



**ARCUTIS**  
BIOTHERAPEUTICS

# **Phase 2b Study of Roflumilast Foam in Adolescents and Adults with Scalp and Body Psoriasis**

November 2020

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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.

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# Today's Presenters



## 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



## 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



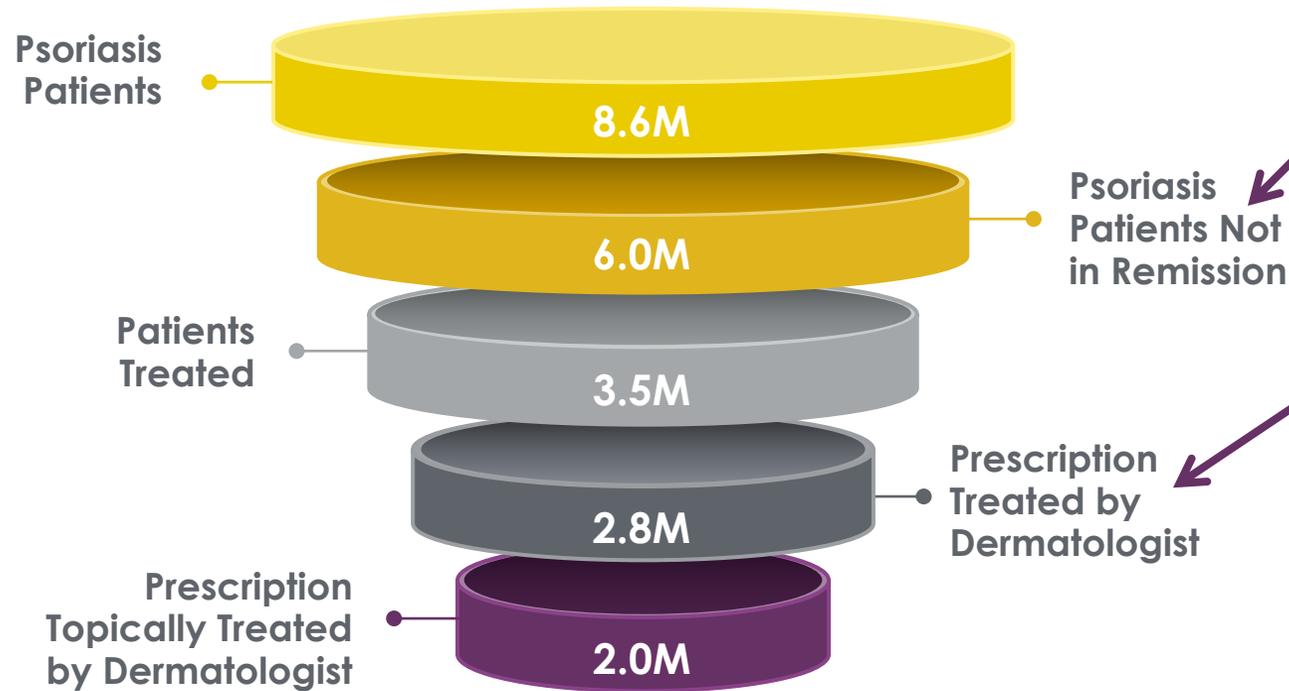
# Scalp Psoriasis Represents an Exciting Opportunity

- Large market: ~ 40% of psoriasis patients (~ 2.5M in US alone)
- High unmet need – no novel therapies in decades, patients and dermatologists unhappy with current options
- Topical roflumilast foam appears uniquely well suited to address dermatologists' & patients' unmet needs
- Very little competition

# Approximately 2.5M US Patients with Scalp Psoriasis

## Scalp Presentation

### General Psoriasis Prevalence



- ~40%<sup>1</sup> of patients present with psoriasis on their scalp, which represents ~2.5M patients
  - Over a lifetime, up to 80%<sup>2</sup> of patients may experience scalp involvement

- Due to QOL concerns, patients with scalp involvement may present to a dermatologist at higher rates

- Derm reported<sup>3</sup> PsO presentation areas:

- 39% Body and scalp
- 17% Scalp only
- 43% Body only



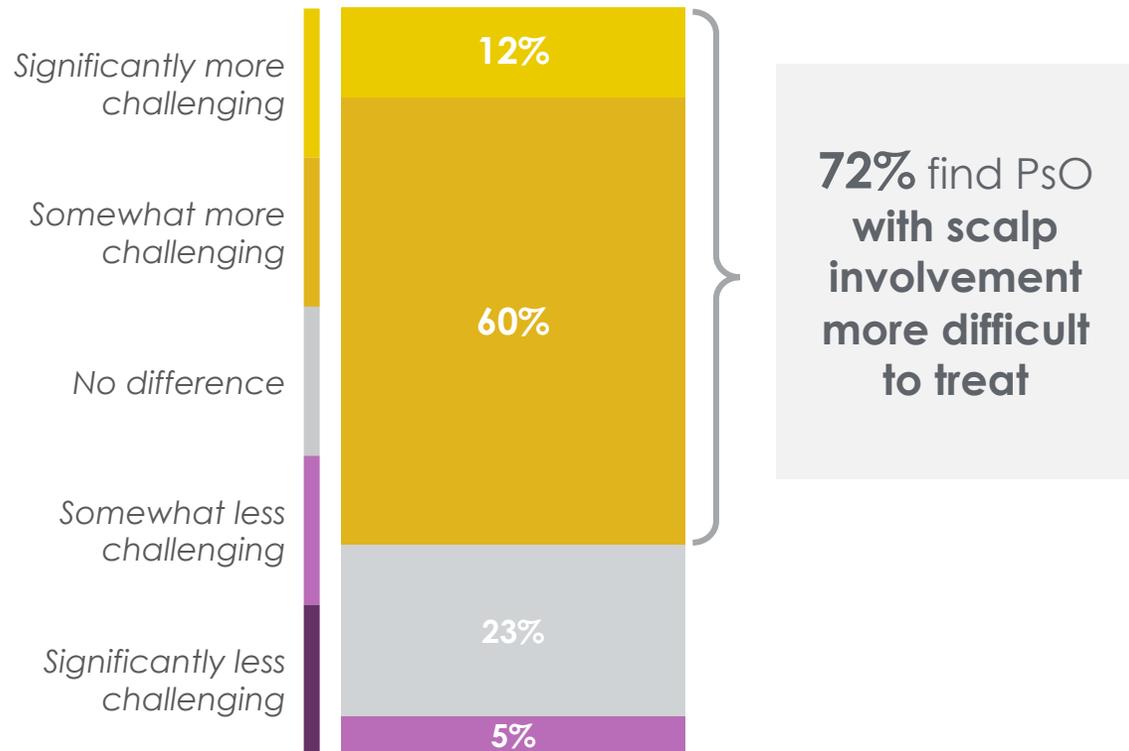
1. Chan CS, Van Voorhees AS, Lebwohl MG, et al. Treatment of severe scalp psoriasis: from the Medical Board of the National Psoriasis Foundation. J Am Acad Dermatol. 2009;60(6):962-971

