ARCUTIS BIOTHERAPEUTICS

Seborrheic Dermatitis

September 2020

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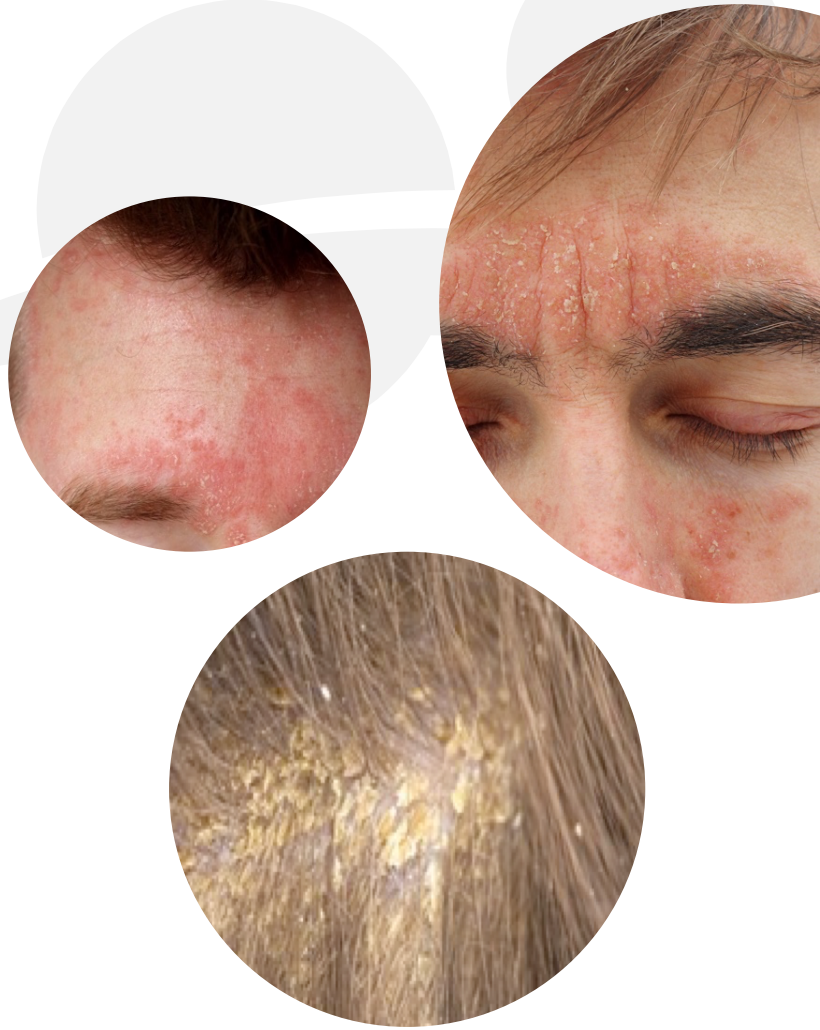
Seborrheic Dermatitis Phase 2 Data Call

Frank Watanabe

President & CEO

Seborrheic Dermatitis (Seb Derm)

- Common, chronic inflammatory skin disease
- Affects 10M people in the U.S.
- Appears as itchy red patches covered by greasy, flaking scales on the scalp, face & chest



Negative Impact on Quality of Life (QoL)

Seb derm can have a significant, negative influence on QoL

Psychological Distress

Oily skin and flakiness in visible areas causes psychological distress

Women Express Particular Self-Consciousness

Limits clothing choices (no black), hairstyle (due to Rx shampoos), and make-up

Significant QoL Impact

QoL impacted by all symptoms: erythema, flaking, oily skin, and pruritus[1]

Perception of Poor Hygiene

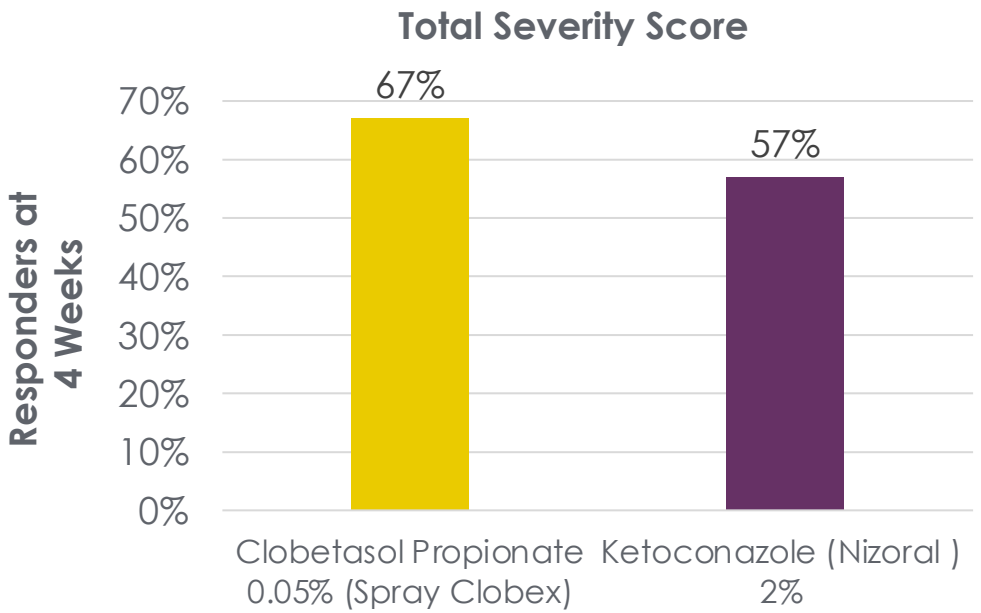
Patients are perceived as "dirty," causes negative impact on self-esteem

