



ARCUTIS
BIOTHERAPEUTICS

Seborrheic Dermatitis

September 2020

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Seborrheic Dermatitis:

Impact, Therapeutic Landscape & Unmet Need

Seborrheic Dermatitis (Seb Derm)

- Common, chronic inflammatory skin disease
- Affects > 6M people in the U.S.
- Appears as itchy red patches covered by greasy, flaking scales on the scalp, face & chest



Seb Derm Incidence

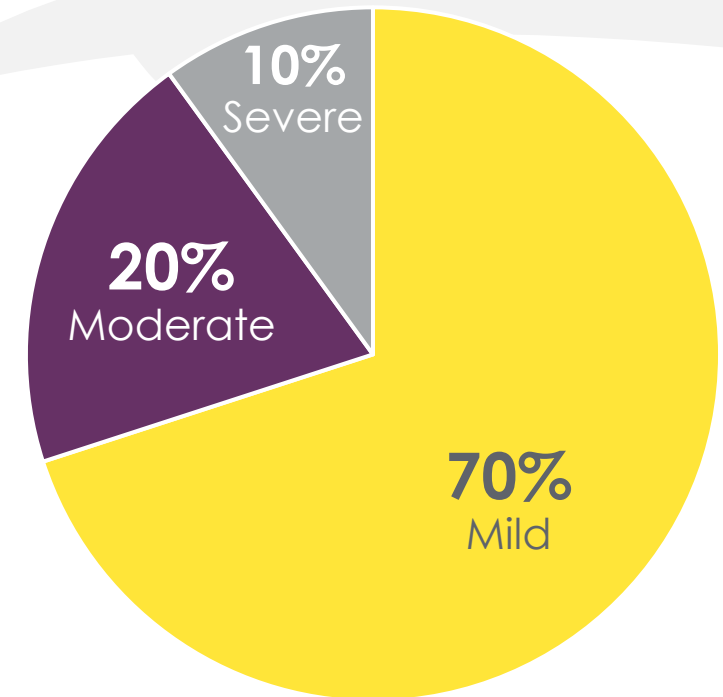
Incidence Peaks During 3 Age Periods

- In infants (cradle cap)
- In adolescents during puberty
- In adults 30 to 70 years, with increasing prevalence in older adults