2. Blakely K, Gooderham M, Management of scalp psoriasis : current perspectives. Psoriasis: Targets and Therapy 29 March 2016

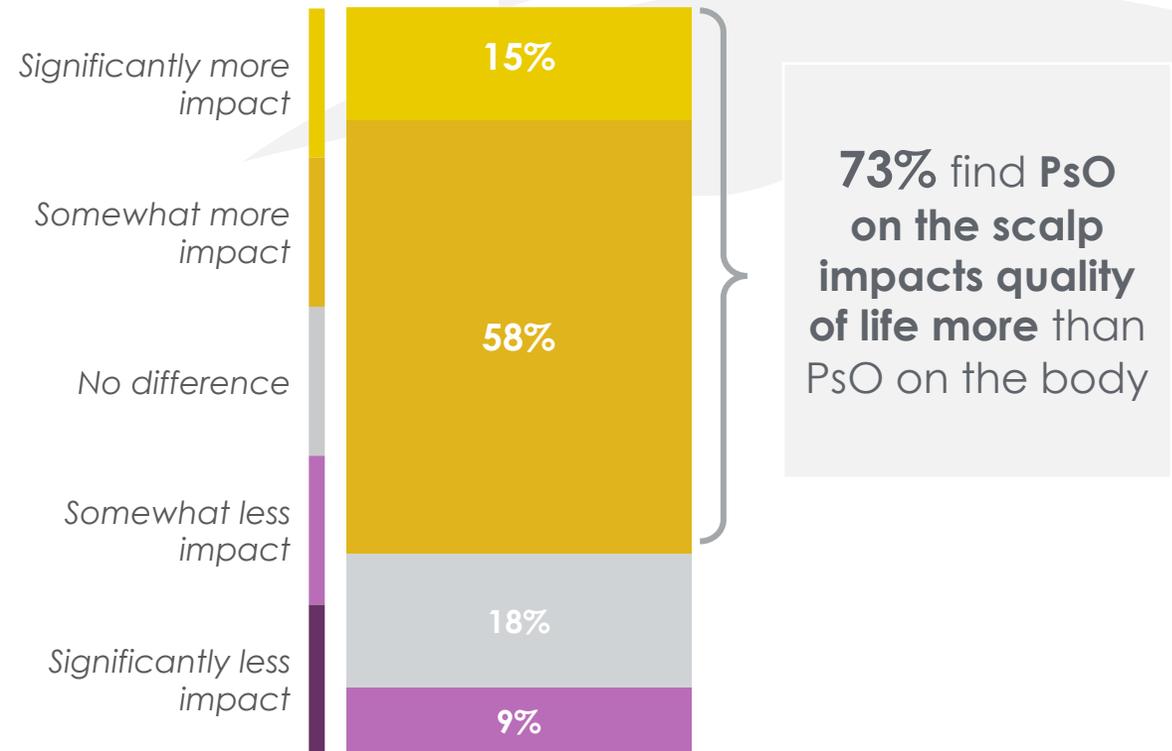
3. Arcutis Quantitative Scalp PsO Research November 2020, n=101 Dermatology HCPs

# Scalp PsO More Challenging to Treat Than Body PsO and More Impactful to Patient QOL

Treatment Challenge of Scalp PsO vs Body



QOL Impact of Scalp PsO vs Body



Arcutis Quantitative Scalp PsO Research November 2020, n=101 Dermatology HCPs

# Scalp PsO Patients' Perspectives on Impact to Quality of Life

**73%**  
Dermatologists believe that scalp has a larger impact on QoL

## Patient testimonials:

"I am so miserable...my most recent flare up started 6 months ago...I alternate between the coal tar shampoo and [ketoconazole] shampoo, but recently my scalp has been on FIRE. It's never felt like this before. My scalp feels tight and it even hurts to lay down in bed at night...I'm just in a lot of pain physically and emotionally."<sup>1</sup>



**"The scalp is the worst.** That's where it started out for me, too. I had some in the back of my head and behind my ears. **After a year it had spread to my entire scalp.** It actually looked like I had a **severe case of dandruff...**"



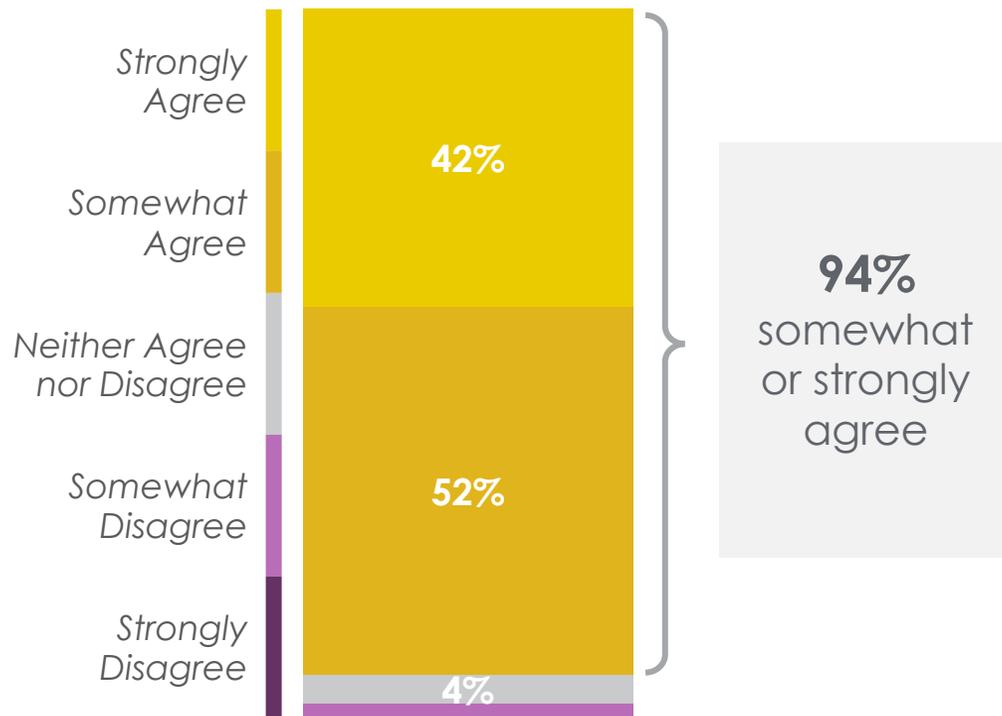
**"Now, my scalp, that's a whole other pain in the ass.** I've tried so many different shampoos... whichever one I use I have to put it on my scalp nice and thick, and let it sit for about 15 minutes. Rinse repeat... The only problem is that I don't feel like sitting around doing all that, **it's a nuisance...**"<sup>1</sup>