QoL is Key Driver for Rx

High patient QoL burden motivates dermatologists to treat seb derm

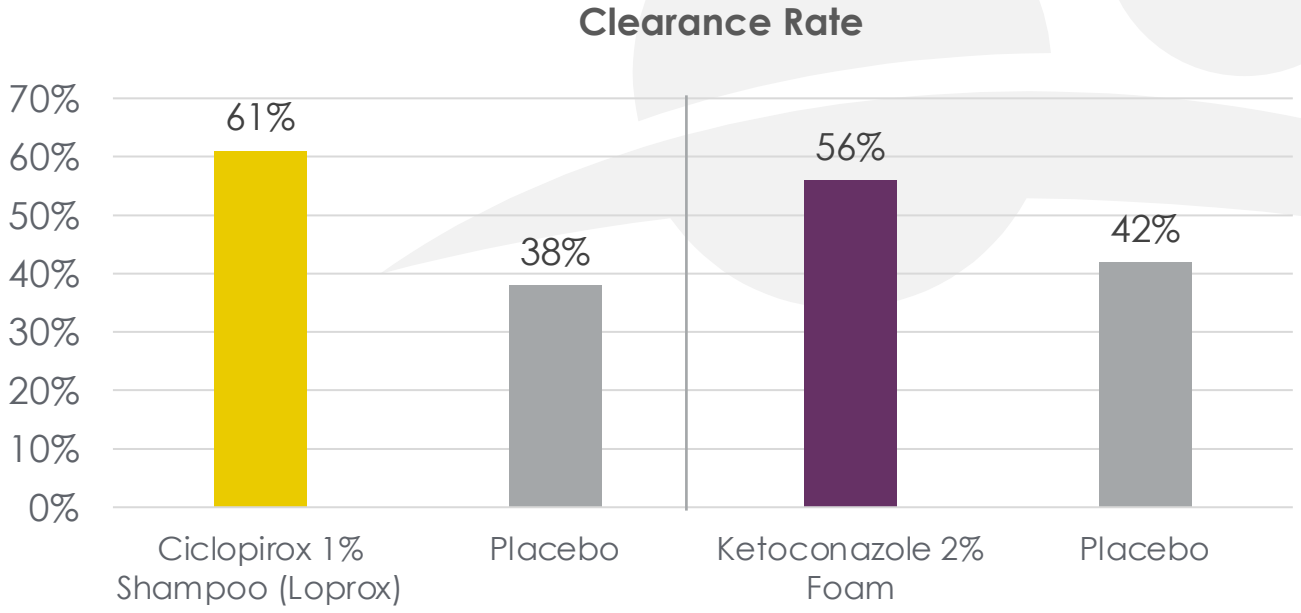
Szepietowski JC, Reich A, Wesołowska-Szepietowska E, Baran E. National quality of life in dermatology group. 2009

Efficacy Benchmarks



n= 326

- Total severity score (TSS) ≥2 defined as sum of erythema, loose desquamation, and adherent desquamation at 4 weeks[1]
- Moderate-to-severe scalp SD (IGA of 3 or 4 on a 5-point scale)
- TEAEs: 5%



n= 183

- Responders equals none or slight (0-1 scores) at 4 weeks[2]

n= 1,162

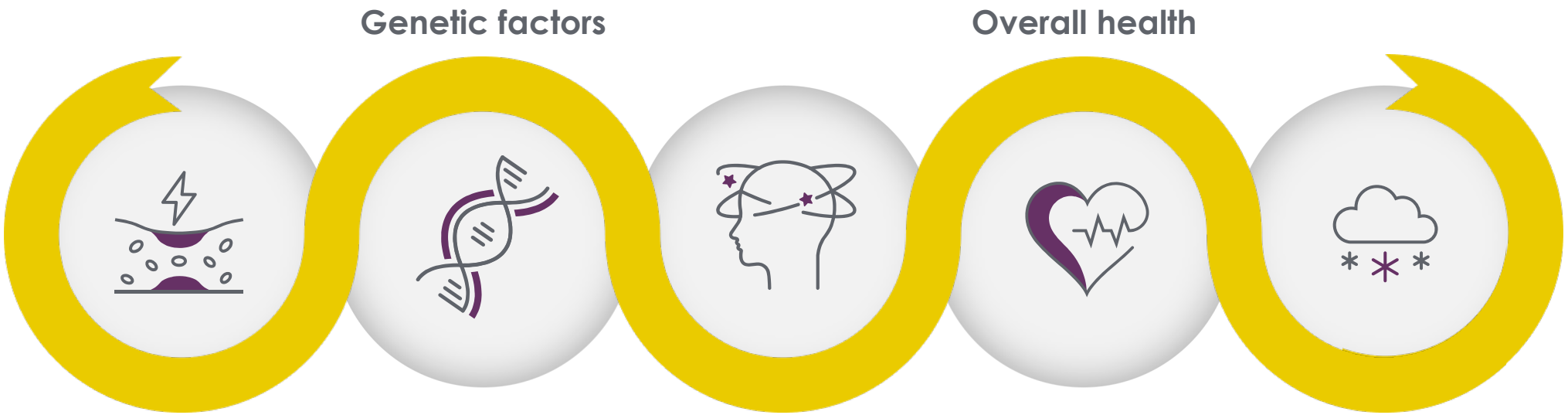
- IGA score of 0 or 1 at 4 weeks equals treatment success[3]
- Placebo rate: 42%
- Predominantly mild subjects
- TEAEs: 14%

References: 1. 2011 (Ortonne, JP – Galderma funded) 2. 2004 (Abeck, D) 3. 2007 (Elewski, BE)

Patrick Burnett, M.D., Ph.D., FAAD

Chief Medical Officer

Seb Derm Contributing Factors



Particular yeast that lives on all human skin

Emotional or physical stress, such as lack of sleep

Climate (usually worse in cold weather)

Limitations of Current Seb Derm Treatments

Topical Anti-Fungals

- Often used as first-line therapy
- Often ineffective for long-term remission

Topical steroids

- Increased risk of glaucoma and cataracts
- No chronic high-potency steroid use beyond 2-4 weeks
- Skin atrophy concerns since skin on face and scalp is thin

Non-steroidals

- Perceived lack of efficacy and/or tolerability

No single product appropriate for both scalp and face/body

- Many patients use 3-5 products
- Time management challenge and complexity
- Reduces patient compliance
- Increases time / expense (multiple co-pays)

Rx shampoos

- Usage usually 2x/week for up to 4 weeks
- Texture of vehicle can mess up hair styles and dry out hair
- Perceived unpleasant smell

Topical Roflumilast Foam

Roflumilast foam offers a highly differentiated clinical profile

Selective, highly potent anti-inflammatory PDE4 inhibitor

Investigated for use as a once daily, non-steroidal, anti-inflammatory topical formulation

“Leave on” foam formulation allows for use on all body parts, including hair-bearing areas

