheic Dermatitis
Prevalence	8.6	19.2	10.0
Rx treated	3.5	6.3	2.7
Topically treated	2.5	5.4	2.7
Rx treated in Derm Setting	2.8	1.2	1.8
<b>Rx treated (Topically) in Derm Setting</b>	<b>2.0</b>	<b>1.0</b>	<b>1.8</b>

Additional opportunities to unlock value of our molecules:

- **6M U.S. patients** Rx topical treated by other specialties (e.g., PCPs or pediatricians)
- Ex-U.S. markets



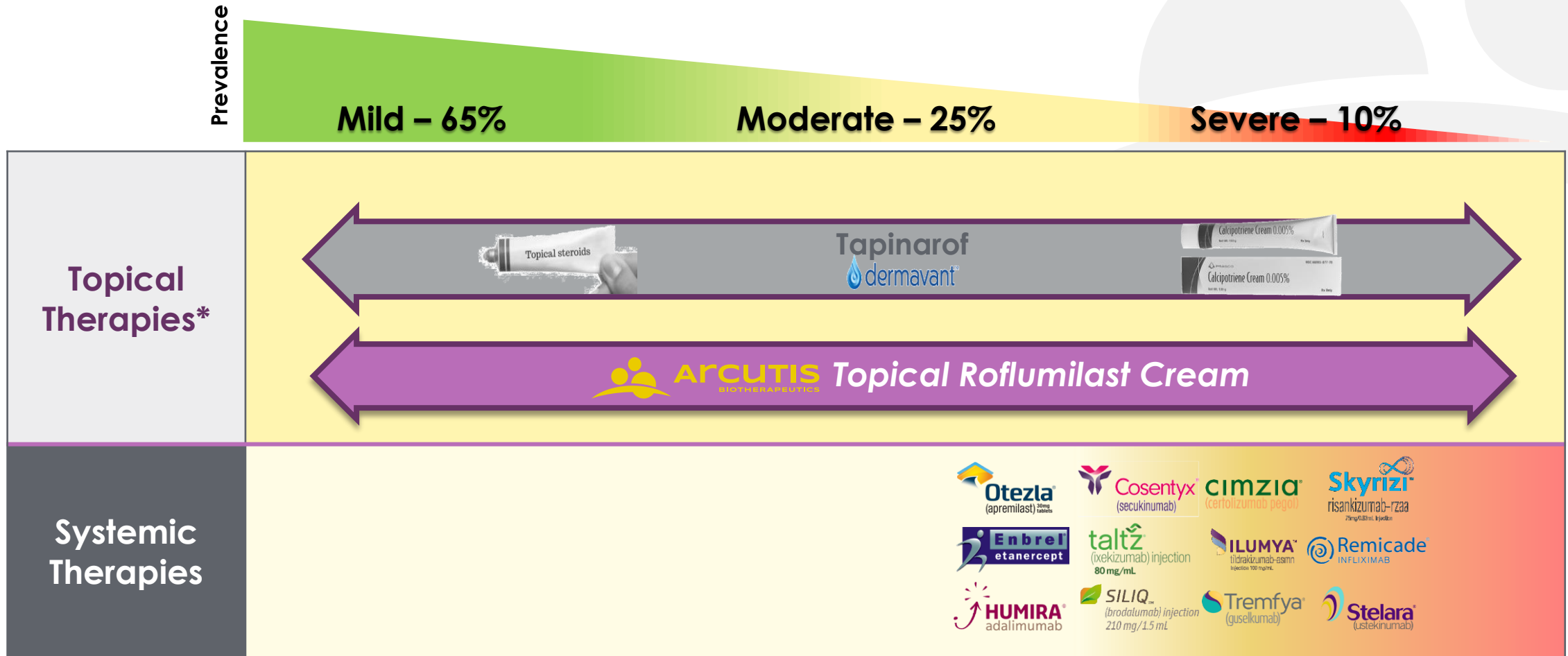
# Large Pool of Easily Accessible Patients



- **~ 6M patients** currently Rx treated by U.S. dermatologists
- **Concentrated prescribers** create sales force efficiencies
  - 75 – 80 sales reps required to cover most prescribers
- **Minimal behavioral change** required to activate utilization
  - Most patients in targeted diseases **already on Rx topical**
- **Highly dynamic market facilitates Start/Switch**
  - Steroids limited to short duration – frequent opportunities to switch
- **Sparse competitive landscape** for innovative topical therapies