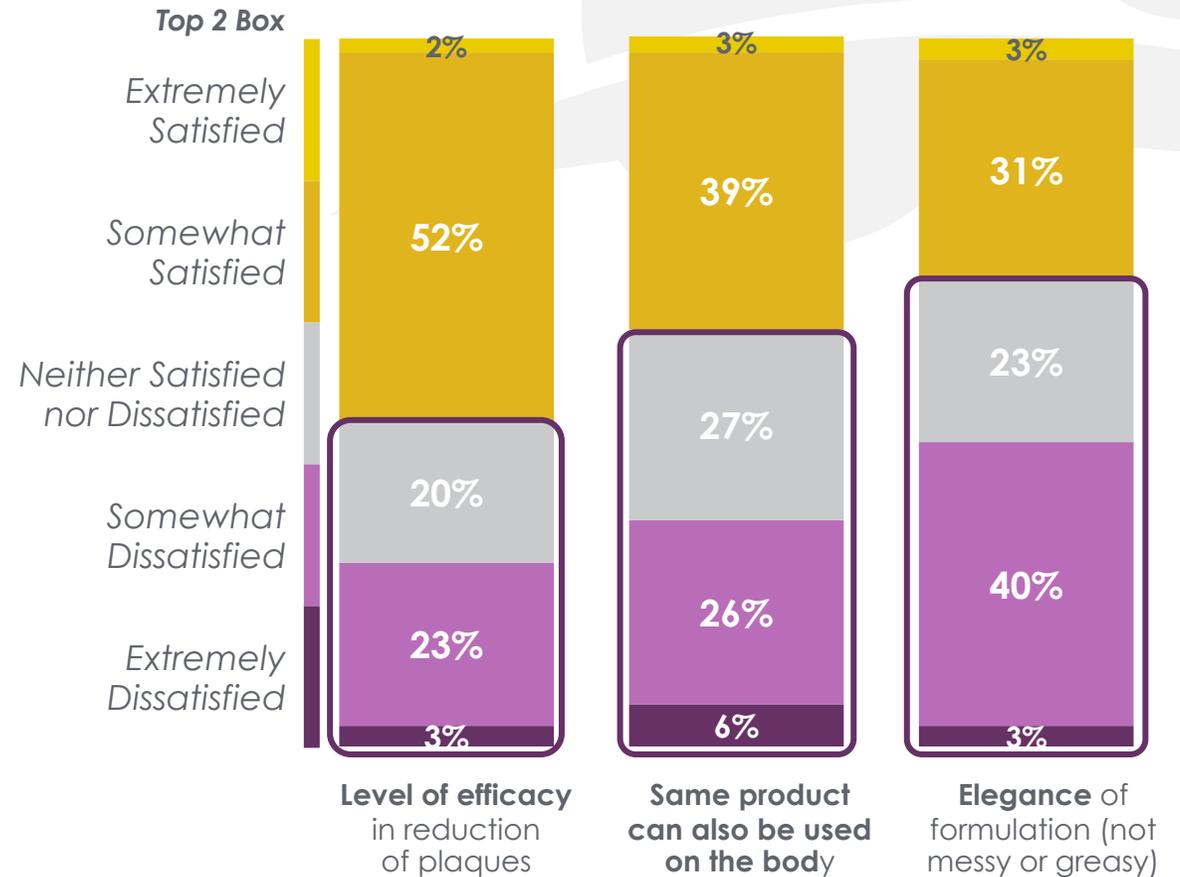
Arcutis Quantitative Scalp PsO Research November 2020, n=101 Dermatology HCPs  
Sources: 1. Reddit r/Psoriasis (Patient)