Dermatologists see many patients





- Seb derm is one of the “bread and butter” conditions of any practice

Most Cases Mild-to-Moderate*



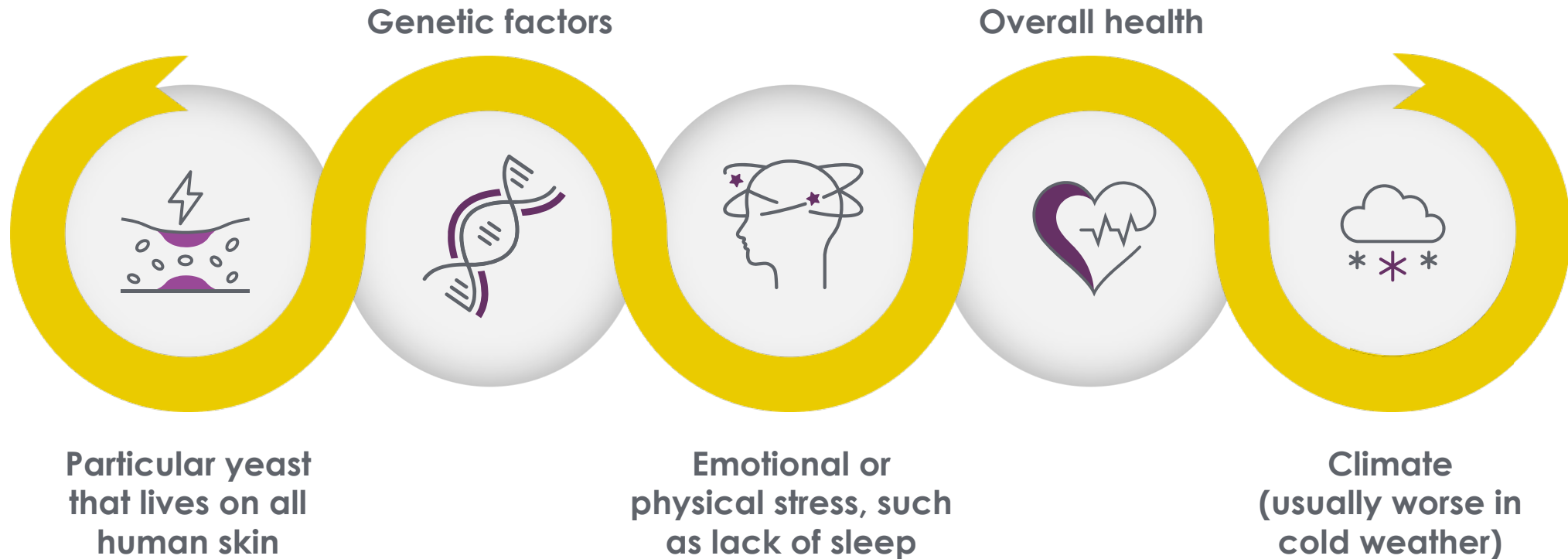
*InThought Primary Research

Seb Derm Is Not Dandruff

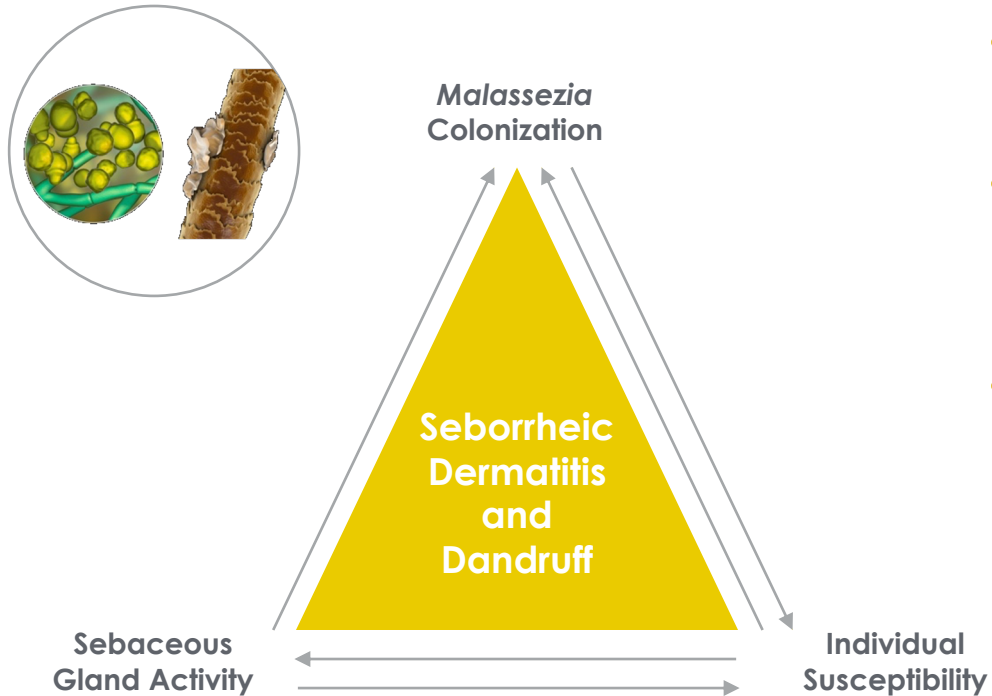
| | Seb Derm | Dandruff |
|---|--|---|
|  Epidemiology | Up to 40% of infants within 3 months of age, 1–3% of the general adult population | 50% of adult population |
|  Location | Scalp, behind the ears, face, upper chest | Scalp |
|  Presentation | Red itchy patches, with large, oily or dry scales | White to yellow flakes on the scalp and hair; no erythema |
|  Treatment | Rx antifungal shampoos & topicals; Rx topical or systemic corticosteroids & immune modulators; phototherapy | OTC shampoos & topicals – usually self treated |

Adapted from Borda — Table 4: Comparison of seborrheic dermatitis and dandruff. J Clin Invest Dermatol. Author manuscript; available in PMC 2016 May 02.

Seb Derm Contributing Factors



Role of *Malassezia Furfur* (M Furfur)



- *M. Furfur* is common yeast that colonizes on the skin³
- *M. furfur* lives off of sebum (skin oil)
 - Sebum-rich areas such as the scalp and face are more prone
- Inflammatory response to over-colonization by *M furfur*
 - Correlation between yeast density and seborrheic dermatitis severity, and efficacy of antifungal agents
 - *M. furfur* digests sebum that releases free radicals
 - Free radicals cause irritation and inflammation

Borda Figure 1: Predisposing factors and their interactions in the pathogenesis of seborrheic dermatitis and dandruff.

Presentation in Dermatology Office



Patients

- May mistake for dandruff
- May go years without adequate treatment



Dermatologists

- Easy for dermatologists to diagnose visually
- Doesn't require biopsies like psoriasis



Education

- Little patient education exists for seb derm
- Opportunity for disease awareness & education

"75% of patients don't realize they have seborrheic dermatitis"
– Dermatologist

*"It gets a little confusing if there's an overlap of psoriasis, or a bacteria or fungal infection, **but for typical dermatologist it's pretty typical and easy**"*
– Dermatologist

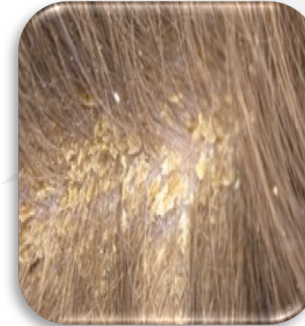
Dermatologist Testimonials



"I start pretty much everyone on a Rx if they are coming to see me. Usually, they have already tried something OTC, so I want to begin slamming it [seborrheic dermatitis] hard. Even if they haven't tried an OTC, I will give a Rx. They need a piece of paper in their hands other than the bill."



"No real formal studies, we've been using stuff that's been around for years and years."