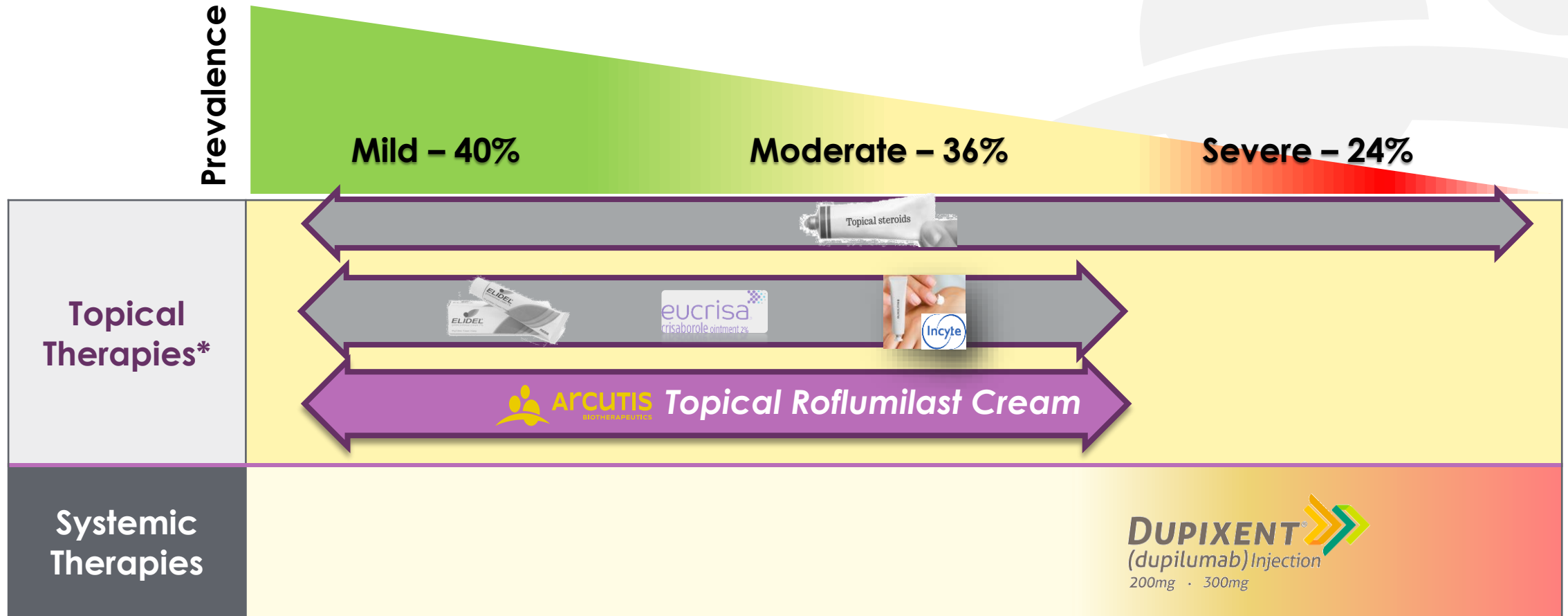


# Psoriasis Landscape: Topical Roflumilast Positioned to Treat the Entire Spectrum



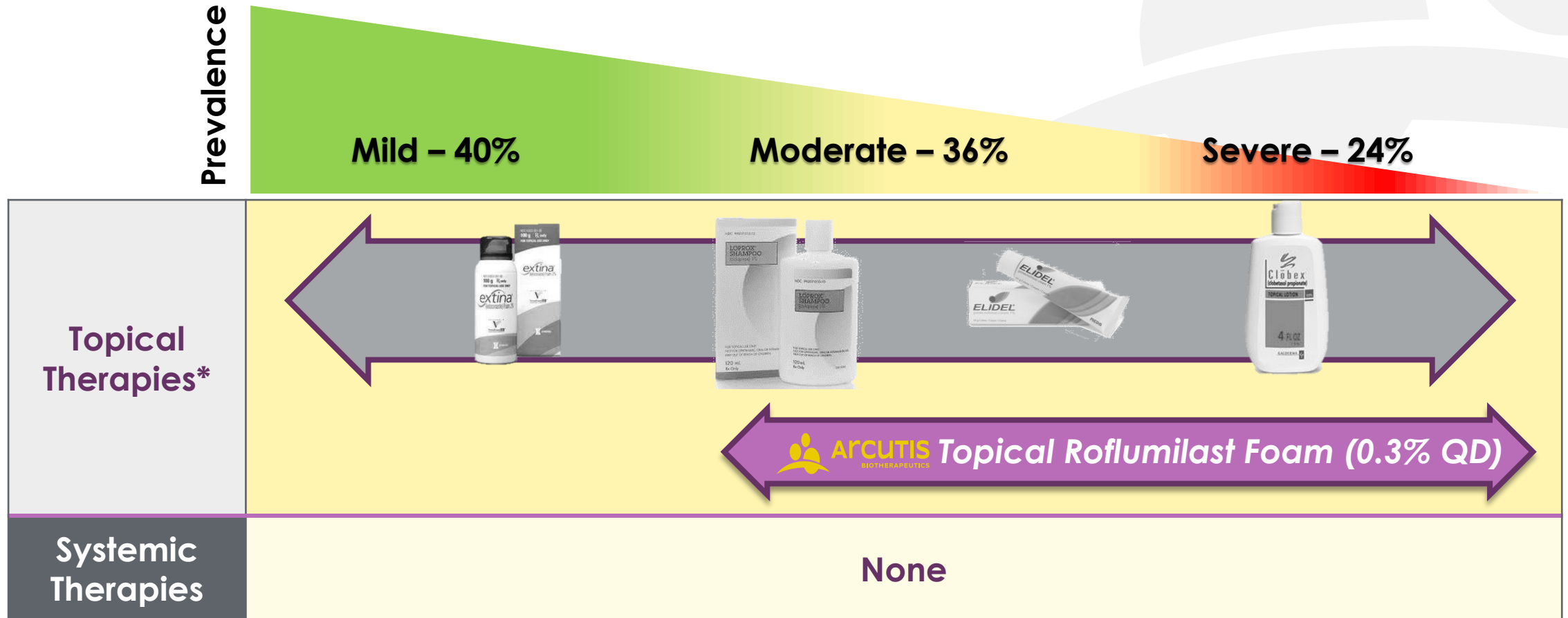
\* Topical therapies are generally indicated for, or expected to be indicated for, across the disease severity spectrum

