ARCUTIS BIOTHERAPEUTICS

# Corporate Overview

January 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-Q filed with U.S. Securities and Exchange Commission (SEC) on November 5, 2020, 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.


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# Investment Highlights

- **Deep pipeline of highly differentiated products** with unique combination of efficacy and tolerability
- **Addressing large markets** – 3 products in the clinic across 6 indications with over 15 million addressable US patients
- **Positive Phase 2 data** in Plaque Psoriasis, Atopic Dermatitis, Scalp Psoriasis, and Seborrheic Dermatitis
- **Capital efficient** - On the cusp of pivotal Phase 3 data while spending $141M since inception[1]
- **Strong balance sheet** - Over $300M of cash with runway into 2022[2]

**Significant Near-Term Catalysts Including Pivotal Phase 3 Psoriasis Data and NDA filing**

1) Cash Flow from Operations from inception through September 30, 2020
2) As of November 5, 2020, includes cash, cash equivalents, and marketable securities


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# Building 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 safety, tolerability and efficacy

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


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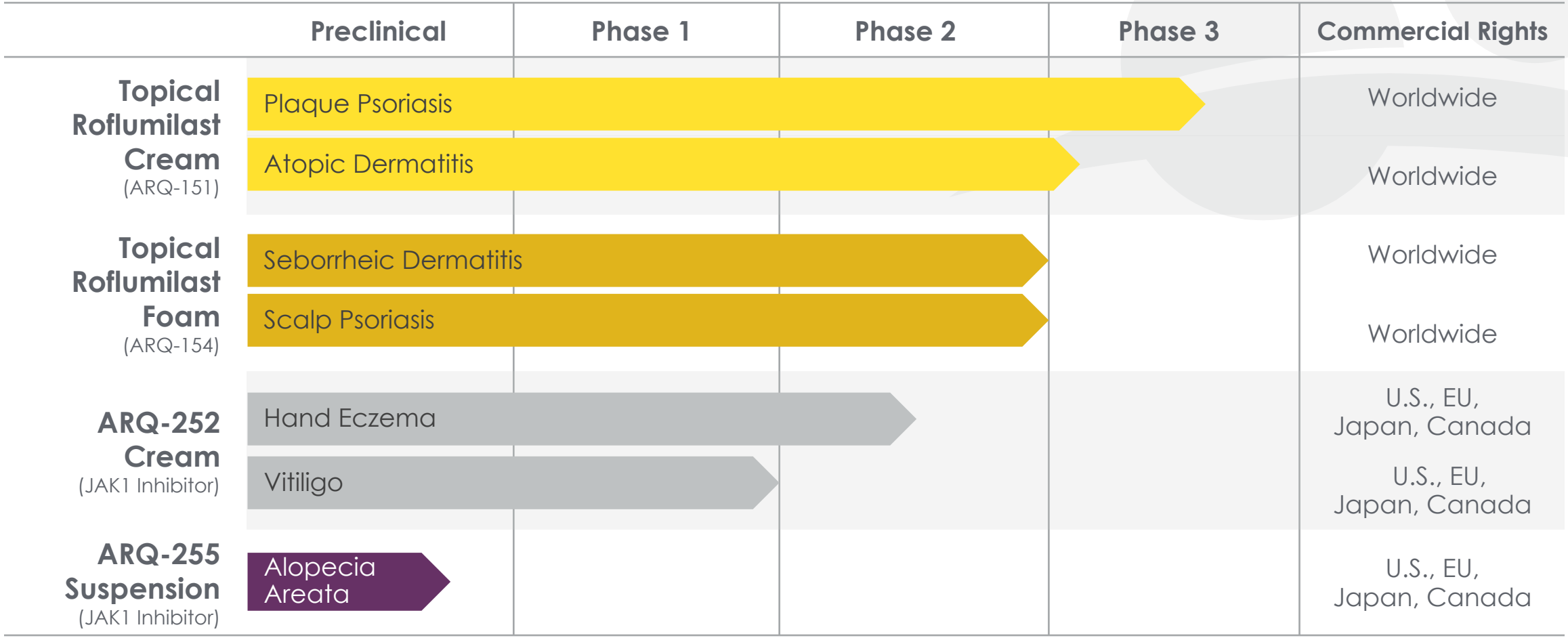
# Arcutis is Building a Robust Dermatology Pipeline

## Multiple "Pipeline in a Molecule" Opportunities





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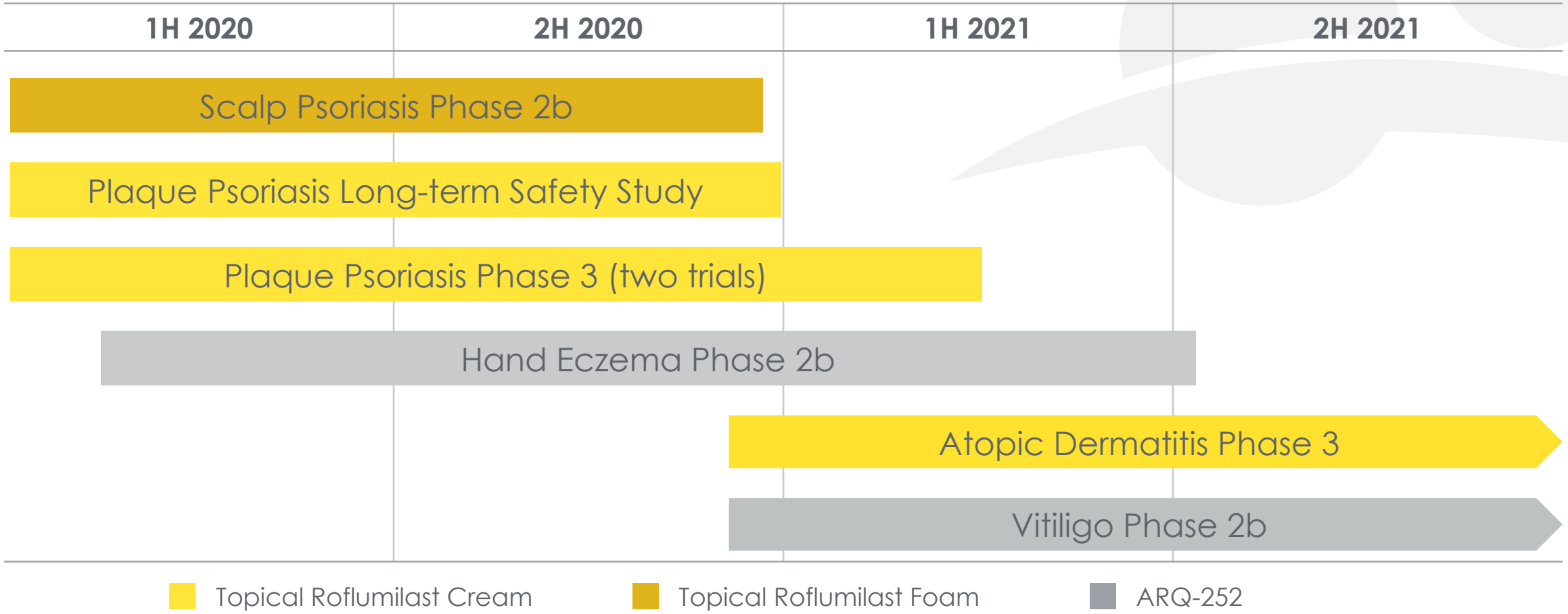
# Steady Flow of Significant Clinical Catalysts