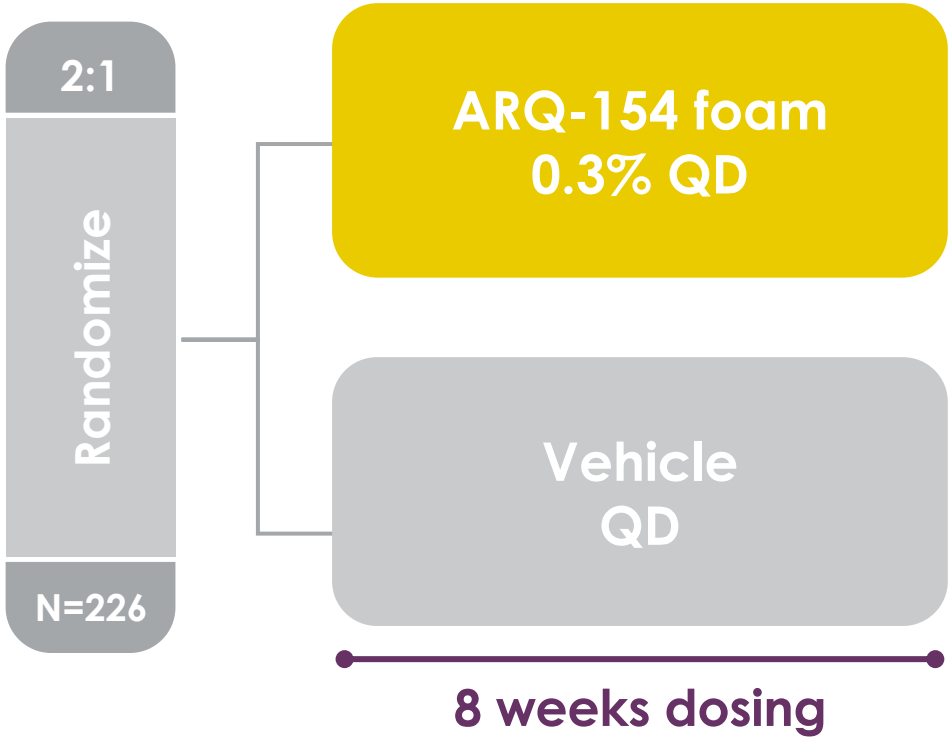
More potent (25- to 300-fold) than the two other FDA-approved PDE4 inhibitors

Oral roflumilast approved by FDA for COPD in 2011

Phase 2 Study of Roflumilast Foam in Seb Derm

Eligibility

- Diagnosis of at least moderate seb derm
- Aged ≥18 y
- ≤20% BSA



Endpoints

Primary

- IGA success at week 8

Secondary

- Overall assessment of erythema
- Overall assessment of scaling
- WI-NRS

Exploratory

- Scalpdex
- DLQI
- BSA

Safety and tolerability

[a]IGA success was defined as IGA score of 0 or 1 (clear or almost clear) with at least a two-grade improvement from baseline.
BSA, body surface area; DLQI, dermatology life quality index; IGA, investigator global assessment; QD, once daily; WI-NRS, worst itch numeric rating scale.
NCT04091646. https://clinicaltrials.gov/ct2/show/NCT04091646. Accessed July 20, 2020.

Study Populations

	ARQ-154 0.3%	Vehicle	Overall
ITT	154 (100%)	72 (100%)	226 (100%)
Safety Population	154 (100%)	72 (100%)	226 (100%)
mITT*	153 (99.4%)	71 (98.6%)	224 (99.1%)
PRU4	125 (81.2%)	59 (81.9%)	184 (81.4%)
PRU2	141 (91.6%)	68 (94.4%)	209 (92.5%)

* Excludes 2 subjects: One roflumilast subject (31003) who was enrolled Mar 6, then withdrew consent due to the fear of contracting COVID-19 (informed site May 1), with no post-baseline visits, and one vehicle subject (17006) who missed week 8 IGA due to COVID, but did not discontinue due to COVID, and came back for the week 9

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
PRU4 population = subset of the ITT population and includes subjects with WI-NRS pruritus score ≥4 at Baseline
PRU2 population = subset of the ITT population and includes subjects with WI-NRS pruritus score ≥ 2at Baseline

Subject Disposition

	ARQ-154 0.3% (N=154)	Vehicle (N=72)	Overall (N=226)
Completed	141 (91.6%)	67 (93.1%)	208 (92.0%)
Prematurely discontinued	13 (8.4%)	5 (6.9%)	18 (8.0%)
Reason for discontinuation			
Withdrawal by subject	4 (2.6%)	1 (1.4%)	5 (2.2%)
Sponsor decision	0	0	0
PI Decision	0	0	0
Non-compliance	0	0	0
Protocol violation	0	1 (1.4%)	1 (0.4%)
Lost to follow-up	6 (3.9%)	2 (2.8%)	8 (3.5%)
Adverse event	2 (1.3%)	1 (1.4%)	3 (1.3%)
Death	0	0	0
Pregnancy	0	0	0
Other	1 (0.6%)	0	1 (0.4%)