# AD Landscape: Topical Roflumilast Faces Limited Competition Across the Spectrum



\* Nonsteroidal topical therapies are generally indicated for, or expected to be indicated for, mild-to-moderate AD

# Seb Derm Landscape: Topical Roflumilast Positioned to Treat Moderate-to-Severe Disease with Limited Competition



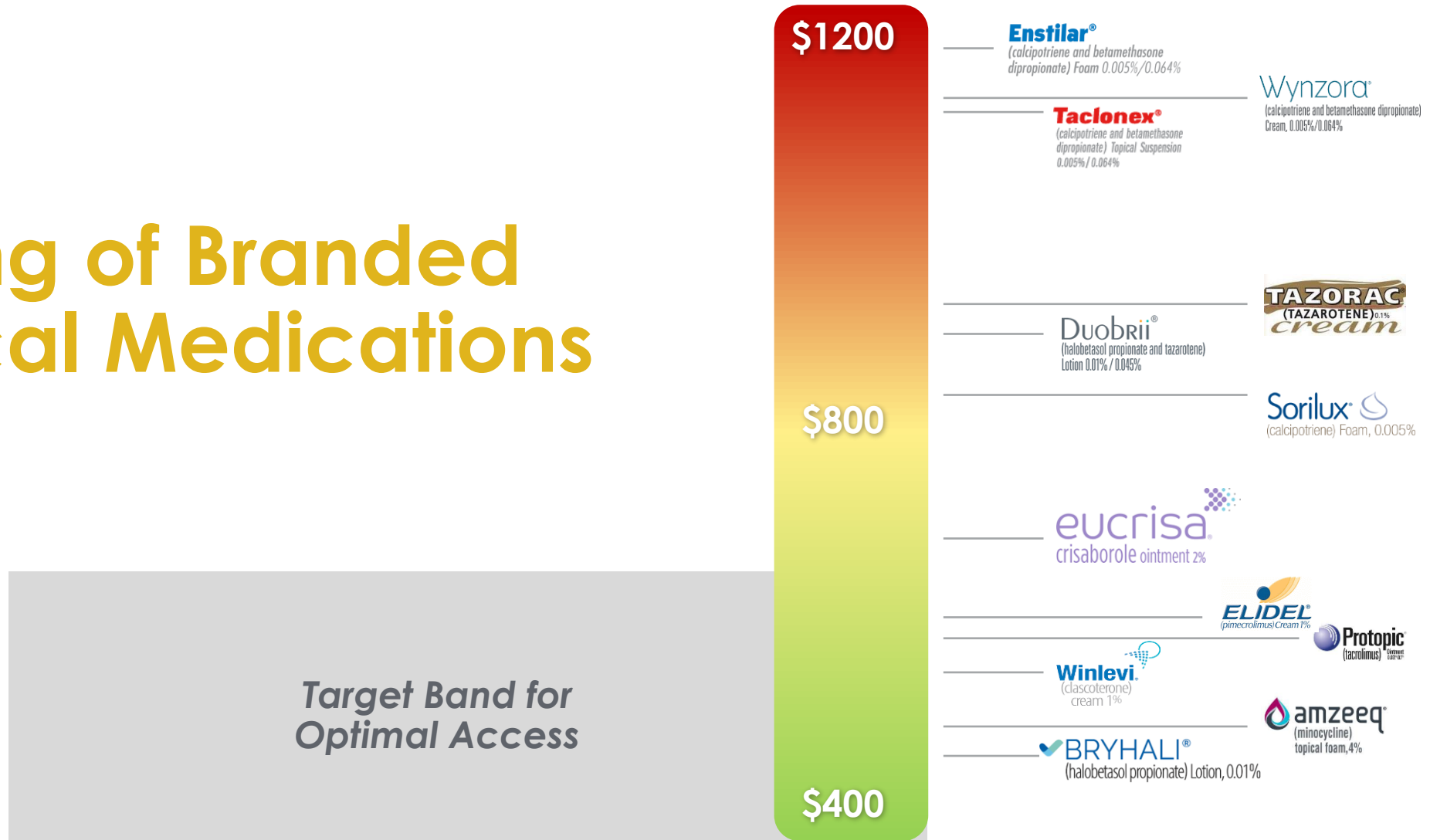
\* Existing topical therapies are generally indicated for across the disease severity spectrum