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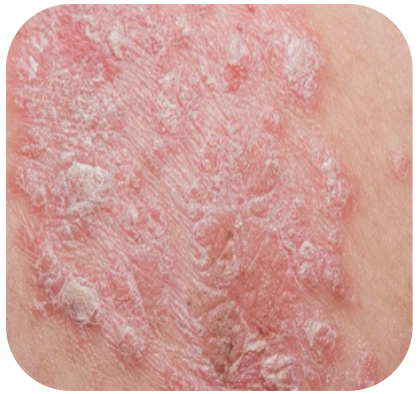
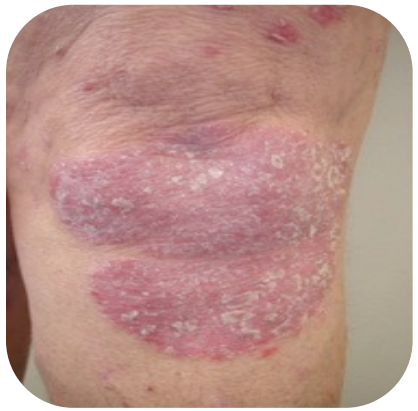
# Significant Unmet Needs in Plaque Psoriasis





- > 90% of US patients treated with topical drugs
- Existing topical therapies have numerous shortcomings
  - High potency steroids
    - Effective but limited treatment duration (2 to 8 weeks)
    - Risk of HPA suppression, stretch marks, skin thinning, spider veins, etc.
    - Can't be used in thin skinned areas like face/intertriginous
  - Vitamin D analogs (e.g., calcipotriene)
    - Less efficacious than high potency steroids
    - Frequently irritating, contraindicated for sensitive areas like face/intertriginous
- Ideal topical: efficacy of high potency steroids, ability to use chronically, and ability to use in all body areas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# Topical Roflumilast May Address Unmet Needs in Plaque Psoriasis

- Efficacy:
  - Symptomatic improvements similar to high potency steroids or Otezla
  - In treating plaque psoriasis across multiple endpoints
  - In treating plaques in intertriginous areas
  - In treating itch associated with psoriasis
  - As early as week 2 – rapid onset
- Well tolerated
- Simple, easy to use once-a-day cream or foam


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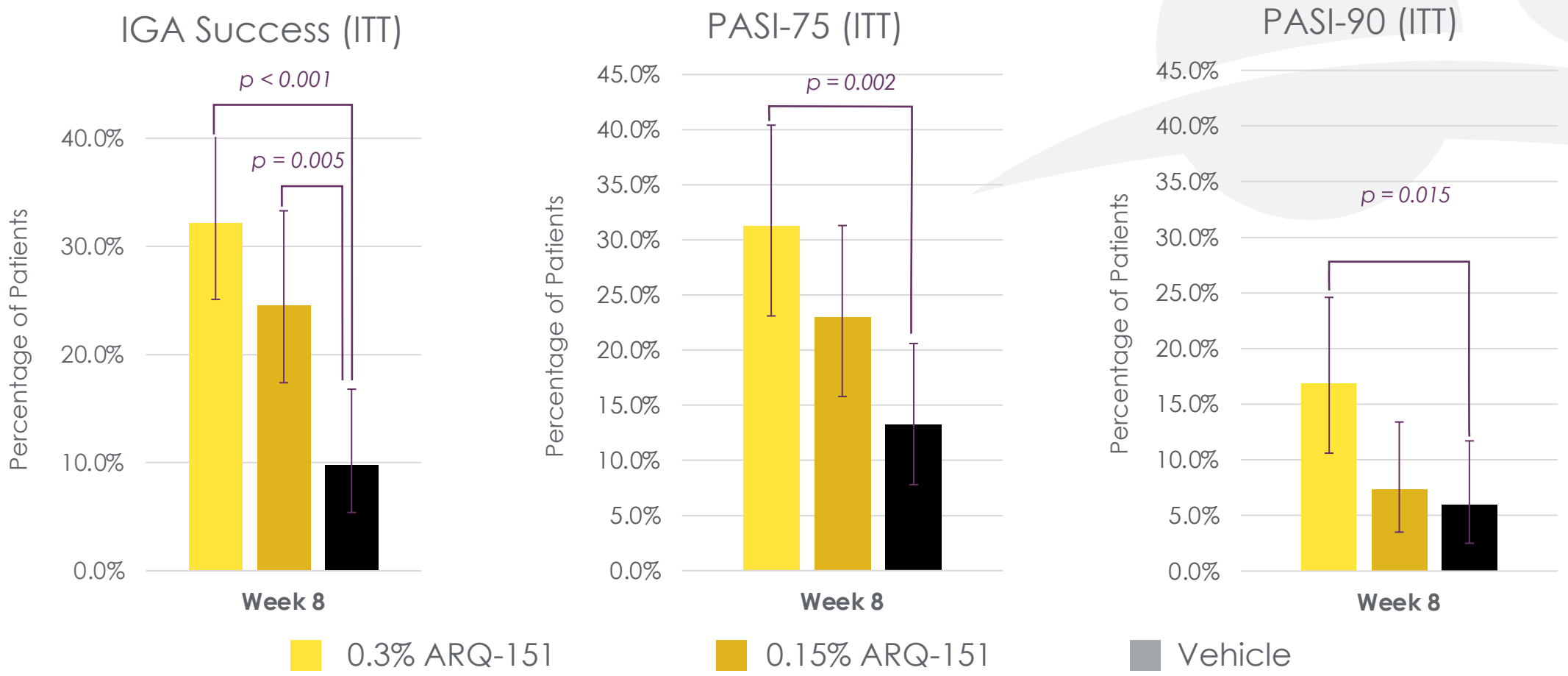
# Statistically Significant Separation from Vehicle on Key Psoriasis Efficacy Endpoints