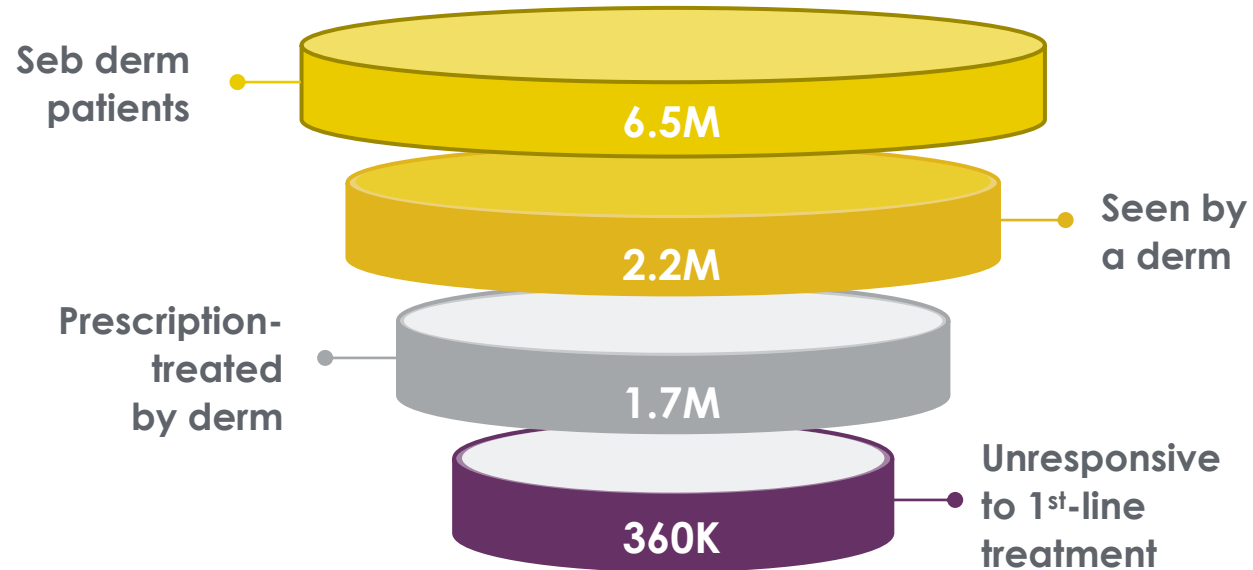


"Seb derm is a major complaint in my office because it effects their QoL."



"If they are frustrated enough to talk to me then I would feel obliged to give them something that is going to be more effective, and Rx grade products often offer that value to patients."

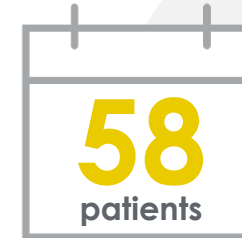
Seb Derm Prevalence



- Dermatologists estimate 10% of practice focused on treating patients with seb derm - more than psoriatic arthritis or atopic dermatitis⁶
- **Of patients presenting in derm offices:** 40% mild, 40% moderate, 20% severe
- Patients may also be treated by their Primary Care Physicians

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

Severity of Seborrheic Dermatitis



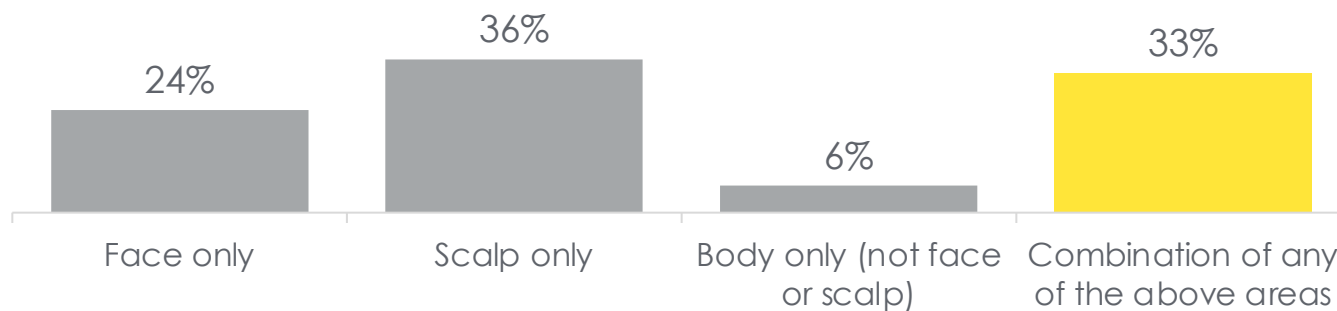
average number of seborrheic dermatitis patients seen in a typical month

41%
Mild

42%
Moderate

17%
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

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 distress²

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 pruritus¹¹

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, Wesolowska-Szepietowska E, Baran E. National quality of life in dermatology group. 2009

Seb Derm Can Affect Self-Confidence

Patients express:

- Embarrassment
- Self-consciousness
- Reduced confidence
- Shame
- Frustration

"I feel embarrassed living with seborrheic dermatitis because it looks like (at least to me) that I'm not taking care of myself or that I'm dirty. I used to wear Bluetooth accessories but I can't do that anymore because I feel like it aggravates that condition."