# Dermatologists See Greater Unmet Needs in Scalp PsO Than Body PsO

## Scalp unmet need is greater than for Body



## Drivers of Dissatisfaction

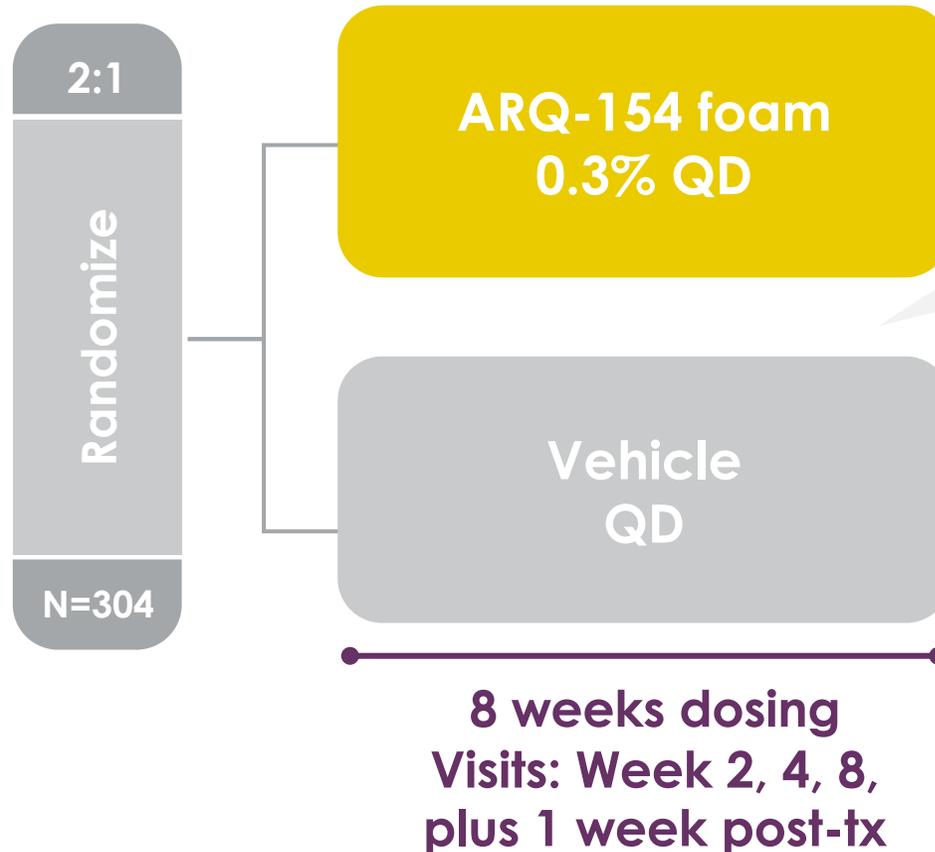


Arcutis Quantitative Scalp PsO Research November 2020, n=101 Dermatology HCPs

# ARQ-154-204 – Phase 2b Study Design

## Eligibility

- Aged  $\geq 12$ y
- Diagnosis of scalp and body plaque psoriasis
- At least Mild severity\* on both scalp (S-IGA) and body (B-IGA) IGAs
- $\leq 25\%$  BSA
- Psoriasis Scalp Severity Index (PSSI)  $\geq 6$
- $\geq 10\%$  of scalp involved
- PASI  $\geq 2$



## Endpoints

### Primary

- Scalp-IGA (S-IGA) success

*Available today*

### Secondary

- Body-IGA (B-IGA) success
- Scalp worst itch NRS (SI-NRS)
- PSSI-50/75/90/100
- S-IGA=0
- Psoriasis Symptoms Diary (PSD)

### Exploratory

- PASI
- WINRS
- DLQI
- BSA

### Safety and Tolerability

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

# Study Populations

	ARQ-154 0.3%	Vehicle	Overall
ITT	200 (100%)	104 (100%)	304 (100%)
Safety Population	198 (99.0%)	104 (100%)	302 (99.3%)
mITT	200 (100%)	102 (98.1%)	302 (99.3%)
Baseline SI-NRS $\geq 4$ , ITT	173 (86.5%)	96 (92.3%)	269 (88.5%)
Baseline WI-NRS $\geq 4$ , ITT	165 (82.5%)	94 (90.4%)	259 (85.2%)

**ITT** = all randomized subjects

**Safety population** = all subjects who are enrolled and received at least 1 confirmed dose of IP

**mITT** = all randomized subjects with the exception of subjects who missed the week 8 IGA assessment specifically due to COVID-19 disruption

**Baseline SI-NRS  $\geq 4$**  population = subset of the ITT that includes subjects with SI-NRS pruritus score  $\geq 4$  at Baseline

**Baseline WI-NRS  $\geq 4$**  population = subset of the ITT or mITT that includes subjects with WI-NRS pruritus score  $\geq 4$  at Baseline

# Subject Disposition

	ARQ-154 0.3% (N=200)	Vehicle (N=104)	Overall (N=304)
Completed	177 (88.5%)	87 (83.7%)	264 (86.8%)
Prematurely discontinued	23 (11.5%)	17 (16.3%)	40 (13.2%)
Reason for discontinuation			
Withdrawal by subject	9 (4.5%)	6 (5.8%)	15 (4.9%)
Sponsor decision	0	0	0
PI Decision	0	0	0
Non-compliance	1 (0.5%)	0	1 (0.3%)
Protocol violation	0	0	0
Lost to follow-up	8 (4.0%)	7 (6.7%)	15 (4.9%)
Adverse event	5 (2.5%)	2 (1.9%)	7 (2.3%)
Death	0	0	0
Pregnancy	0	0	0
Other	0	2 (1.9%)	2 (0.7%)

# Demographics (ITT Population)

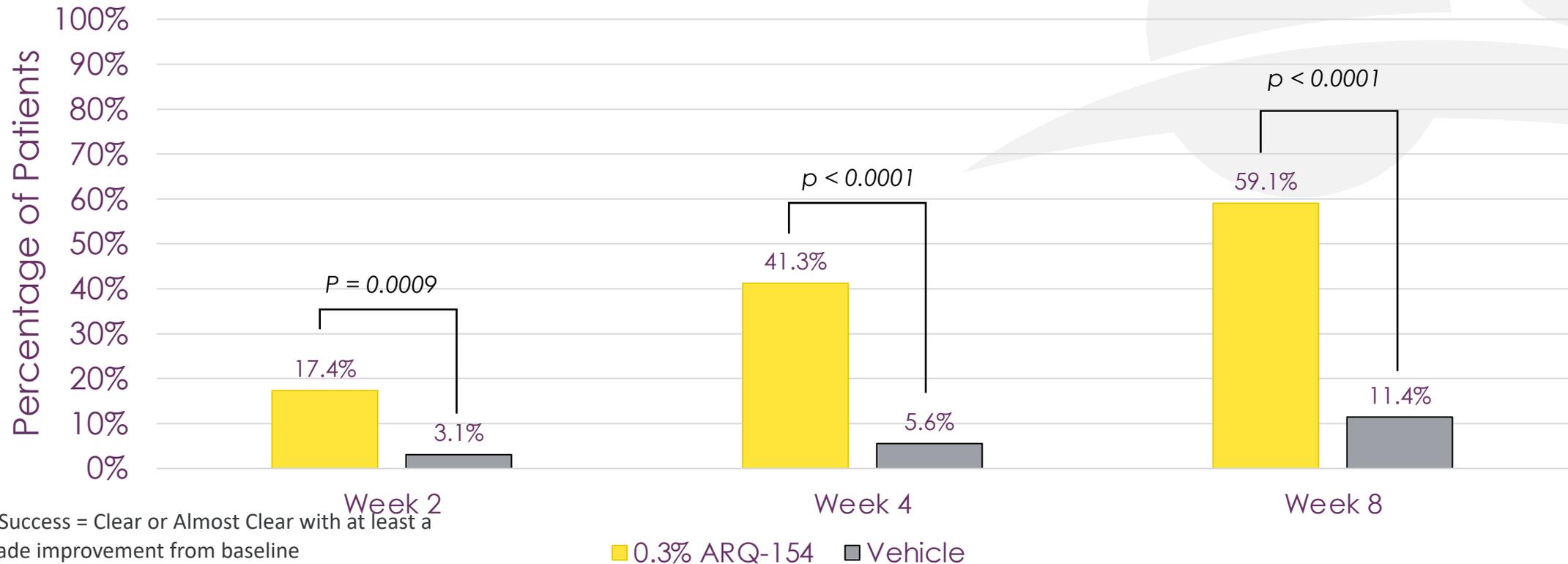
	ARQ-154 0.3% (N=200)	Vehicle (N=104)	Overall (N=304)
Age, mean (yrs)	45.2	45.0	45.1
<b>Gender</b>			
Male	96 (48.0%)	47 (45.2%)	143 (47.0%)
Female	104 (52.0%)	57 (54.8%)	161 (53.0%)
<b>Ethnicity</b>			
Hispanic or Latino	38 (19.0%)	25 (24.0%)	63 (20.7%)
Not Hispanic or Latino	161 (80.5%)	79 (76.0%)	240 (78.9%)
<b>Race</b>			
American-Indian or Alaskan Native	0	0	0
Asian	7 (3.5%)	4 (3.8%)	11 (3.6%)
Black or African-American	9 (4.5%)	6 (5.8%)	15 (4.9%)
Native Hawaiian or Other Pacific Islander	0	1 (1.0%)	1 (0.3%)
White	180 (90.0%)	91 (87.5%)	271 (89.1%)
Other	1 (0.5%)	0	1 (0.3%)
More than one race	1 (0.5%)	1 (1.0%)	2 (0.7%)