ITT = Intent to treat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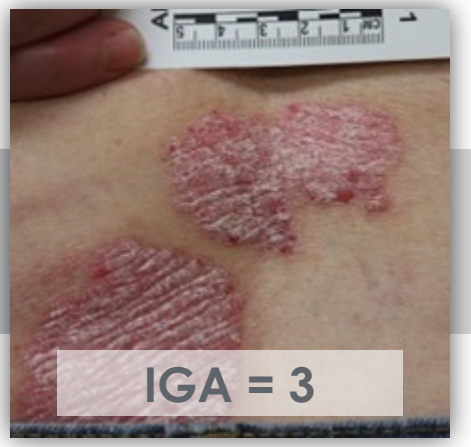
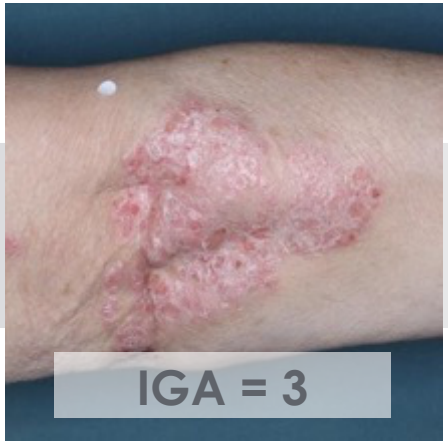
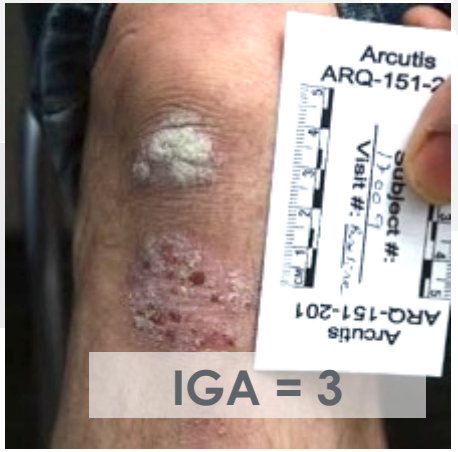
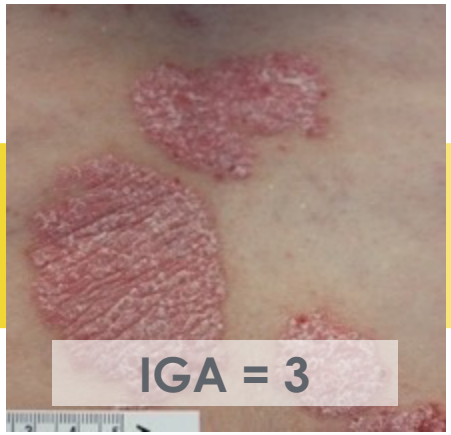
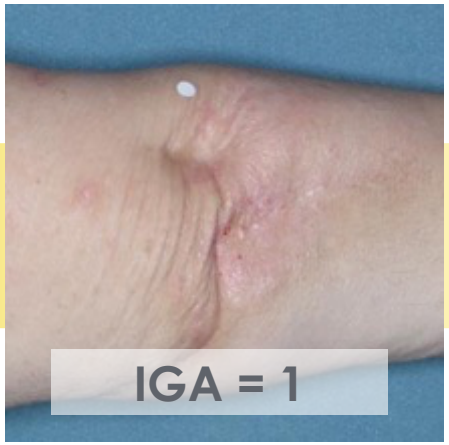
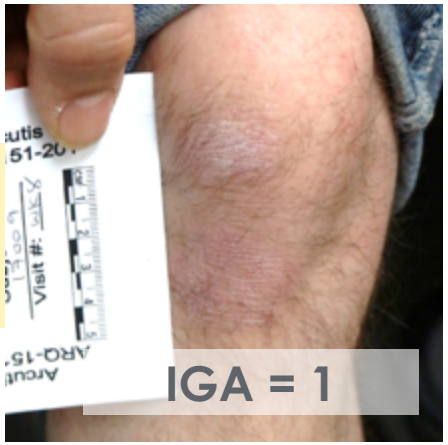
# Phase 2b Psoriasis Study

| | Vehicle | Topical Roflumilast 0.15% | Topical Roflumilast 0.3% |
|---|---|---|---|
| Baseline |  IGA = 3 |  IGA = 3 |  IGA = 3 |
| Week 8 of Treatment |  IGA = 3 |  IGA = 1 |  IGA = 1 |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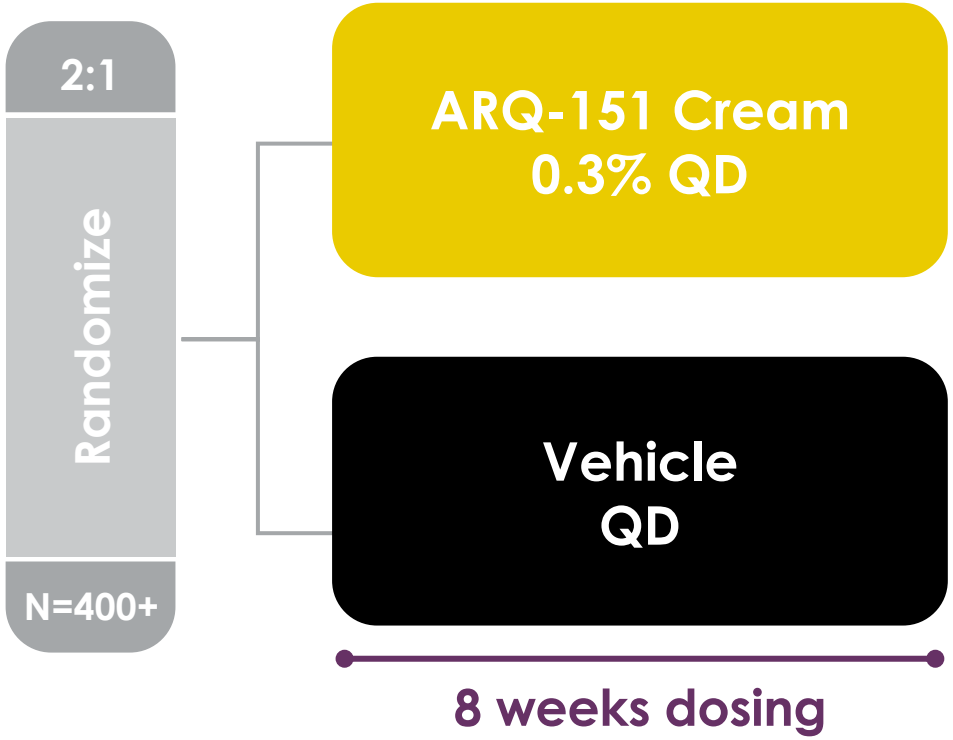
# ARQ-151 – Psoriasis – DERMIS-1/2 Phase 3 Studies

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




## 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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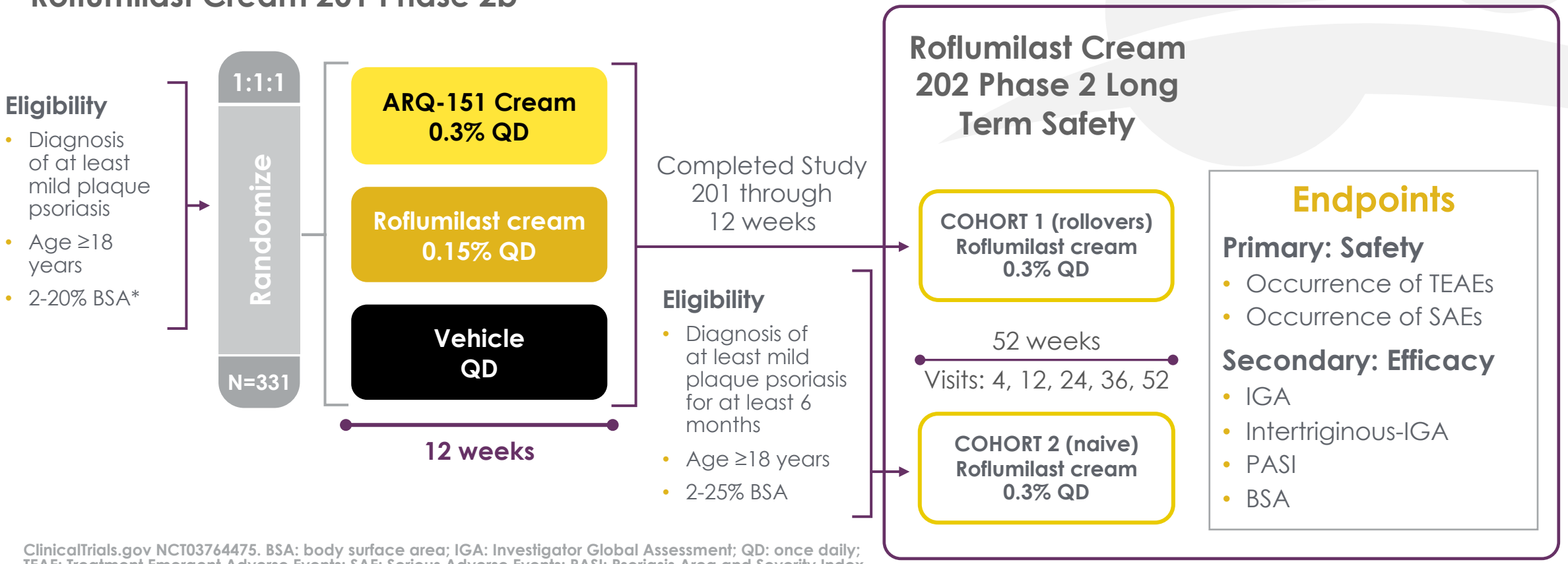
# ARQ-151-202 Psoriasis Phase 2 Long-term Safety Study

## Roflumilast Cream 201 Phase 2b[1]




ClinicalTrials.gov NCT03764475. BSA: body surface area; IGA: Investigator Global Assessment; QD: once daily; TEAE: Treatment Emergent Adverse Events; SAE: Serious Adverse Events; PASI: Psoriasis Area and Severity Index.