*I like putting on makeup and stuff and I have to interact with people a lot so it **made me feel kind of ashamed because I look like a dirty person because it looks like I'm not using proper hygiene. I would want to isolate myself and not be around crowds** and it can be **depressing** because you think it is going to get better and then sometimes it doesn't."*

Treatment Goals



Symptoms

Reduce or eliminate:

- Flakes/scaling/peeling
- Itch (scalp)
- Pain/burning
- Dryness
- Discomfort



Clinical Presentation

- Clearance
- Improve appearance
- Minimize flares
- Reduce inflammation
- Reduce redness



QoL

- Live a normal life
- Look/Feel better
- Improve well-being
- Improve self confidence
- Better personal life
- Wear the clothes they want



Less Hair Washing

- Particularly within African American community
- Frequent washing can cause dry hair/breakage
- Patients want to maintain hair routine

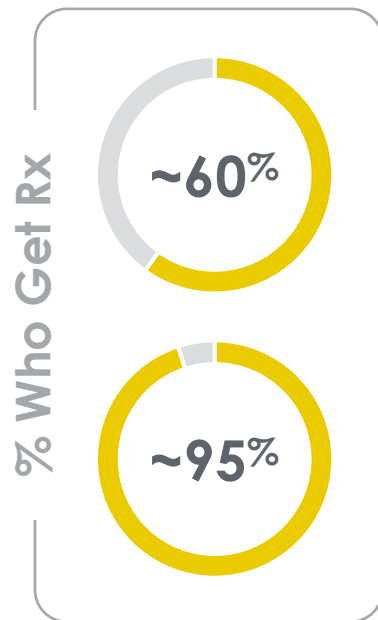


Easier Routine

- Many use > 3 products
- Increases time burden and complexity
- A single product is simpler and more efficient

Seb Derm Treatment Options

- Most patients will have tried OTC products
- Dermatologists think patients seeking treatment should get a prescription



Mild

- OTC medications
- Prescription therapy (rx topical anti-fungals or low-potency steroids)

Moderate-to-Severe

- Rx topical anti-fungals or low-potency steroids
- Intermittent higher potency steroids
- Topical calcineurin inhibitors

Current Treatment Options

| | Medications | Formulations | Regimens | Side Effects |
|-------------------------------|---|---|---------------------------------------|--|
| Antifungals | Ketoconazole Bifonazole Miconazole Ciclopirox Olamine Selenium Sulfide Zinc Pyrithione | Shampoo, cream, gel, foam, or ointment | 2 – 3 x / week up to 1 – 2 x / day | Irritant contact dermatitis (ICD), Itching, burning sensation, dryness, orange- brown scalp discoloration |
| Cortico- steroids | Hydrocortisone Betamethasone Dipropionate Desonide Flucinolone | Shampoo, cream, gel, foam, or ointment | 2 – 3 x / week up to 1 – 2 x / day | Risk of skin atrophy, telangiectasias, folliculitis, hypertrichosis, hypopigmentation with prolonged use |
| Immuno- modulators | Pimecrolimus (off-label) Tacrolimus (off-label) | Cream or ointment | 1 – 2 x / day | Risk of skin malignancy and lymphoma with prolonged use, stinging/burning |
| Miscellaneous | Coal Tar | Shampoo | 1 – 2 x / week | Local folliculitis, ICD on fingers, psoriasis aggravation, skin atrophy, telangiectasias |

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J Clin Invest Dermatol. Author manuscript; available in PMC 2016 May 02.

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

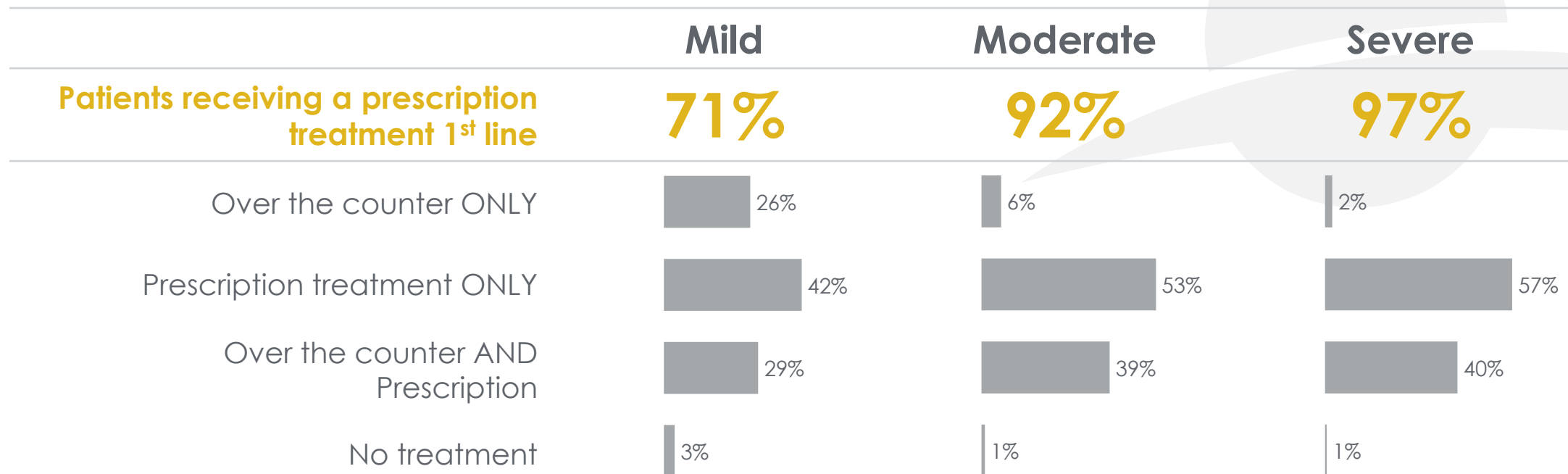
No single product appropriate for both scalp and face/body