# Baseline Characteristics (ITT Population)

	ARQ-154 0.3% (N=200)	Vehicle (N=104)	Overall (N=304)
BSA, mean %	8.0	7.6	7.9
<b>Baseline S-IGA</b>			
2 – Mild	18 (9.0%)	14 (13.5%)	32 (10.5%)
3 – Moderate	151 (75.5%)	80 (76.9%)	231 (76.0%)
4 – Severe	29 (14.5%)	10 (9.6%)	39 (12.8%)
<b>Baseline B-IGA</b>			
2 – Mild	69 (34.5%)	39 (37.5%)	108 (35.5%)
3 – Moderate	119 (59.5%)	60 (57.7%)	179 (58.9%)
4 – Severe	10 (5.0%)	5 (4.8%)	15 (4.9%)
PSSI, mean (SD)	22.4 (12.52)	20.9 (11.70)	21.9 (12.25)
PASI, mean (SD)	7.18 (4.288)	6.78 (4.383)	7.04 (4.317)
SI-NRS, mean (SD)	6.4 (2.35)	6.6 (2.25)	6.5 (2.31)
SI-NRS, $\geq 4$ , N (%)	173 (86.5%)	96 (92.3%)	269 (88.5%)
WI-NRS, mean (SD)	6.4 (2.48)	6.7 (2.32)	6.5 (2.42)
WI-NRS, $\geq 4$ , N (%)	165 (82.5%)	94 (90.4%)	259 (85.2%)

# S-IGA Success at Each Visit (ITT)

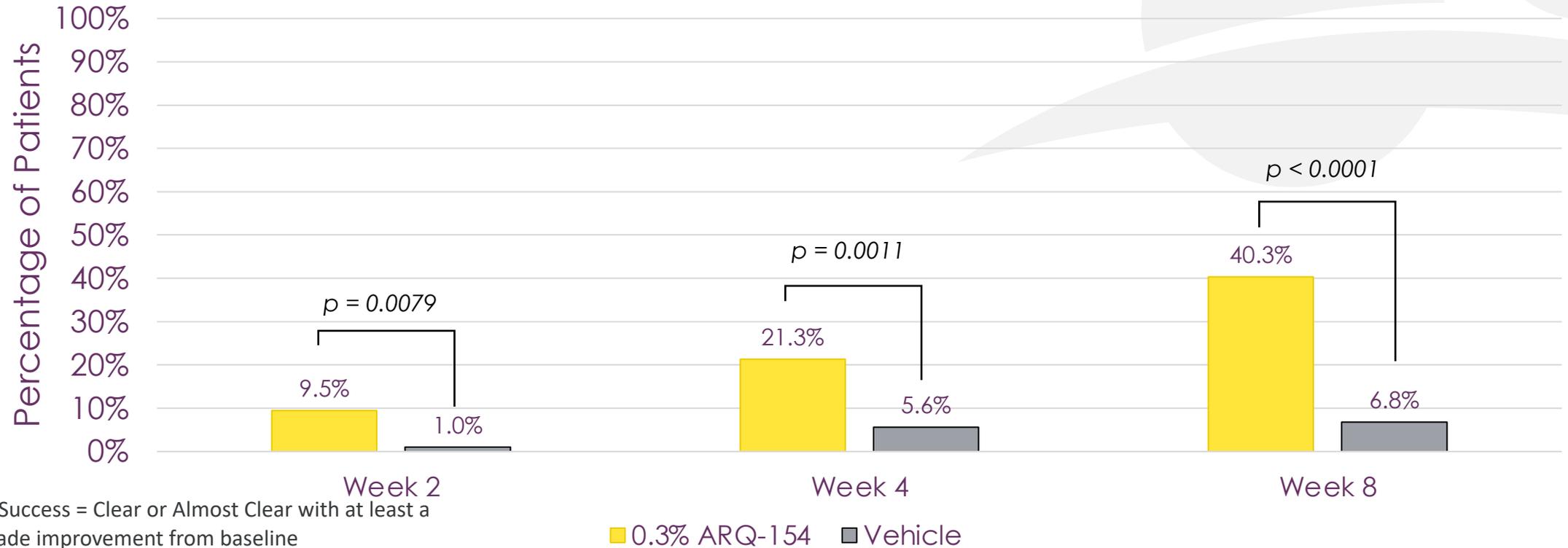
~ 60% of Patients Achieved S-IGA Success at Week 8