1. Lebwohl MG, et al. N Engl J Med. 2020;383:229-239.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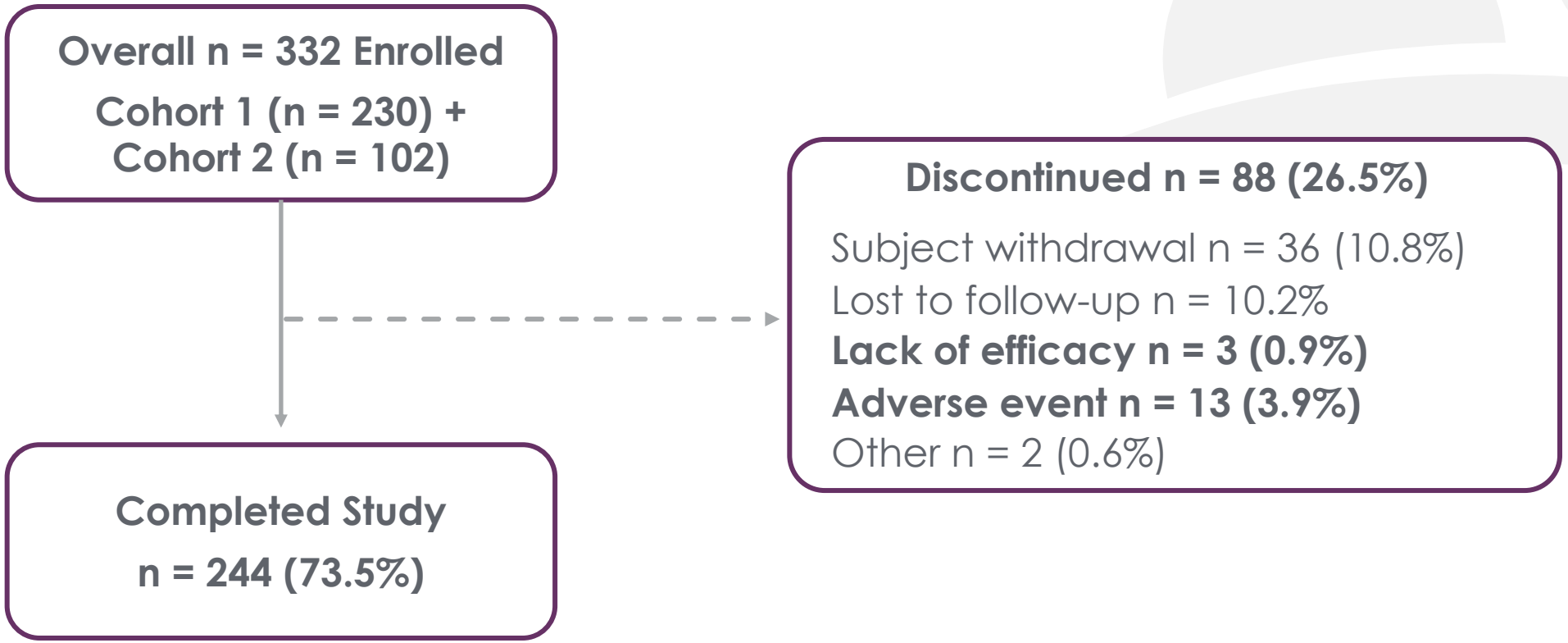
# Long Term Safety
# Subject Disposition – Overall




Median duration of participants on study = **52 weeks**

Study ARQ-151-202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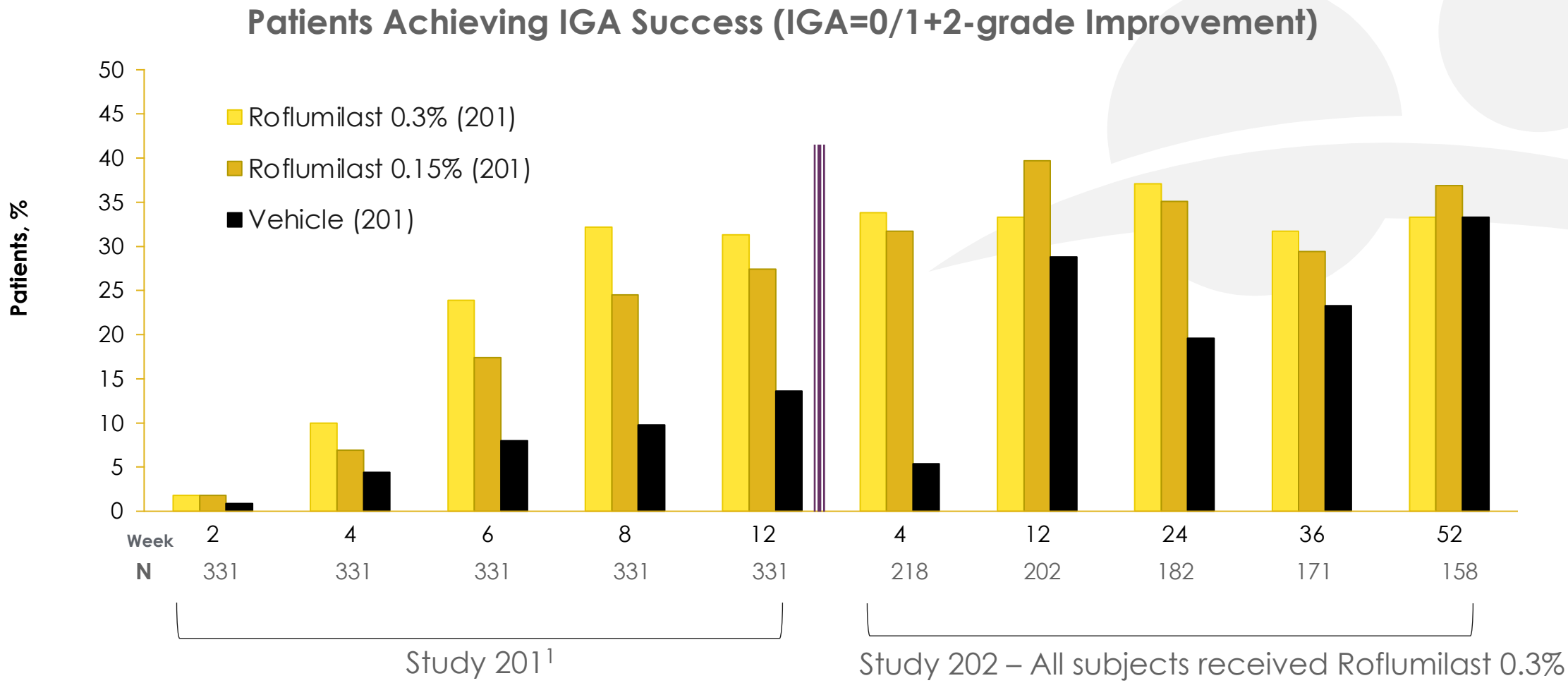
# Cohort 1: IGA Success by Treatment Sequence




No imputation of missing values. Baseline is defined as the last observation prior to the first dose of ARQ-151 cream in either the ARQ-151-201 or ARQ-151-202 study.