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

Rx shampoos

- Usage usually 3x/week for ~15 minutes
- Texture of vehicle can mess up hair styles and dry out hair
- Perceived unpleasant smell

Most Seb Derm Patients Receive a Rx



- Large opportunity in dermatology setting
- Most patients receive a prescription treatment for 1st line, regardless of severity level

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

What Dermatologists Want in Seb Derm Therapy



Better non-steroidals

- A non-steroidal as effective as a low-potency topical steroid
- Ability to use on face and near eyes



Innovation

- Few new treatment options in decades
- Want to enable patient satisfaction with safe and effective new treatment



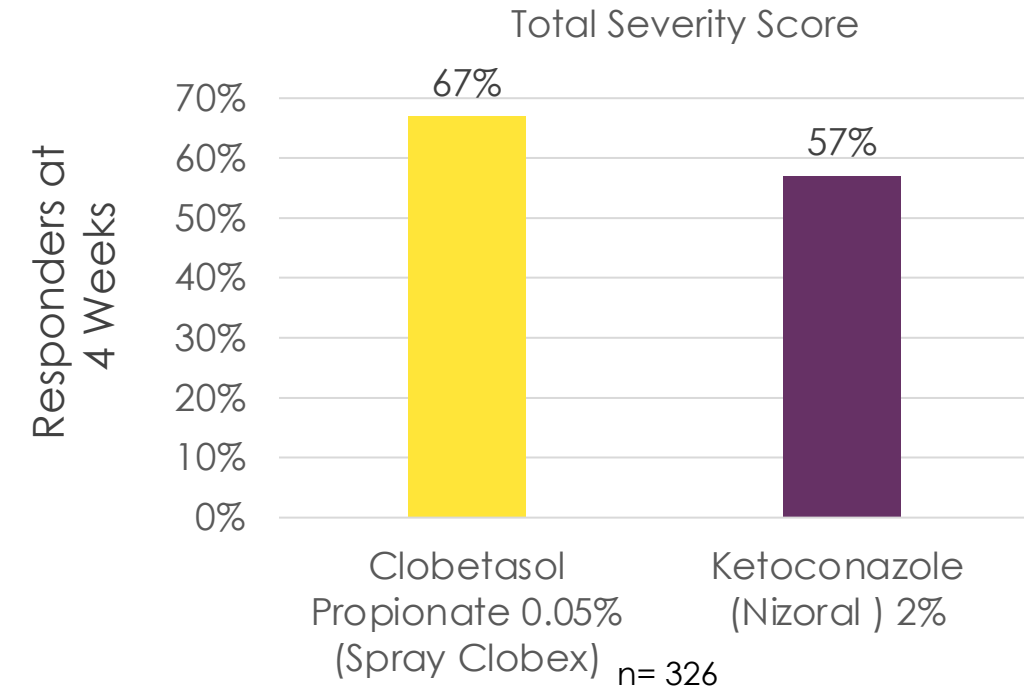
Cosmetically Elegant

- To enable patient compliance
- To improve quality of life
- To make the condition less bothersome