**34.3% of patients on active achieved S-IGA = clear versus 3.4% on vehicle**

# B-IGA Success at Each Visit (ITT)

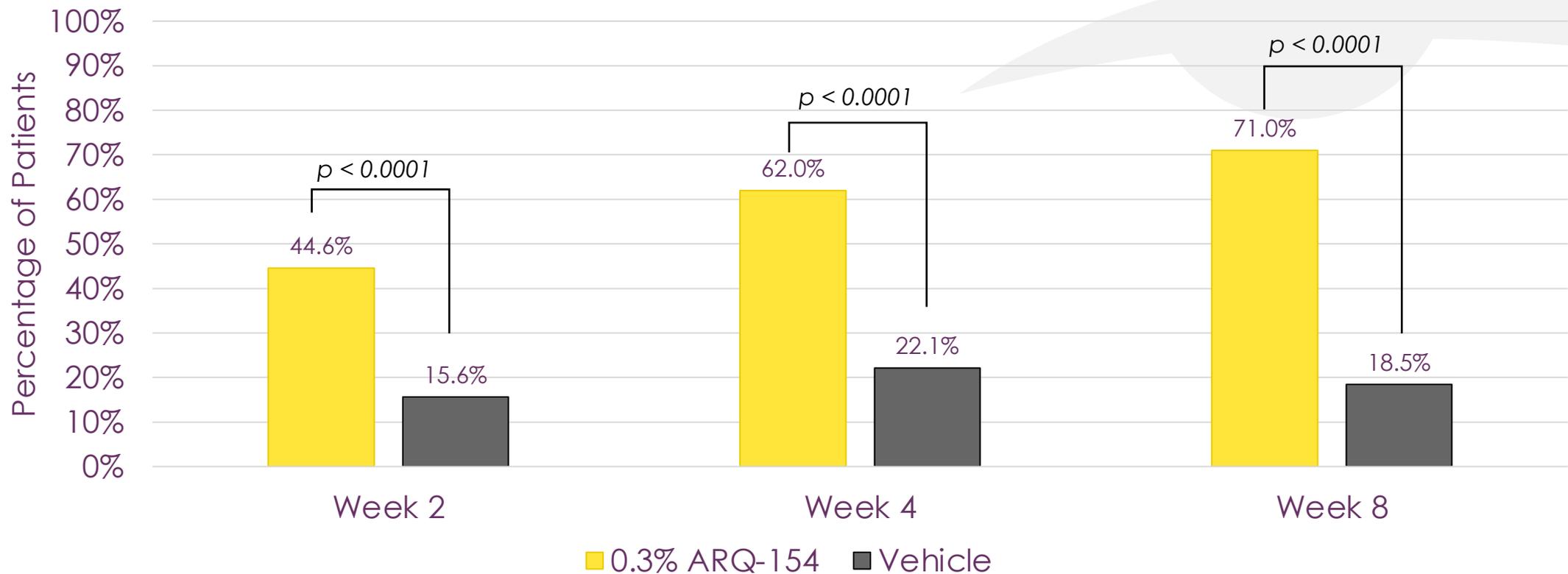
## 40% of Patients Achieved B-IGA Success at Week 8



**26.0% of patients on active achieved B-IGA = clear versus 3.4% on vehicle**

# Scalp Itch (SI-NRS) Response in Patients with a SI-NRS Score $\geq 4$ at Baseline

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



# Low Rates of Adverse Events (Safety Population)

	ARQ-154 0.3% (N=198)	Vehicle (N=104)	Overall (N=302)
Subjects with any TEAE	46 (23.2%)	20 (19.2%)	66 (21.9%)
Subjects with any Tx-Related TEAE	8 (4.0%)	9 (8.7%)	17 (5.6%)
Subjects with any SAE	1 (0.5%)	0	1 (0.3%)
Subjects who discontinued Study Drug due to AE	5 (2.5%)	2 (1.9%)	7 (2.3%)
Subjects who discontinued Study due to AE	5 (2.5%)	2 (1.9%)	7 (2.3%)

1 SAE = Testicular torsion, unrelated

# Most Common TEAEs by Preferred Term

**≥ 1.5% in any group**

Preferred Term	ARQ-154 0.3% (N=198)	Vehicle (N=104)	Overall (N=302)
Application site pain	2 (1.0%)	4 (3.8%)	6 (2.0%)
COVID-19	3 (1.5%)	2 (1.9%)	5 (1.7%)
Psoriasis	1 (0.5%)	2 (1.9%)	3 (1.0%)
Sinusitis	1 (0.5%)	2 (1.9%)	3 (1.0%)
Hypertension	3 (1.5%)	1 (1.0%)	4 (1.3%)
Diarrhea	3 (1.5%)	0 (0.0%)	3 (1.0%)

# Scalp PsO: Topical Treatment Options

	Regimens	Efficacy	Side Effects	List Price
<b>CLOBETASOL</b> <b>Olux (foam / emulsion)</b> <i>Mod, severe of scalp and mild, moderate non-scalp, excluding face &amp; intertriginous</i>	2x/ day	63% IGA 0/1 @ 2 weeks  Single study: 188 subjects	No localized scalp adverse reactions reported in the subjects treated with OLUX Foam Non-scalp region: 10% burning	\$536
<b>FLUOCINOLONE</b> <b>Acetonide</b> <b>Topical Oil</b>	1x a day overnight with shower cap	60% IGA 0/1 @ 3 weeks	Dryness, folliculitis, acne, contact dermatitis	\$178
<b>CALCIPOTRIENE</b> <b>Dovonex Scalp (solution)</b> <i>"moderately severe"</i>	2x/ day	31% IGA 0/1	Transient burning, stinging 23% Rash 11% Dry skin, worsening of PsO 1-5%	\$768
<b>CALCIPOTRIENE</b> <b>Sorilux (foam)</b> <i>Scalp &amp; body, 12 yrs+</i>	2x/ day	41% ISGA 0/1 @ 8 wks (n = 181)	Pain 4% Pruritis 4% Erythema 3%	\$829

Pricing Source: ProspectRx, October 2020 ; Product FDA Package Inserts

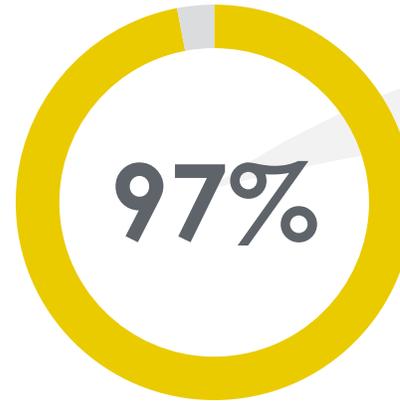
# Scalp PsO: Topical Combination\* Options

	Regimens	Efficacy	Side Effects	List Price
<b>BETAMETHASONE CALCIPOTRIENE COMBO</b> <b>Taclonex Suspension</b> <i>Scalp and body</i>	1x/ day up to 8 weeks	Trial 1: IGA 0/1 Week 2: 55% IGA 0/1 Week 8: 70% Trial 2: Week 2: 47% IGA 0/1 Week 8: 67%	<ul style="list-style-type: none"> <li>• Burning</li> <li>• Folliculitis</li> </ul>	\$1113
<b>Enstilar Foam</b> <i>No specific scalp indication</i>	2x/ week for 4 weeks	Trial 1: 45% Trial 2: 53% IGA 0 / 1 @ 4 weeks	Adverse reactions reported in <1% of pediatric patients: acne, erythema, application site pain, and skin reactions	\$1113