[1]Lebwohl MG, et al. N Engl J Med. 2020;383:229-239.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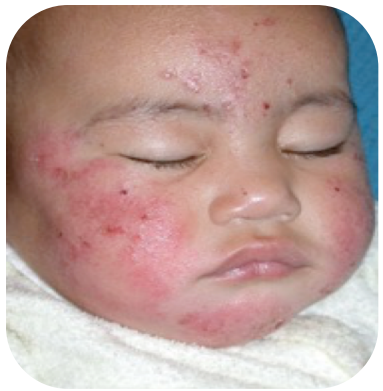
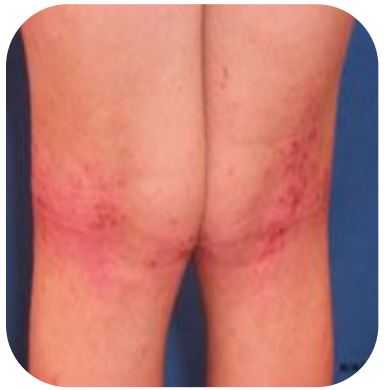
# Significant Unmet Needs in Treatment of Atopic Dermatitis





- 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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# 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
- Plan to initiate Phase 3 trial in atopic dermatitis in early 2021


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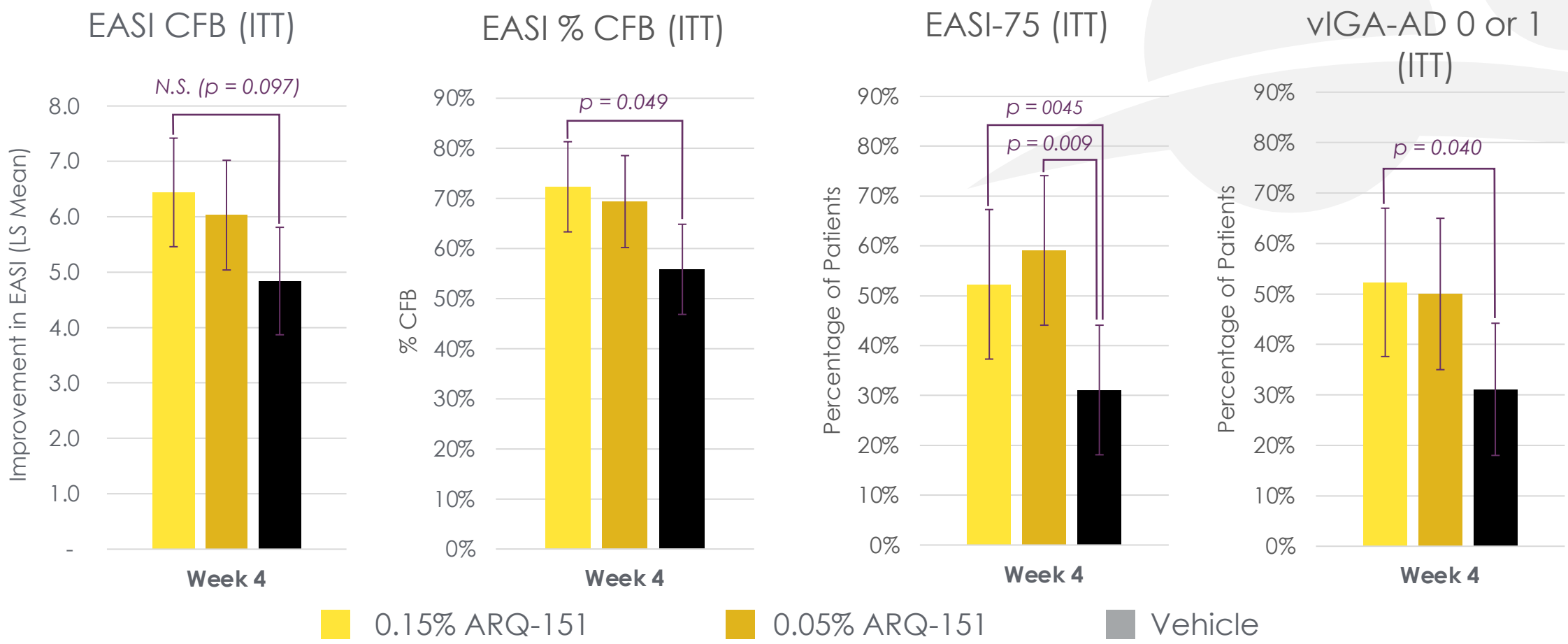
# Consistent Evidence of Efficacy in AD Across Endpoints




*N.S. = Not significant*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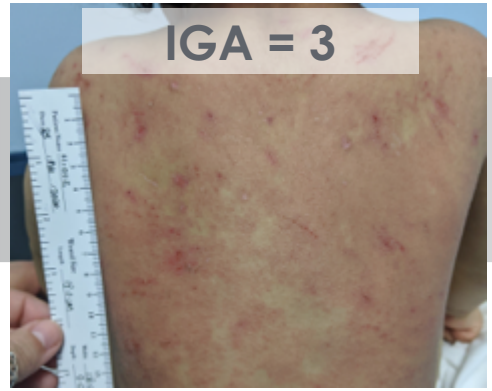
# Roflumilast Cream 0.15% Atopic Dermatitis