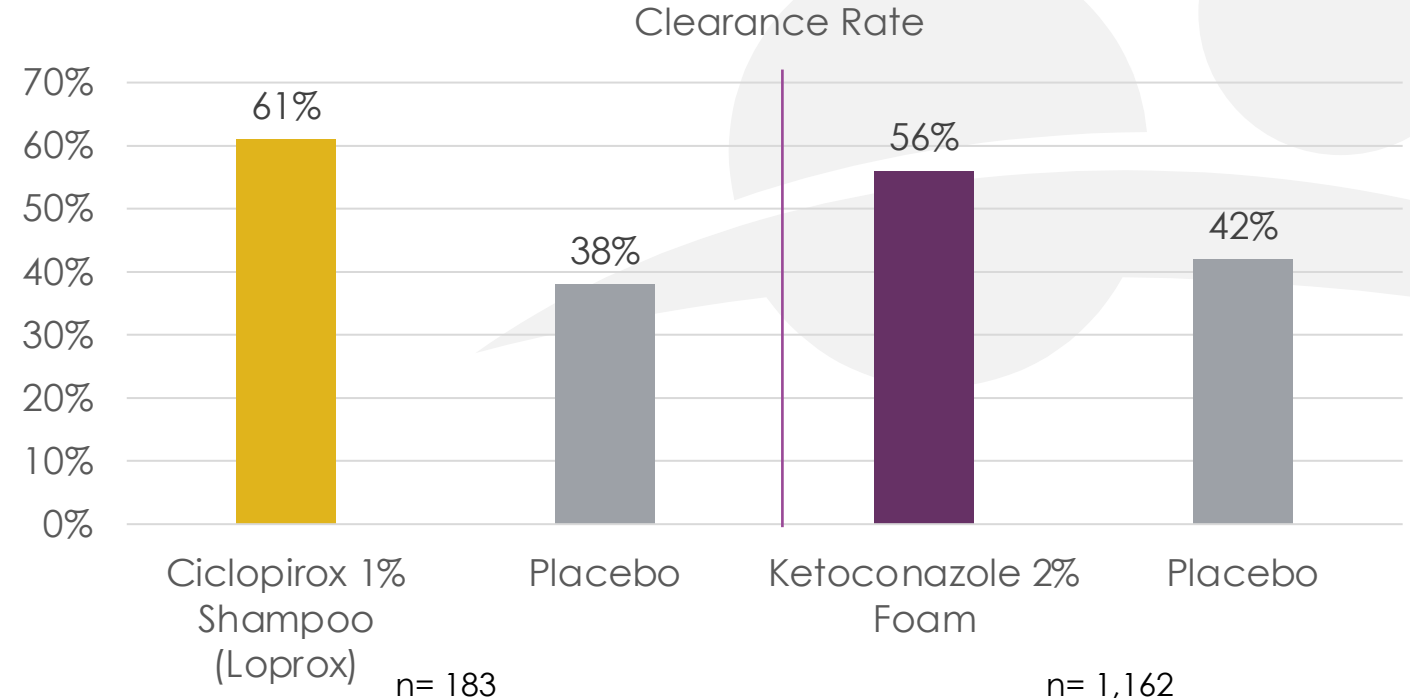
Challenges in Comparing Performance in Seb Derm Studies

- Very few used an IGA of any kind (or similar response criteria)
- Most included many (often a majority) mild subjects
- Most were short duration (2-4 weeks)
- Most are quite old (up to 20 years)
- There is variability in body location treated (face and/or scalp)

Efficacy Benchmarks



- Total severity score (TSS) ≥ 2 defined as sum of erythema, loose desquamation, and adherent desquamation at 4 weeks¹
- Moderate-to-severe scalp SD (IGA of 3 or 4 on a 5-point scale)
- TEAEs: 5%



- Responders equals none or slight (0-1 scores) at 4 weeks²

- IGA score of 0 or 1 at 4 weeks equals treatment success³
- Placebo rate: 42%
- TEAEs: 14%

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

Treatments Can Be Frustrating

Opportunity exists to simplify the routine, and offer an alternative to shampoos

Patient Perspectives

"I have four things I have to use and it's annoying, sometimes I forget to do it, sometimes I just do not feel like it."

"I would typically only wash my hair once a week, but my doctor recommends I use this shampoo multiple times a week. With my type of hair, this dries out my scalp and skin. I feel like I spend hours a day just dealing with all of this."

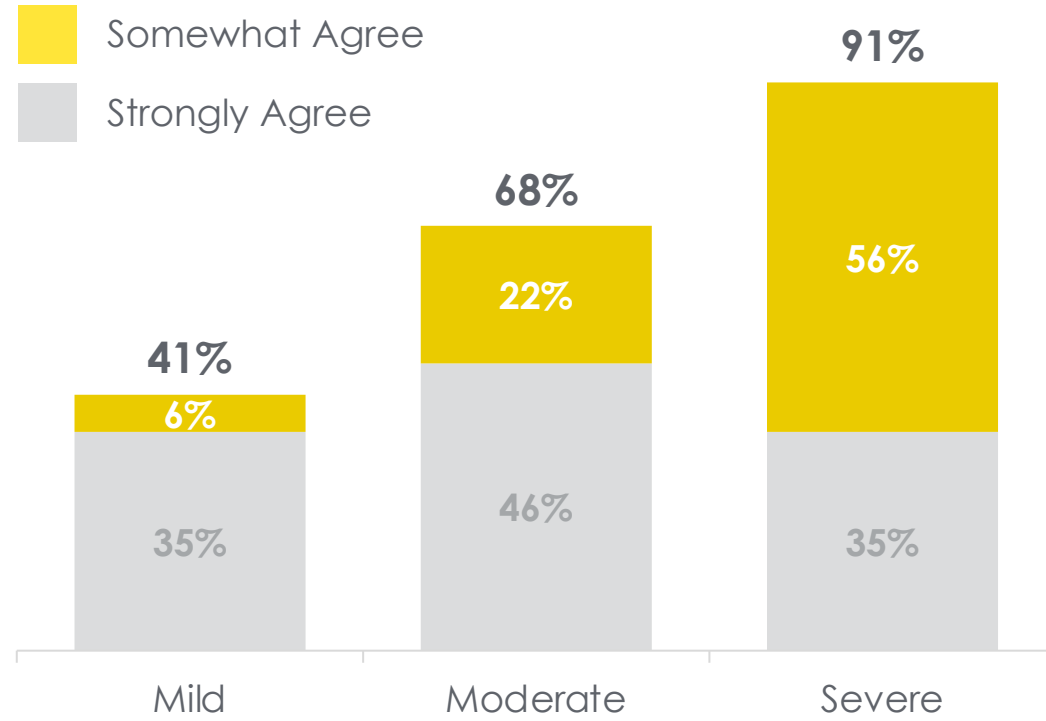
Example Instructions:

"I also want you to use this steroid cream on your face, but be careful not to overuse, and here is another steroid, but this one you can use on your scalp. Eventually I want you to stop using the steroids, but you should continue with the shampoo."