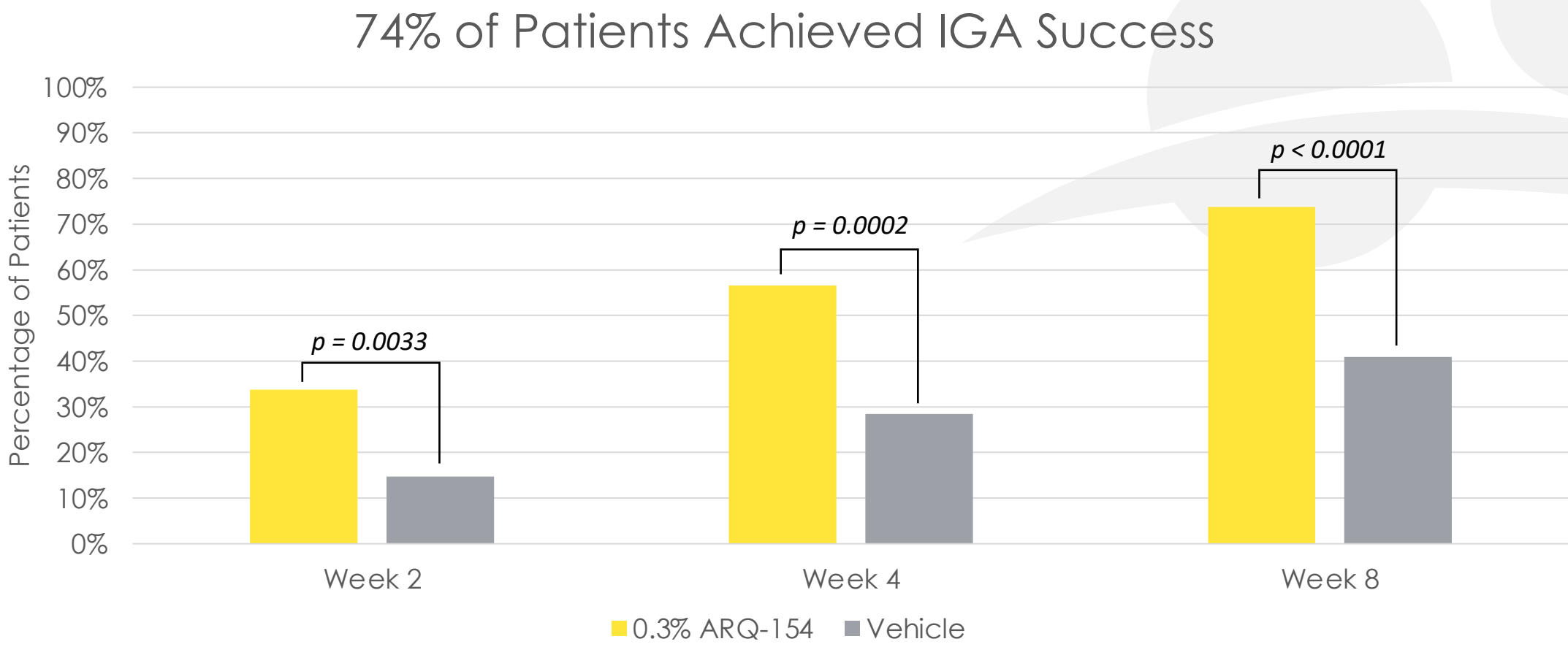
Demographics (Safety Population)

	ARQ-154 0.3% (N=154)	Vehicle (N=72)	Overall (N=226)
Age, mean (yrs)	45.3	44.2	44.9
Gender			
Male	76 (49.4%)	40 (55.6%)	116 (51.3%)
Female	78 (50.6%)	32 (44.4%)	110 (48.7%)
Ethnicity			
Hispanic or Latino	29 (18.8%)	16 (22.2%)	45 (19.9%)
Not Hispanic or Latino	125 (81.2%)	56 (77.8%)	181 (80.1%)
Race			
American-Indian or Alaskan Native	1 (0.6%)	0	1 (0.4%)
Asian	7 (4.5%)	1 (1.4%)	8 (3.5%)
Black or African-American	17 (11.0%)	6 (8.3%)	23 (10.2%)
Native Hawaiian or Other Pacific Islander	0	0	0
White	123 (79.9%)	62 (86.1%)	185 (81.9%)
Other	1 (0.6%)	2 (2.8%)	3 (1.3%)
More than one race	5 (3.2%)	1 (1.4%)	6 (2.7%)

Baseline Characteristics (Safety Population)

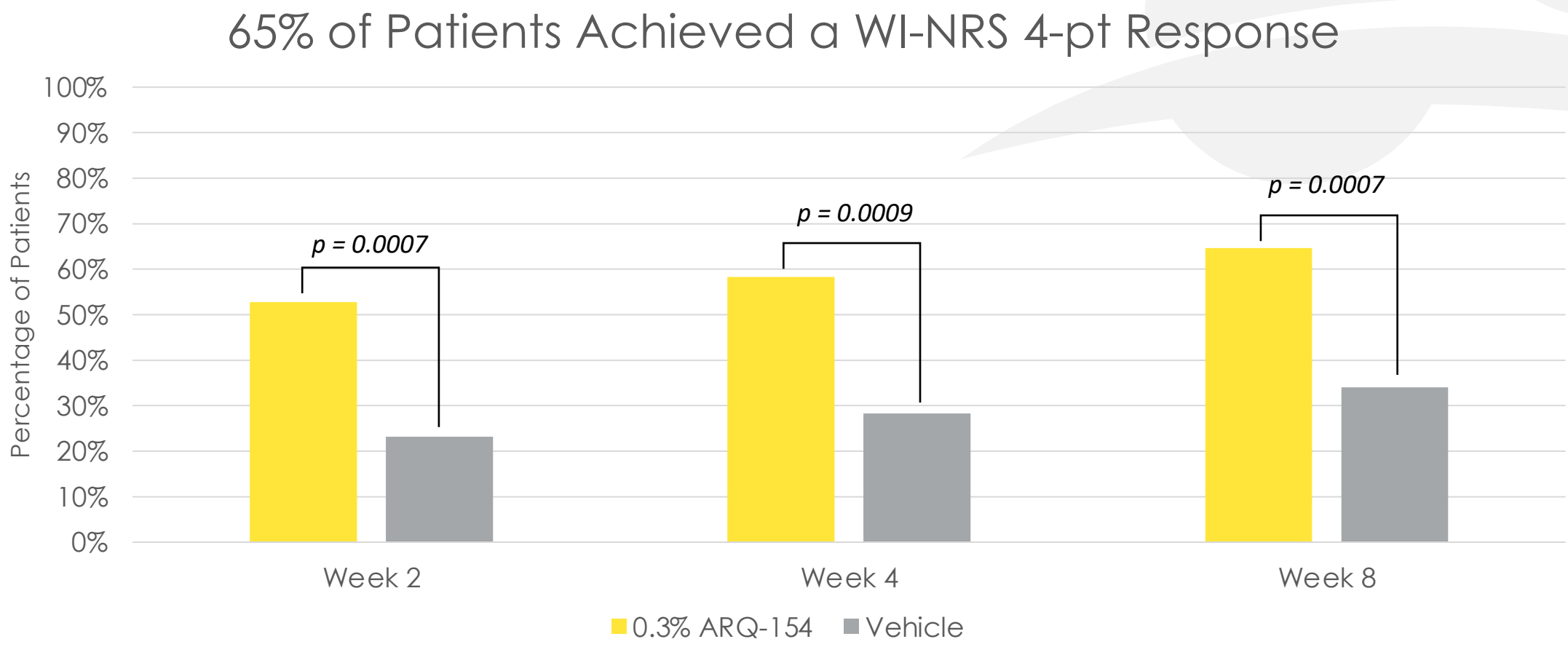
	ARQ-154 0.3% (N=154)	Vehicle (N=72)	Overall (N=226)
BSA, mean (%)	3.3	3.0	3.2
Baseline IGA (0-4)			
3 – Moderate	141 (91.6%)	69 (95.8%)	210 (92.9%)
4 – Severe	13 (8.4%)	3 (4.2%)	16 (7.1%)
Baseline Erythema (0-3)			
2 – Moderate	135 (87.7%)	66 (91.7%)	201 (88.9%)
3 – Severe	19 (12.3%)	6 (8.3%)	25 (11.1%)
Baseline Scaling (0-3)			
2 – Moderate	130 (84.4%)	58 (80.6%)	188 (83.2%)
3 – Severe	24 (15.6%)	14 (19.4%)	38 (16.8%)
WINRS			
Mean	5.8 (2.66)	5.7 (2.33)	5.8 (2.56)
Median	6.0	6.0	6.0
$\geq$4	125 (81.2%)	59 (81.9%)	184 (81.4%)
Facial involvement	100 (64.9%)	36 (50.0%)	136 (60.2%)