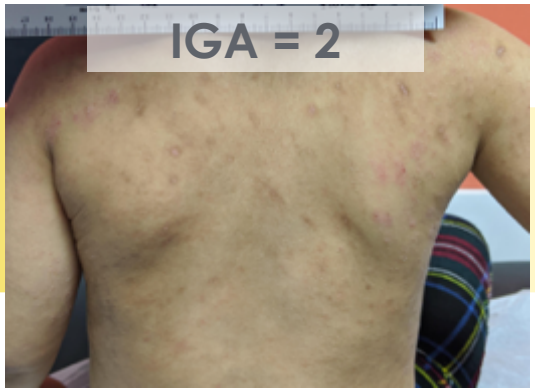
## Phase 1 Study

### Topical Roflumilast 0.15%

**Baseline**



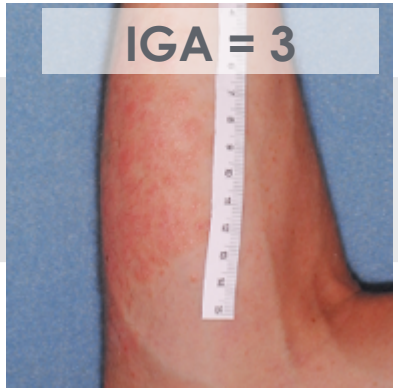

**Week 2 of Treatment**



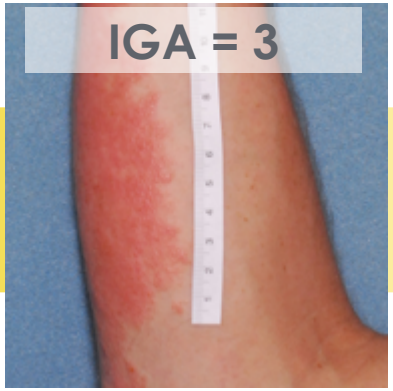

## Phase 2 Study

### Vehicle

**Baseline**

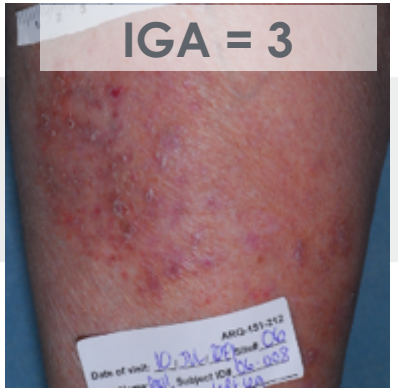



**Week 4 of Treatment**

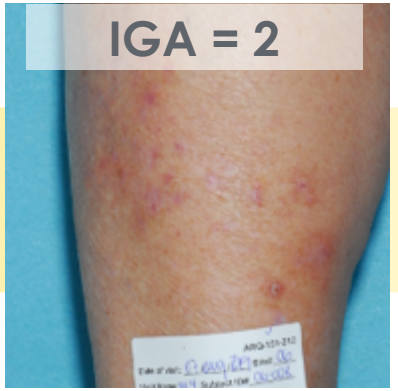



### Topical Roflumilast 0.15%

**Baseline**




**Week 4 of Treatment**

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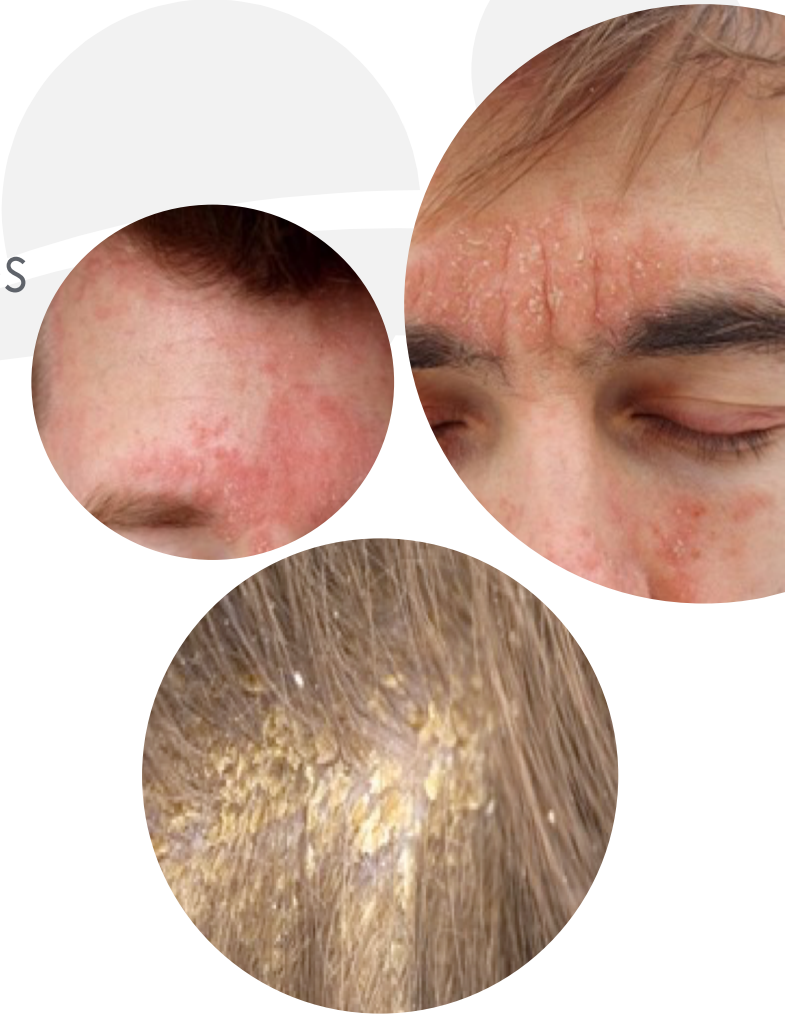
# Significant Unmet Needs in Seborrheic Dermatitis (Seb Derm)

- Common, chronic inflammatory skin disease
- Itchy red patches covered by greasy, flaking scales on the scalp, face & 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

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# 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


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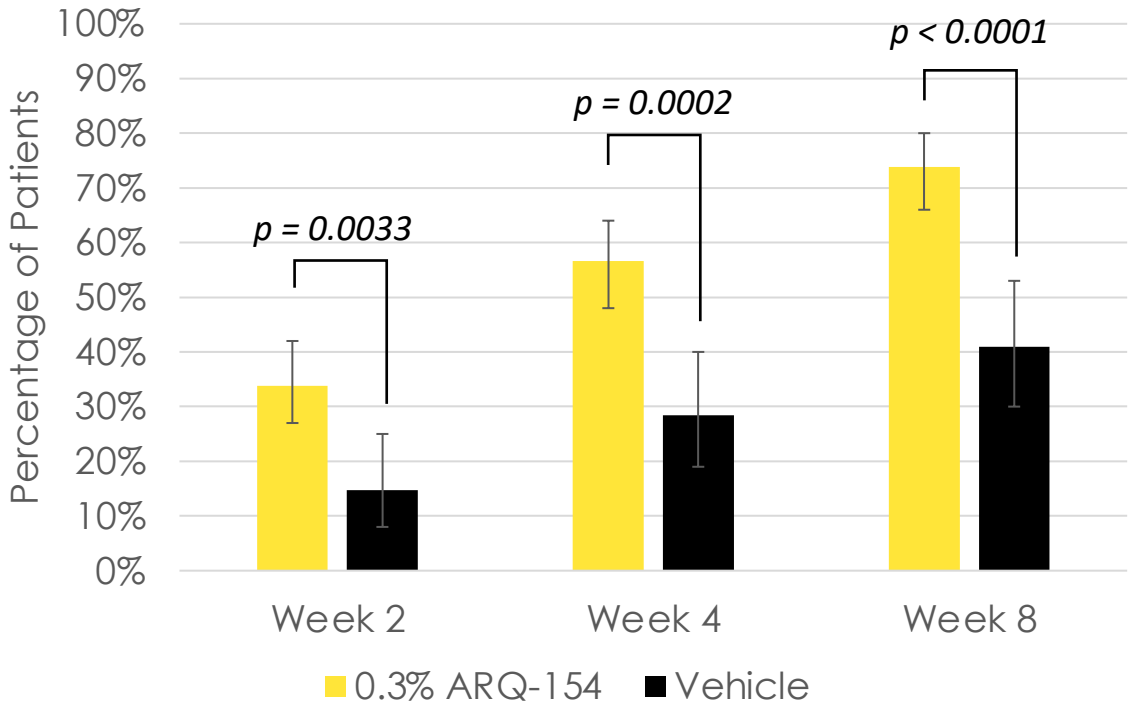
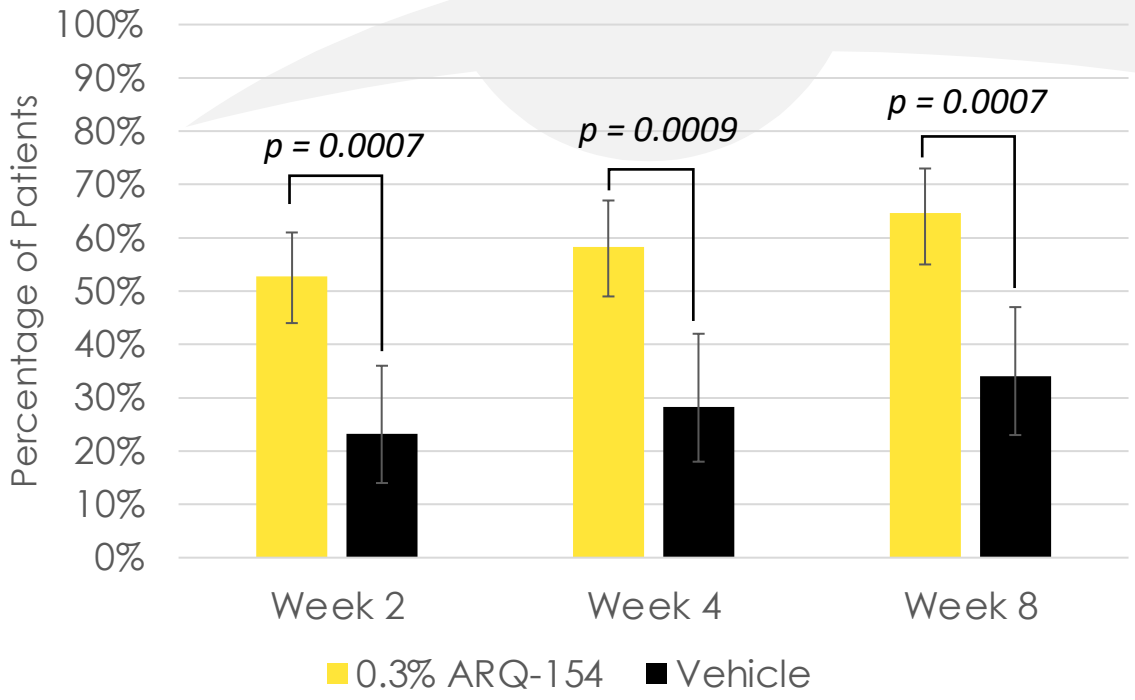
# Rapid and Robust Efficacy on Key Seb Derm Efficacy Measures