\*calcipotriene and betamethasone dipropionate  
Pricing Source: ProspectRx, October 2020 ; Product FDA Package Inserts

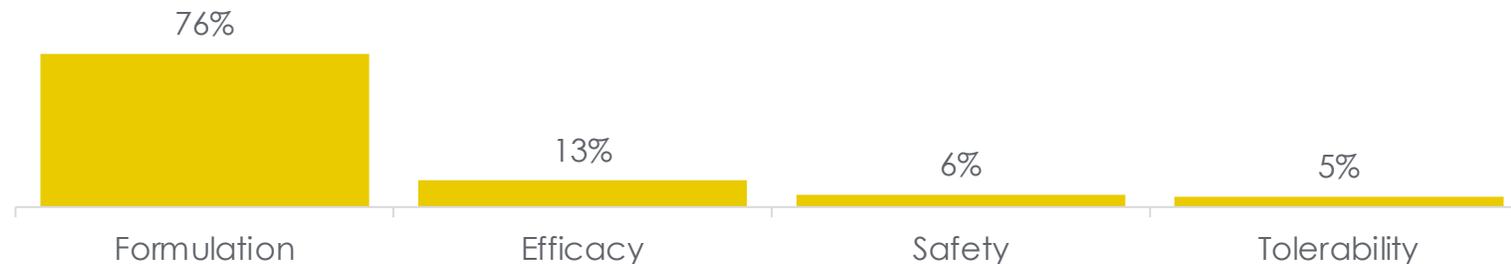
# Majority of Patients with Scalp Involvement Receive Multiple Treatments

Use of topicals for patients with PsO on scalp and body



Of surveyed HCPs would like to have a **single non-steroidal topical treatment** that would work **on both** the scalp and body

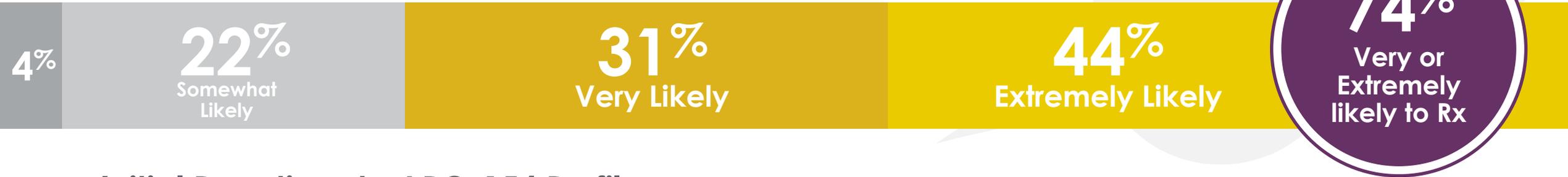
Primary reasons for using different topicals to treat the scalp and body



Arcutis Quantitative Scalp PsO Research November 2020, n=101 Dermatology HCPs

# High Derm Interest in Roflumilast Foam

## Dermatologist Likelihood to Prescribe Roflumilast Foam



## Initial Reactions to ARQ-154 Profile (Open End)

*"It would be exciting to have **one product for body and scalp that is non-steroidal.**"*

*"I like the idea of a foam that will **penetrate the hair without leaving it greasy**, the PDE-4 mechanism of action is a new concept and **could be used on full body with no safety concerns.**"*

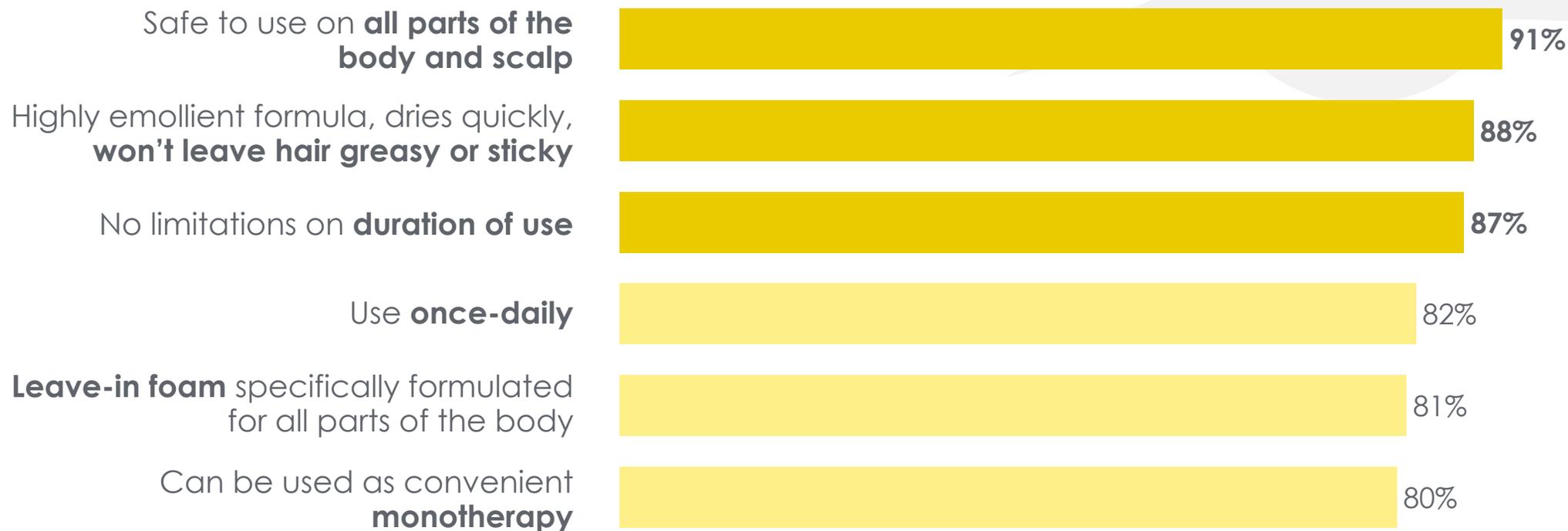
*"Product X looks great, because it is **non-steroidal**, in a foam formulation that is **easy to apply**, can be **used long term**, can be used for **all parts of the body**, and shows **improvement within 2 weeks.**"*

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# Derms Especially Interested in Ability to Use Everywhere, Vehicle, and Chronic Use