IGA Success at Each Visit (mITT)



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

WI-NRS 4-pt Response (PRU4 Population)



Low Rates of Adverse Events (Safety Population)

	ARQ-154 0.3% (N=154)	Vehicle (N=72)	Overall (N=226)
Subjects with any TEAE	37 (24.0%)	13 (18.1%)	50 (22.1%)
Subjects with any Tx-Related TEAE	3 (1.9%)	3 (4.2%)	6 (2.7%)
Subjects with any SAE	0	0	0
Subjects who discontinued Study Drug due to AE	2 (1.3%)	2 (2.8%)	4 (1.8%)
Subjects who discontinued Study due to AE	2 (1.3%)	1 (1.4%)	3 (1.3%)

Most Common TEAE's by Preferred Term ≥ 2% *in any group*

Preferred Term	ARQ-154 0.3% (N=154)	Vehicle (N=72)	Overall (N=226)
Contact Dermatitis	3 (2%)	2 (3%)	5 (2%)
Insomnia	3 (2%)	1 (1%)	4 (2%)
Nasopharyngitis	3 (2%)	0 (0%)	3 (1%)

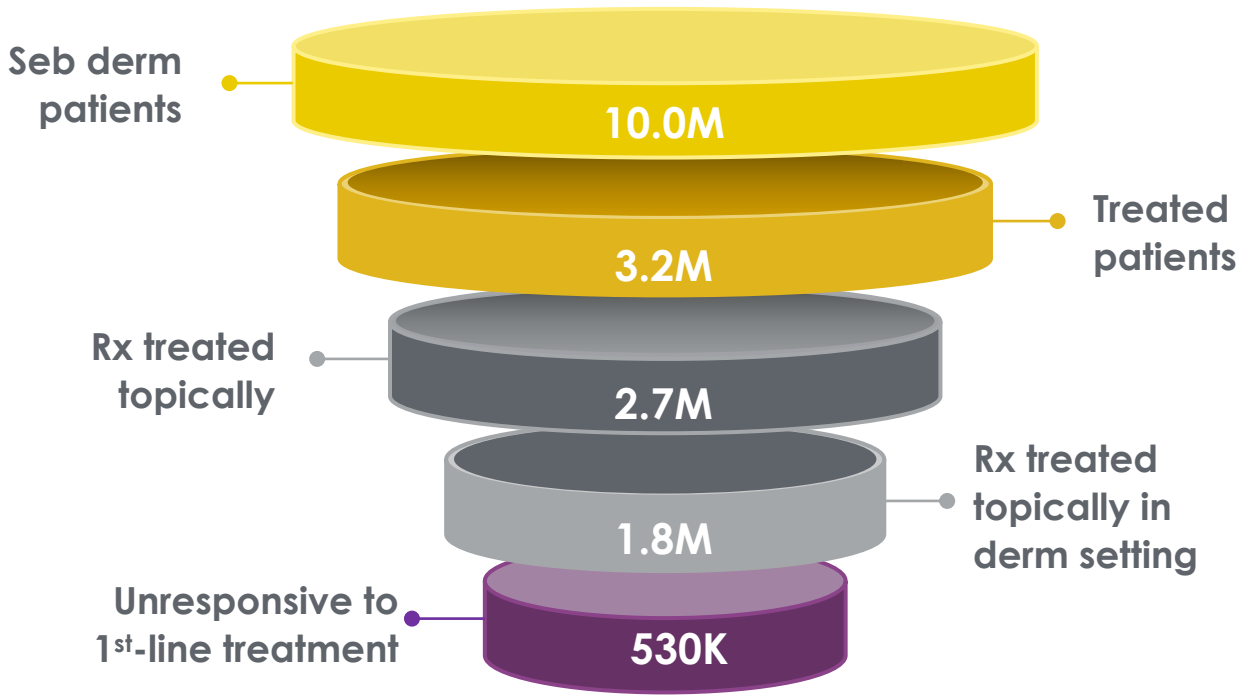
Dr. Matthew Zirwas, M.D.

Founder of the Bexley Dermatology Research Clinic and Investigator in the Trial

Ken Lock

Chief Commercial Officer

Seb Derm Prevalence



Additional opportunities to drive value in Seb Derm:

- Market growth due to educational efforts and promotional investment
- U.S. patients treated by other specialties (e.g., PCPs)
- Ex-US markets

In Derm Offices the Volume and Severity Is In-line with Psoriasis

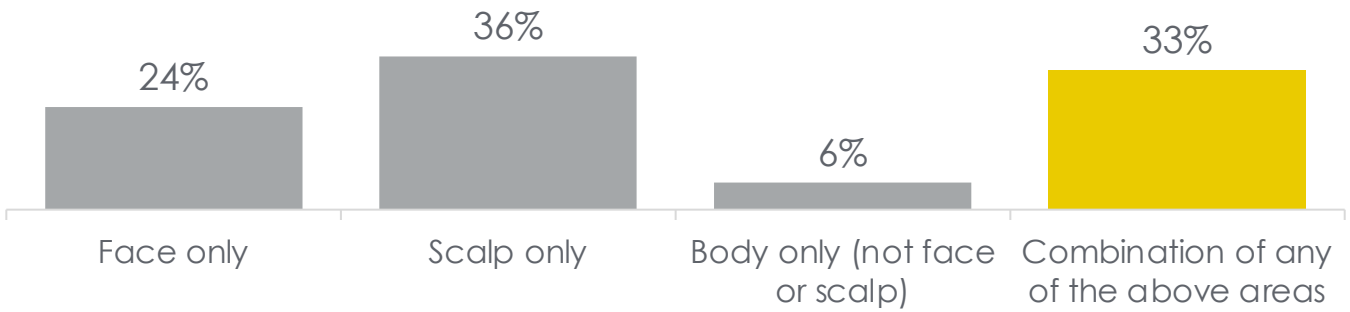
55 patients

average number of seborrheic dermatitis patients seen in a typical month

Severity of Seborrheic Dermatitis

41%	42%	17%
Mild	Moderate	Severe

Symptoms Experienced in Each Area



From qualitative research and pilot interviews, most of the combinations HCPs are seeing are **Face + Scalp**