## 74% of Patients Achieved IGA Success at Week 8




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

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




WI-NRS response = 4 point reduction in WI-NRS in patients with WI-NRS ≥ 4 at baseline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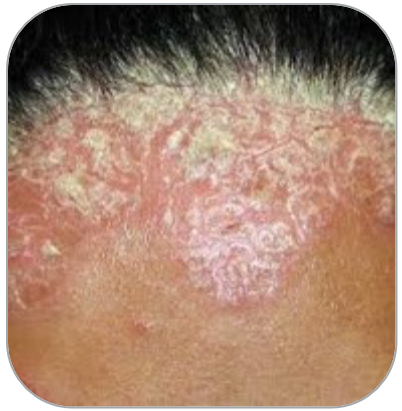
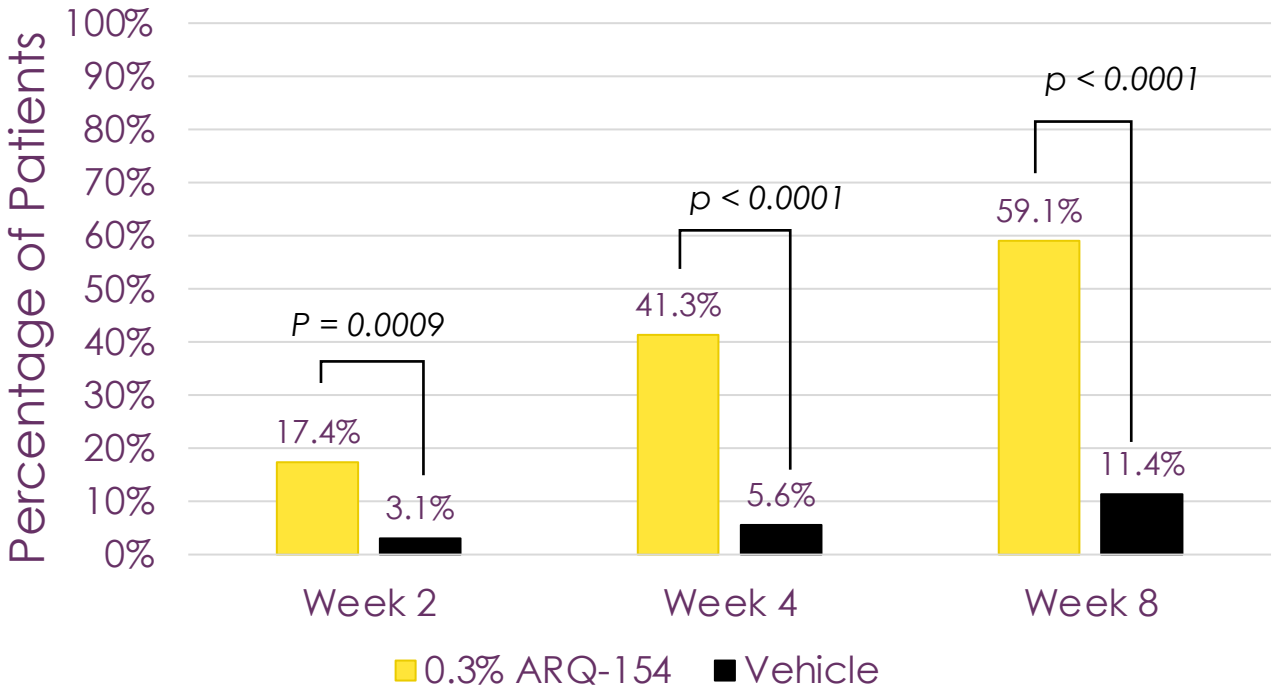
# Topical Roflumilast May Address Unmet Needs in Scalp Psoriasis



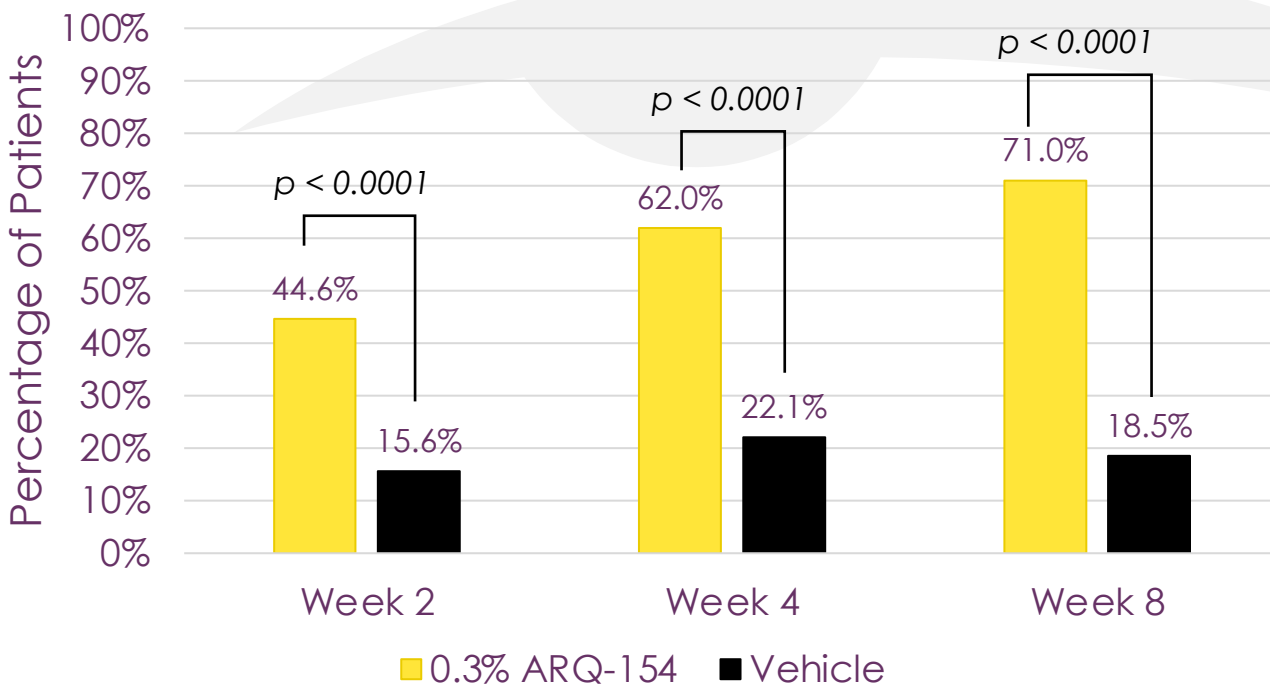
- Scalp psoriasis
  - Affects over 2.5 million U.S. patients
  - Difficult to treat because of drug access into hair-bearing regions
  - Significant unmet need for effective treatment safe for chronic use
- Roflumilast foam ideal for scalp psoriasis
  - Suitable for chronic use
  - Foam is ideal for hair-bearing areas such as scalp, where cream, lotion, or ointment 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**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IGA Success = Clear or Almost Clear with at least a 2-grade improvement from baseline