# We Intend to Optimize Patient Access to Our Innovative Treatments



- Seek **broad access** and **reduced prescriber burden** to maximize volume opportunity
  - Highly innovative products at **appropriate pricing allow for broad and rapid adoption**
  - Ability for HCP to **get drug when prescribed** and **patient affordability** are as important as profile itself, hassle factor is anathema to prescribing
  - Rapid introductions of follow-on indications allow for **portfolio volumes across multiple indications** supporting payer value

# Pricing of Branded Topical Medications



Source: Analysource – 1/11/21

# Arcutis Enjoys Strong IP Protection<sup>1</sup>



**Patent  
Protection  
Expected At  
Least Into 2037**

- 7** Issued U.S. and foreign patents on ARQ-151/154 formulation
- 3** Pending patents on topical roflumilast PK profile
- 1** Pending patent on anti-fungal properties of PDE4 inhibitors
- 1** Pending patent on novel restorative effect of the ARQ-151 vehicle
- 1** Pending patent for method of use on a critical ingredient in the ARQ-151/154 formulation
- 1** Pending patent for the Deep Dermal Drug Delivery (4D) Technology underlying ARQ-255
- 1** Pending patent for novel JAK inhibitor formulation (ARQ-252)

1. As of 12/31/20



# Leadership Team Has Developed or Commercialized More than 50 FDA-Approved Products



**Frank Watanabe, MA, President & CEO**

- Former COO and Co-Founder, Kanan Therapeutics
- Former VP, Strategy and Corporate Development, Kythera
- Former Executive, Amgen and Eli Lilly



**Keith Klein, JD, General Counsel**

- Former General Counsel, Unity Biotechnology, Sienna Biopharmaceuticals, Kythera Biopharmaceuticals
- Former Senior Associate General Counsel, Amgen



**Matthew Moore, Chief Business Officer**

- Former VP, Business Development and Alliance Mgmt, Allergan
- Former Executive Director, Business Development, Actavis/Allergan
- Former Executive Director, Business Development, Forest



**Patrick Burnett, M.D., Ph.D., FAAD, Chief Medical Officer**

- Former CMO, Verrica Pharmaceuticals
- Former Associate VP of Clinical Development, Sun Pharmaceuticals
- Former Global Program Medical Director, Novartis



**Ken Lock, MBA, Chief Commercial Officer**

- Former senior marketing lead for inflammation, Gilead
- Former head, U.S. Dermatology Marketing, Amgen
- Sales and marketing leadership roles; Amgen, Gilead, Wyeth



**Patricia Turney, MBA, SVP, Operations**

- Former VP External Supply and Manufacturing, Amgen
- Former head, Manufacturing Site Operations, Amgen Breda
- Manufacturing, Engineering, EH&S, R&D, and Quality leadership roles, Amgen



**Scott Burrows, MBA, Chief Financial Officer**

- Former VP / Head of Int'l Investor Relations, Shire
- Finance leadership roles at Amgen
- Former Consultant, Arthur Andersen



**Raj Madan, MBA, Chief Digital & Information Officer**

- Former VP of Digital, Data/ Analytics & Innovation at GSK
- Former Global Head of Digital Solutions at Novartis
- IT leadership roles at L'Oreal



**David Osborne, PhD, Chief Technical Officer**

- Former CSO of Tolmar
- Former VP Product Development, Dow Pharmaceutical
- Former VP Product Development, Atrix



# Financial Position



**\$411M<sup>1</sup>**  
(as of 6/30/21)

Cash, cash equivalents, restricted cash, and marketable securities



**Cash Runway**

Current cash, cash equivalents, and marketable securities, expected to fund planned operations well into 2023



**~50M**  
(as of 6/30/21)

Shares of common stock outstanding

1. Preliminary, unaudited, and subject to change



# Thank You