Arcutis Quantitative Seb Derm Research August 2020, n=100 Dermatology HCPs

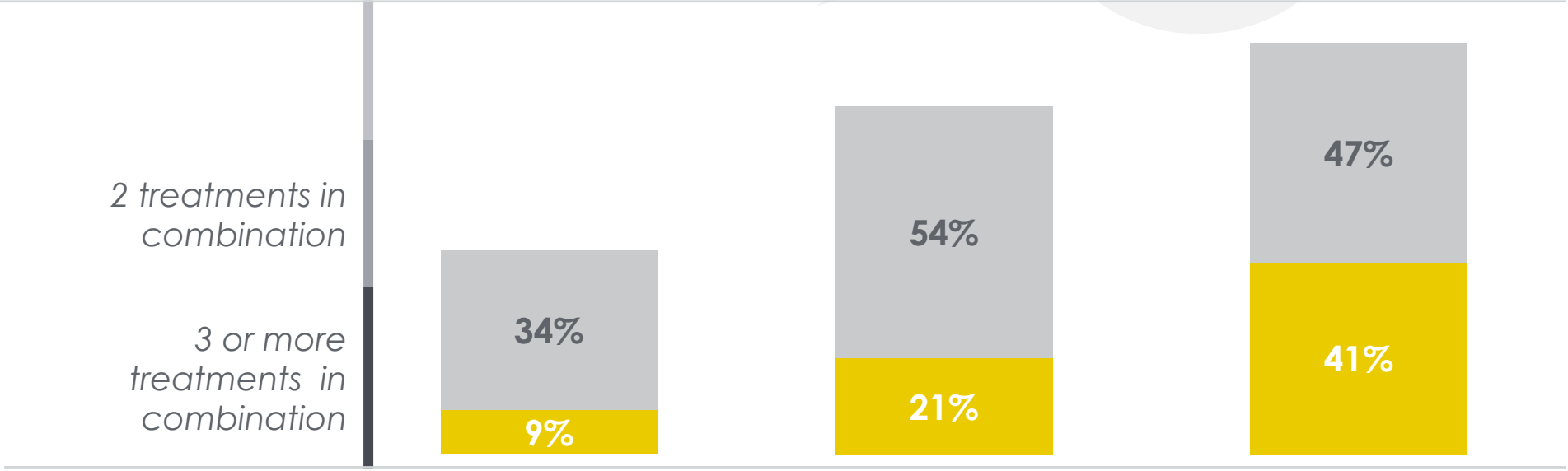
FDA Approved Seb Derm Treatment Options

	Regimens	Side Effects	Approx List Price
LOCOID Solution ***Hydrocortisone Butyrate 0.1%*** **Approved 1982**	2-3x/ daily	Burning, itching, irritation, dryness, folliculitis (these reactions are listed in an approximate decreasing order of occurrence)	$65
LOPROX Shampoo ***Ciclopirox 1%*** **Approved 1997**	2x/ week for 4 weeks with a min of 3 days between applications	1% application site reaction 1% increased itching (n=626)	$55
XOLEGEL Gel ***Ketoconazole 2%*** **Approved 2006**	1x/ day for 2 weeks	4% application site burning (the most common treatment-related adverse reaction)	$970
EXTINA Foam ***Ketoconazole 2%*** **Approved 2007**	2x/ day	Burning: 10% Extina 10% vehicle	$785

* Data from USPIs of Select Products

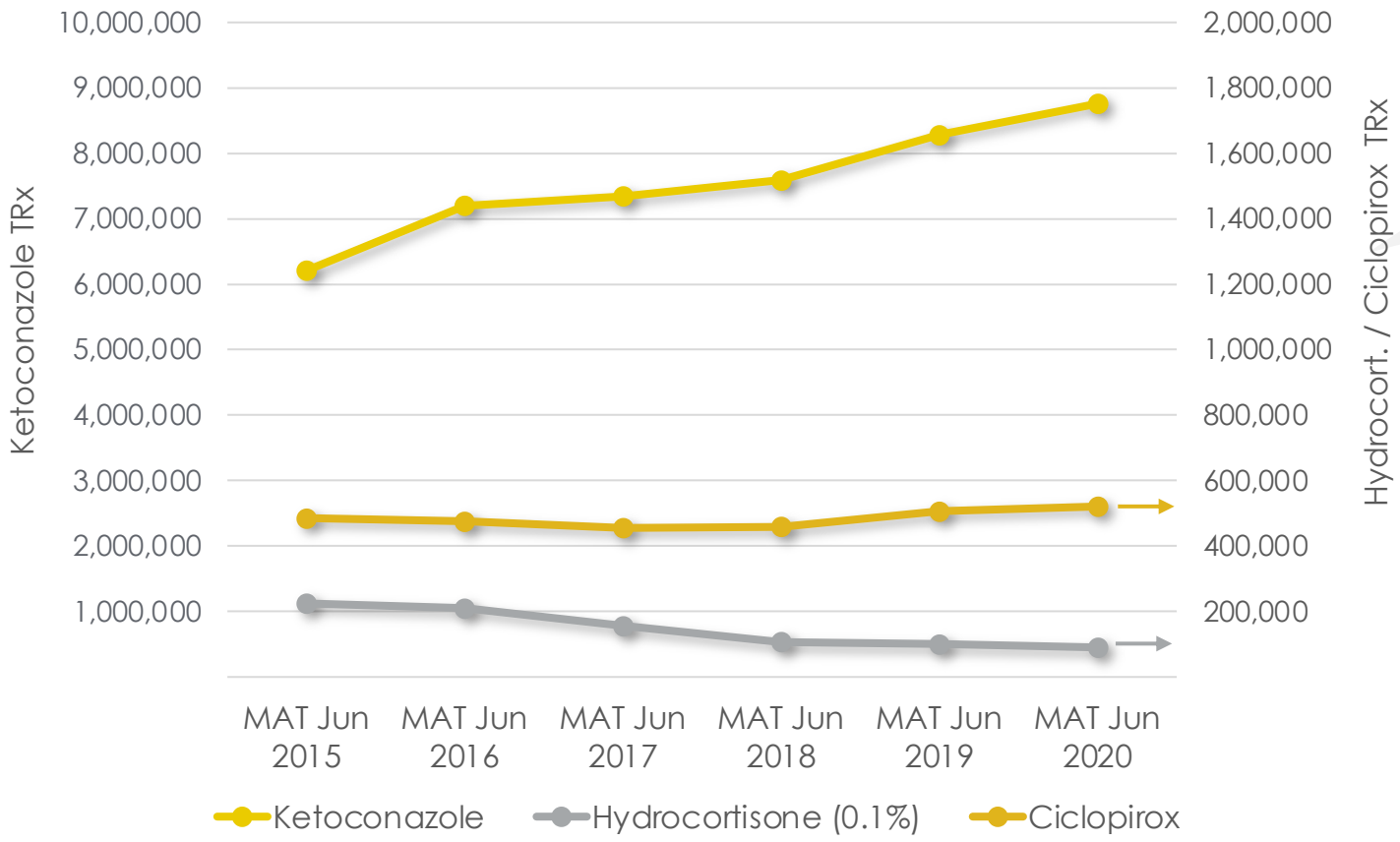
Most Patients Require 2 or More Products