"I am also going to recommend you use this other type of shampoo in between usage of the one I am prescribing you. And make sure you keep your skin moisturized."

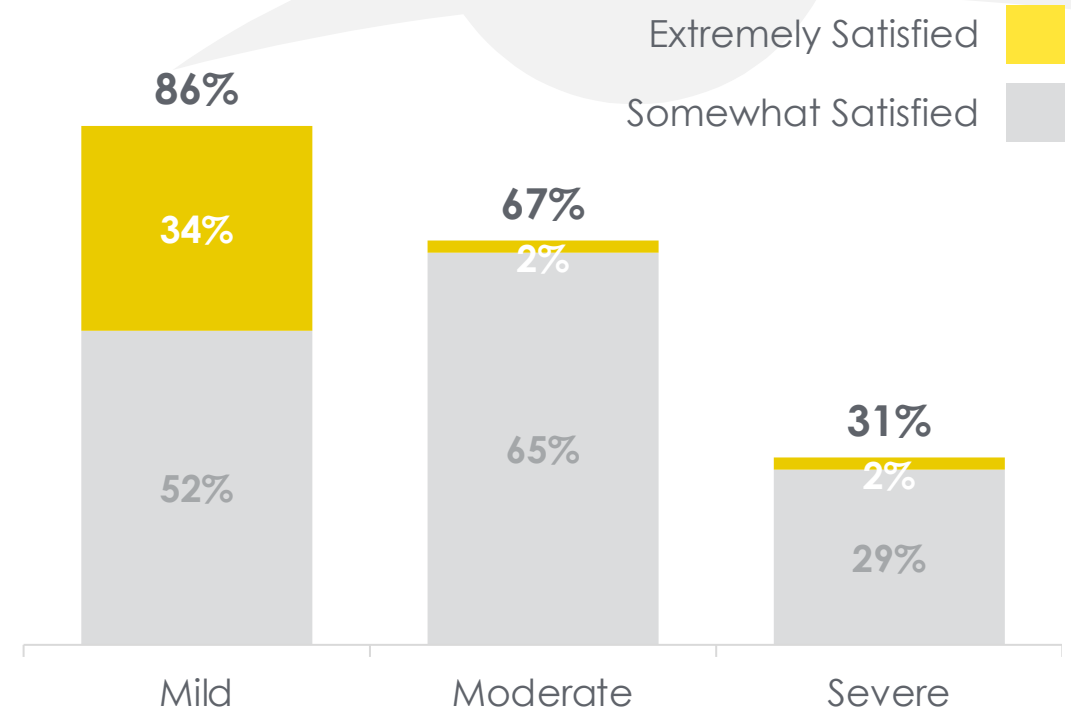
Unmet needs and dissatisfaction with current treatments are greater as severity increases.