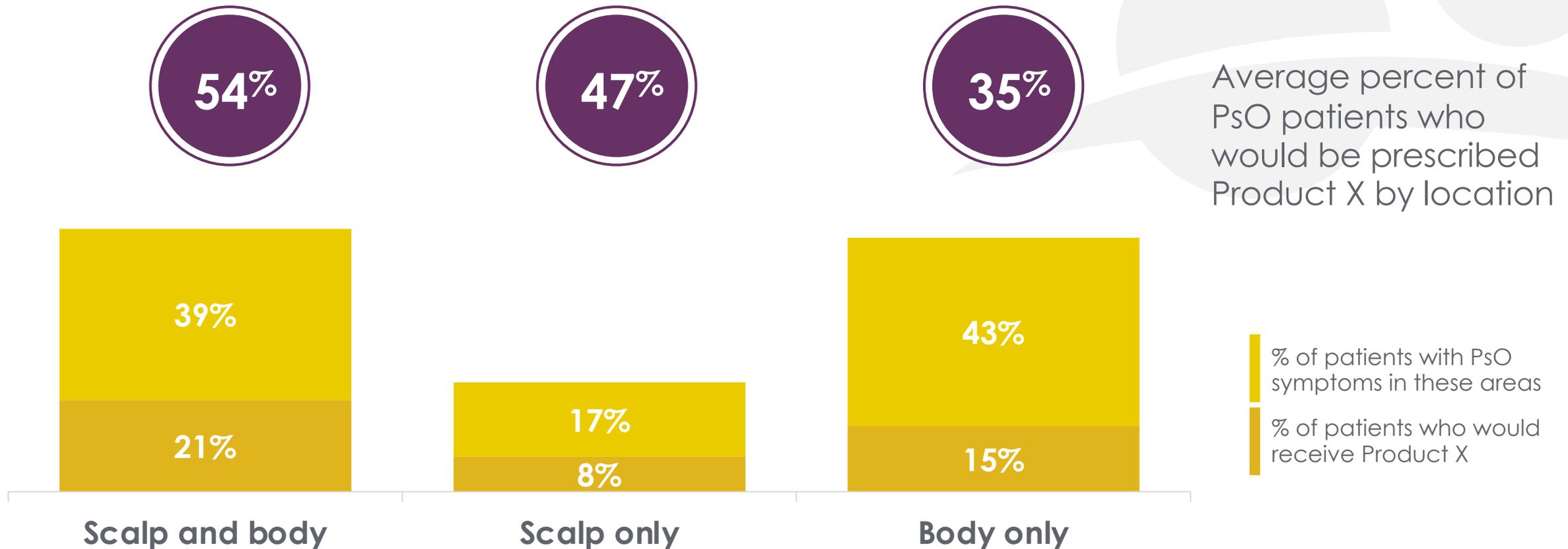
## Compelling Product Profile Statements

(top 2 – very/extremely compelling, see notes for full statements)



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# Derms Expect to Use in Patients both with and without Scalp Involvement



Arcutis Quantitative Scalp PsO Research November 2020, n=101 Dermatology HCPs

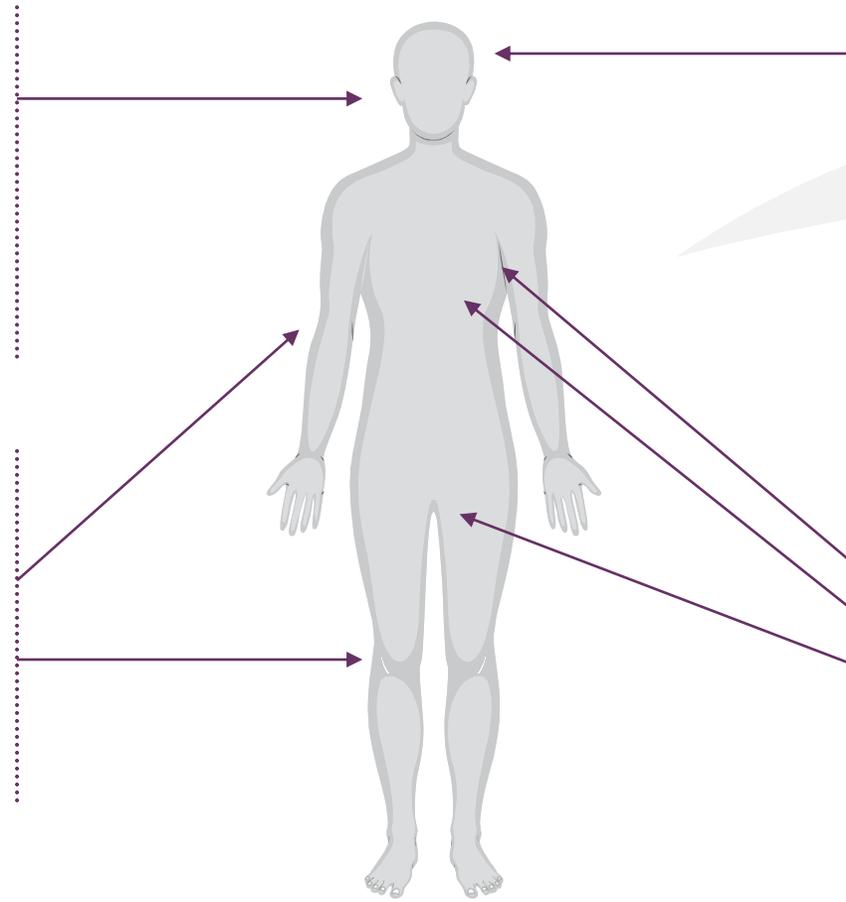
# Topical Roflumilast Foam Allows for Treatment of all Challenging Areas of the Body

## ✓ Face ~10%

- More easily irritated
- Thin skin, greater drug absorption
- Risks if steroids get in eyes

## ✓ Elbows/Knees ~35%

- Often resistant to treatment



## Scalp ~40% ✓

- Difficult to deliver drug to skin
- Can't use creams or ointments
- Effect on hair style can impact compliance

## Intertriginous ~15% ✓

- More easily irritated
- Thin skin, greater drug absorption
- More prone to stretch marks

1. National Psoriasis Foundation

# Roflumilast Foam Potentially “Best-in-Class” Treatment for Scalp Psoriasis

- Efficacy on par with high potency steroids or Otezla
- Favorable tolerability profile even on sensitive areas
- Suitable for chronic use
- Foam vehicle is ideal for hair-bearing areas such as scalp, where cream, lotion, or ointment not suitable
- Safe to use near the eyes
- One treatment can be used on all areas of the body, obviating need for polypharmacy

# Thank You