	Mild	Moderate	Severe
% Patients getting 2 or more Treatments	43%	75%	88%



Arcutis Quantitative Seb Derm Research August 2020, n=100 Dermatology HCPs

TRx Trends for Approved Therapies



- There are >9M on-label TRx on an annual basis for FDA Approved therapies
- Other off-label products are used (e.g. TCSs, TCIs)
- Ketoconazole is dominant therapy and utilization is growing

Source: IQVIA June 2020 Data

Payor Sentiment

Top National Pharmacy Benefit Managers and Health Plans representing over 80 million formulary lives were surveyed

- Seborrheic dermatitis is considered a **lower payer management priority** compared to conditions like psoriasis and atopic dermatitis
- Review of current medical policies of top National PBMs and Health Plans demonstrate Rx coverage and **benefit exclusions are rare**
- Payers expressed **minimal budget impact and superior efficacy** were the most likely ways for a brand product to avoid management in predominantly generic/OTC categories

Surveyed currently view seborrheic dermatitis as a **medical condition that warrants prescription therapy**

Source: Arcutis Payer market research (August 2020, n=25)

High Interest in Roflumilast Foam

Dermatologist Likelihood to Prescribe Roflumilast Foam

Provides another possible option for these difficult-to-treat cases.(…) *The most important symptoms for most patients is the itching.*

Very, very excited that a PDE inhibitor would come to market especially in a ***foam vehicle and a non-steroidal****!"*

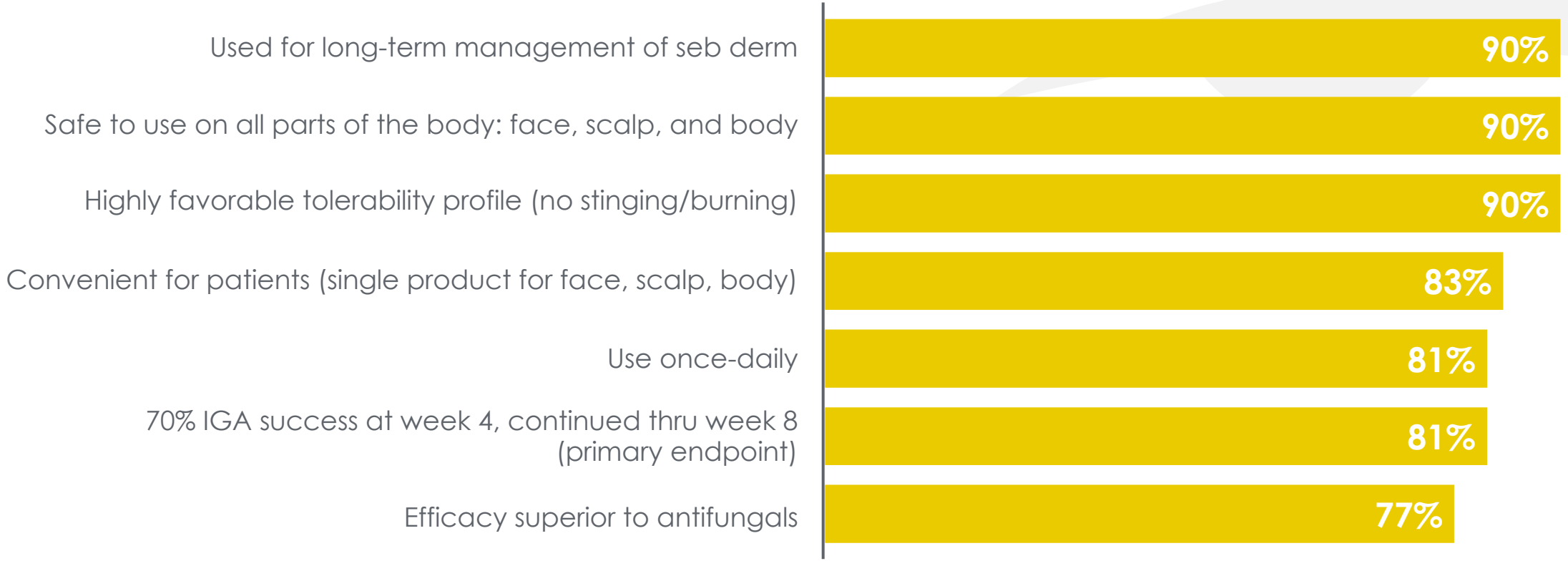
It sounds like an attractive option as it is a foam and thus ***can be used on the scalp and face.*** *I also like that it does not have alcohol which may sting the skin. It's great that it is not a topical steroid and the time frames listed for improvement are reasonable."*