# Favorable Adverse Event Profile Across Indications

***In psoriasis, AD, scalp and seb derm Phase 2 studies:***

- > 2400 individuals already treated with topical roflumilast
- Treatment-related AEs rare & 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)
- No evidence of side effects typical of oral PDE4 inhibitors
- Supported by extensive oral roflumilast experience
  - >1M patient years of exposure

**89-94%**

**of subjects treated with topical roflumilast completed Phase 2 studies**


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# We Expect Topical Roflumilast to be Highly Differentiated

## Potential target product profile

- Robust efficacy in multiple inflammatory dermatoses
- Symptomatic improvements similar to high potency steroids
- 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
- No boxed warning

# 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
- Our topical JAK inhibitor (ARQ-252) may be "best in class"
  - Highly potent and highly selective inhibitor of JAK1
  - Oral study shows highly potent JAK1 inhibitor with good side effect profile
- Commenced Phase 1/2b study with ARQ-252 in chronic hand eczema in 1H20
  - Topline data anticipated by mid-2021
- Phase 2a proof-of-concept study in vitiligo planned for 2H20
- Ongoing formulation work on ARQ-255
  - A "deep penetrating" formulation of ARQ-252 for alopecia areata

# ~5 Million PsO, AD, Seb Derm Patients Topical Rx Treated 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:

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


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# Arcutis Enjoys Strong IP Protection

- ARQ-151/154 covered by multiple patents and pending patents
  - 5 issued U.S. patents and 5 pending U.S. patents
  - Formulation patents won't expire before June 2037 (without PTE)
  - Patents in Japan, Canada, and China
  - Pending patents in Australia, Brazil, Europe, Hong Kong, India, Israel, Japan, Mexico, New Zealand, and PCT
  - Additional formulation and PK provisional patents pending or filed
  - Rights to issued topical roflumilast patents licensed from AstraZeneca
- ARQ-252/255 covered by composition of matter patents
  - U.S. composition of matter patents won't expire before 2033 (without PTE)
  - Opportunity for formulation patents and other additional protection

# 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

**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

**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

**Keith Klein, JD, General Counsel**
- Former General Counsel, Unity Biotechnology, Sienna Biopharmaceuticals, Kythera Biopharmaceuticals
- Former Senior Associate General Counsel, Amgen

**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

**John Smither, Chief Financial Officer**
- Former CFO of Kythera, Unity, Sienna; interim CFO, Kite
- Independent Director, eFFECTOR, Achaogen
- Former Executive at Amgen and Audit Partner, Ernst & Young

**David Osborne, PhD, Chief Technical Officer**
- Former CSO of Tolmar
- Former VP Product Development, Dow Pharmaceutical
- Former VP Product Development, Atrix


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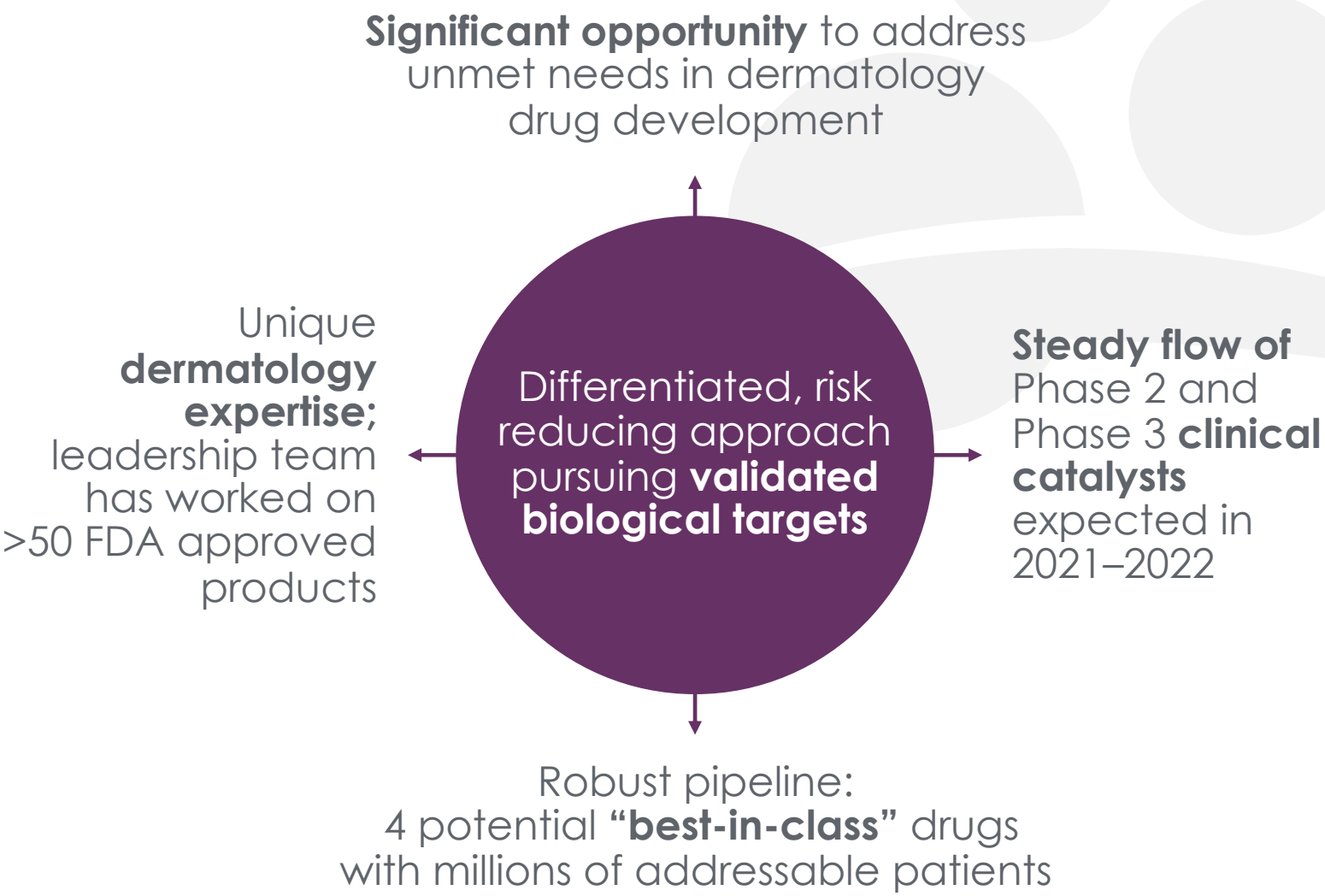
# Developing Differentiated Medicines; Maximizing Probability of Success



# Financial Position

**>$300M[1]**
(as of 11/5/20)

Cash, cash equivalents, and marketable securities

**Cash Runway**
(as of 11/5/20)

Expect cash, cash equivalents, and marketable securities to fund planned operations into 2022

**~43.6M**
(as of 10/31/20)

Shares of common stock outstanding

1) Over $300M after recent equity financing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# Thank You