There are **still unmet needs** for my seborrheic dermatitis patients



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

Satisfaction with current treatments for seborrheic dermatitis



Topical Roflumilast Foam

Roflumilast foam offers a highly differentiated clinical profile

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

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



Selective, highly potent anti-inflammatory PDE4 inhibitor



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



Oral roflumilast approved by FDA for COPD in 2011

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

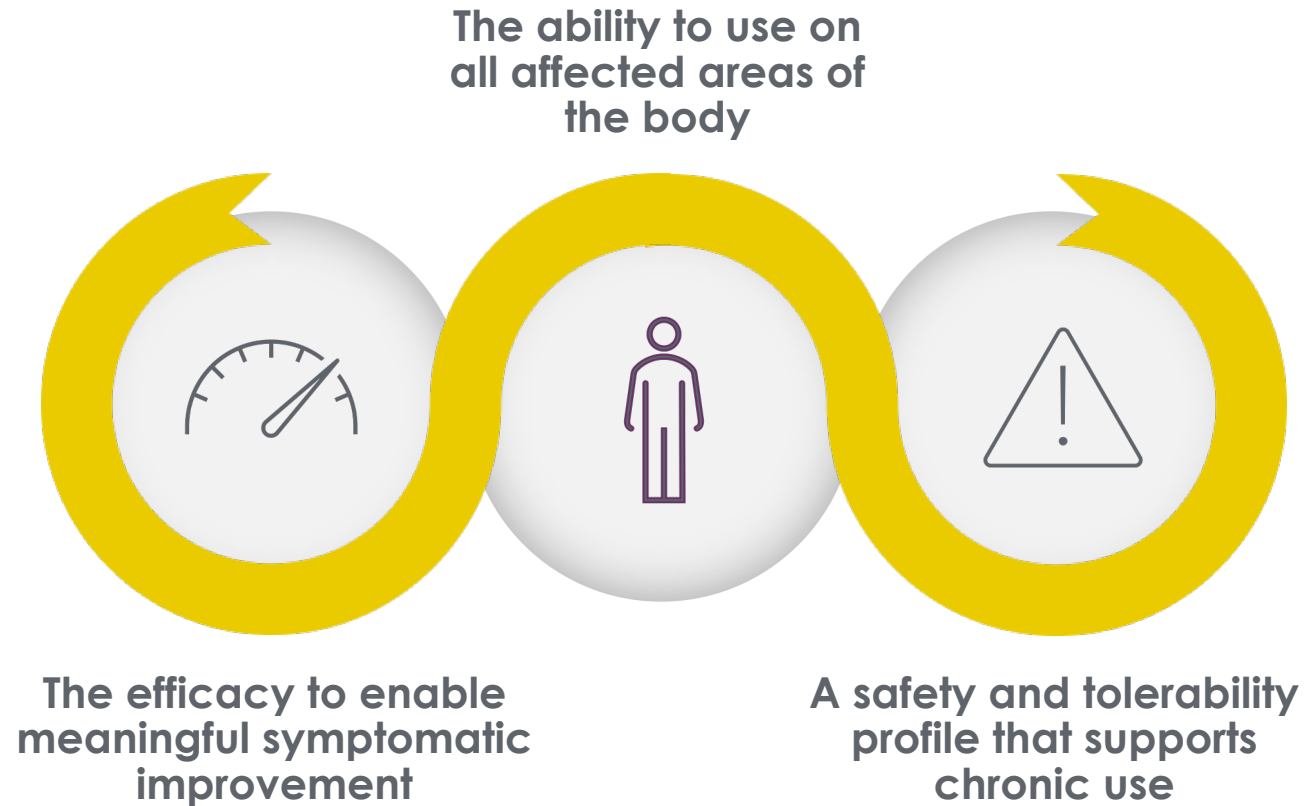
- ✗ No single product works for scalp, face and body
- ✗ Most patients need an arsenal of products to manage disease
- ✗ Steroids not meant to be used chronically
- ✗ Shampoos can be drying

Roflumilast Foam

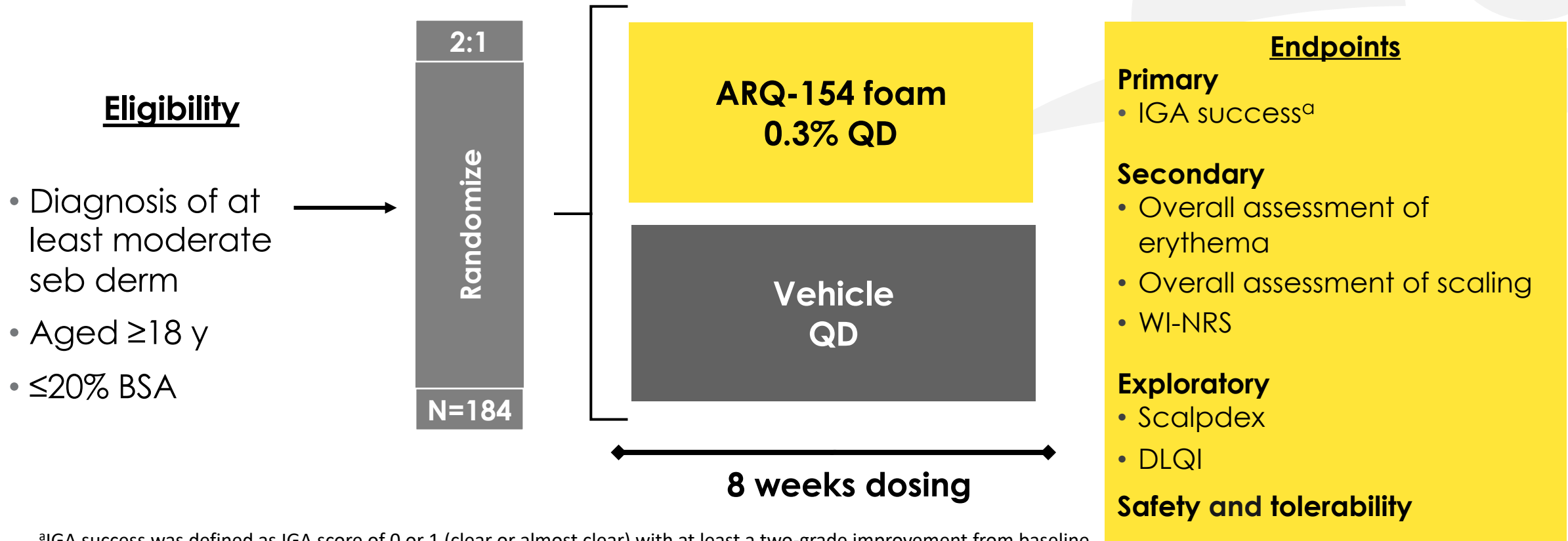
- ✓ Roflumilast can be used on all body areas, including hair-bearing
- ✓ Once-a-day roflumilast offers the convenience of a single product
- ✓ Has shown efficacy and long-term safety – suitable for long-term use
- ✓ Dries quickly, is unscented and contains no drying ethanol

Potential To Become Standard of Care

Potential to fill the significant need for a new standard of care in seb derm



Phase 2 Proof-of-Concept Study of Roflumilast Foam in Seb Derm



^aIGA 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.

Thank You