Arcutis Quantitative Seb Derm Research August 2020, n=100 Dermatology HCPs

Most Compelling Aspects of Roflumilast Foam

Compelling Product Profile Statements

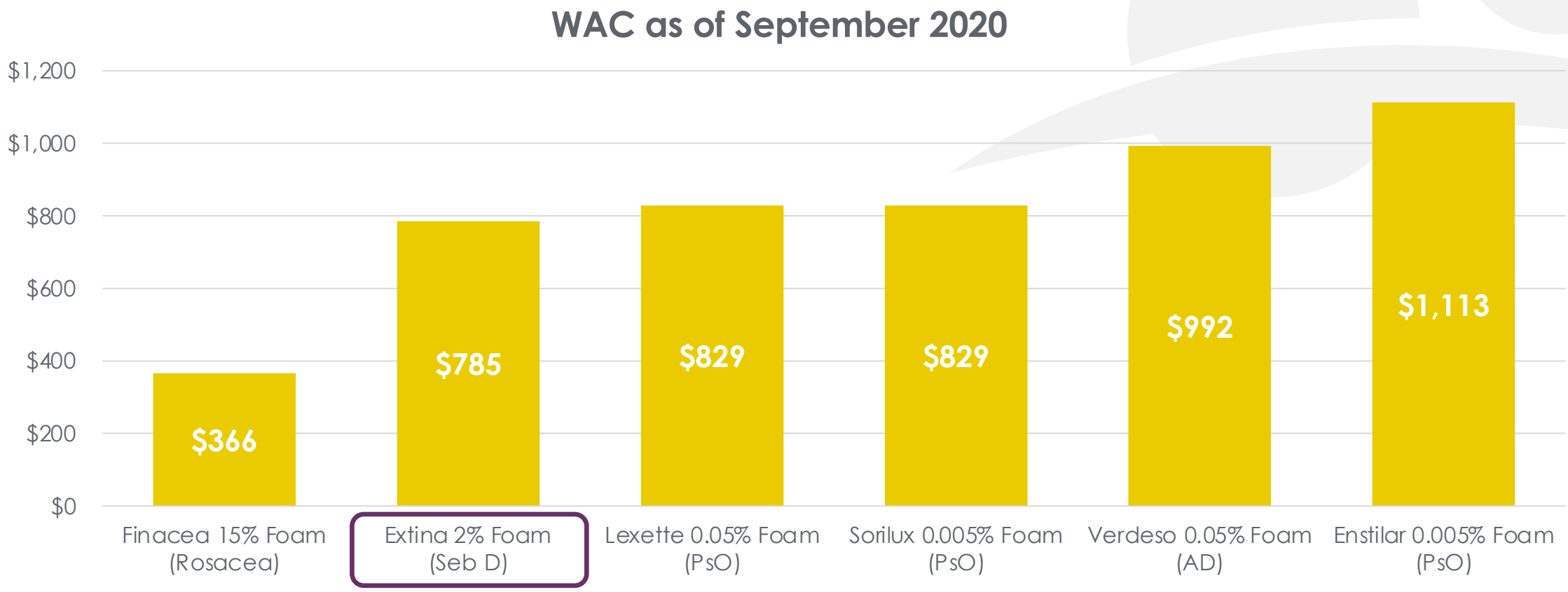
(top 2 – very/extremely compelling)



Arcutis Quantitative Seb Derm Research August 2020, n=100 Dermatology HCPs

Pricing of Current Foam Therapies

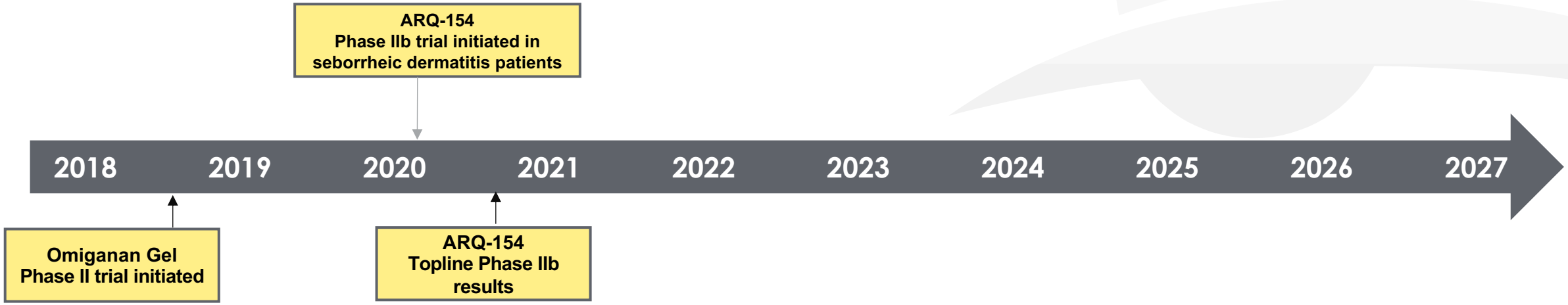
Ranges from ~$365 - $1100



Source: ProspectRx, September 2020

Seb Derm Competitive Pipeline

Development timeline for Seb Derm therapies



- 1.75% BID Gel
- Facial SD Only
- Mild to Moderate Pts
- Antifungal MOA

Source: Clintrials.gov Sept 2020 Seborrheic Dermatitis Trials

~5 Million Patients Currently Treated Topically by Dermatologists in US

US 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
Rx treated (Topically) in Derm Setting	**2.0**	**1.0**	**1.8**

Additional opportunities to unlock value of our molecules:

- U.S. patients treated by other specialties (e.g., PCPs or pediatricians)
- Ex-US markets

If Approved, Roflumilast Foam:

Novel Mechanism

- Will be first treatment in decades to offer a novel mechanism of action for the treatment of seb derm

"Best in Class"

- Has potential to be a "best in class" treatment for patients with seb derm

Convenience

- Will be an easy-to-use, once daily, single treatment option for both scalp and face/body

Suitability

- Will be suitable for use in hair-bearing areas (unlike creams), as well as face and around the eyes (unlike steroids)

The Potential of Roflumilast Foam

Current Treatments

- No single product works for scalp, face and body
- Most patients need an arsenal of products to manage disease
- Steroids not meant to be used chronically
- Shampoos can be drying

Roflumilast Foam

- Roflumilast can be used on all body areas, including hair-bearing
- Once-a-day roflumilast offers the convenience of a single product
- Has shown efficacy and is well tolerated – suitable for long-term use
- Dries quickly, is unscented and contains no drying ethanol

Thank You