UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 12, 2022

ARCUTIS BIOTHERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	001-39186	81-2974255
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

3027 Townsgate Road, Suite 300
Westlake Village, CA 91361
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (805) 418-5006

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	**ARQT**	**The Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter). Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

On November 15, 2022 and December 12, 2022, Arcutis Biotherapeutics, Inc. (the "Company") announced positive topline results from its “INterventional Trial EvaluatinG roflUMilast cream for the treatmENt of aTopic dermatitis” 1 (INTEGUMENT-1) trial and its “INterventional Trial EvaluatinG roflUMilast cream for the treatmENt of aTopic dermatitis” 2 (INTEGUMENT-2) trial, respectively. These twin pivotal phase 3 trials investigated roflumilast cream 0.15% as a potential treatment for adults and children ages six years and older with mild to moderate atopic dermatitis. Each trial was a phase 3, randomized, parallel group, double-blind, vehicle-controlled trial in which subjects ages six and older with mild to moderate atopic dermatitis involving 3% or greater body surface area received four weeks of (i) roflumilast cream 0.15% once daily or (ii) vehicle once daily. A total of 654 subjects were enrolled in INTEGUMENT-1 and a total of 683 subjects were enrolled in INTEGUMENT-2.

In each of INTEGUMENT-1 and INTEGUMENT-2, results from the four-week treatment period demonstrated statistically significant improvements compared to matching vehicle. The primary endpoint for each trial was the percentage of patients achieving Investigator Global Assessment (IGA) success, which was defined as a validated Investigator Global Assessment – Atopic Dermatitis (vIGA-AD) score of "clear" or "almost clear" plus a 2-grade improvement from baseline at week four. For INTEGUMENT-1, 32.0% of patients treated with roflumilast cream 0.15% achieved IGA success, compared to 15.2% of patients treated with vehicle ($p < 0.0001$). For INTEGUMENT-2, 28.9% of patients treated with roflumilast cream 0.15% achieved IGA success, compared to 12.0% of patients treated with vehicle ($p < 0.0001$).

In each of INTEGUMENT-1 and INTEGUMENT-2, roflumilast cream 0.15% also demonstrated statistically significant improvements compared to vehicle on key secondary endpoints, including 75% reduction in Eczema Area and Severity Index (EASI-75) and reductions in itch as measured by the Worst Itch-Numerical Rating Scale (WI-NRS). The following table sets forth a summary of the topline results from INTEGUMENT-1 and INTEGUMENT-2:

	INTEGUMENT-1 Week 4			**INTEGUMENT-2 Week 4**		
	Roflumilast cream	**Vehicle**	**P-value**	**Roflumilast cream**	**Vehicle**	**P-value**
vIGA-AD	32.0%	15.2%	P<0.0001	28.9%	12.0%	P<0.0001
EASI-75	43.2%	22.0%	P<0.0001	42.0%	19.7%	P<0.0001
WI-NRS	33.6%	20.7%	P<0.01	30.2%	12.4%	P<0.01

In each of INTEGUMENT-1 and INTEGUMENT-2, roflumilast cream 0.15% was well-tolerated, with rates of treatment-emergent adverse events ("TEAEs") low across the active treatment and vehicle arms, with most TEAEs assessed as mild to moderate in severity. Overall, adverse events were uncommon, with no adverse event occurring in more than 3.5% of subjects in either arm of either trial. In INTEGUMENT-1, the most frequent adverse events (>1%) included headache, nausea, application site pain, nasopharyngitis, COVID-19, diarrhea, and vomiting. In INTEGUMENT-2, the most frequent adverse events (>1%) included headache, nausea, vomiting, diarrhea, upper respiratory tract infection, and COVID-19. Of the subjects treated with roflumilast cream 0.15% in INTEGUMENT-1 and INTEGUMENT-2, 404 (93% of subjects) and 410 (90% of subjects), respectively, completed the study. In each trial, there were few discontinuations due to adverse events in both the roflumilast cream 0.15% group and the vehicle group. In INTEGUMENT-1, six subjects treated with roflumilast cream 0.15% (1.4% of subjects treated with roflumilast cream 0.15%) and three subjects in the vehicle group (1.4% of subjects in the vehicle group) discontinuing the trial due to an adverse event. In INTEGUMENT-2, eight subjects treated with roflumilast cream 0.15% (1.8% of subjects treated with roflumilast cream 0.15%) and two subjects in the vehicle group (0.9% of subjects in the vehicle group) discontinuing the trial due to an adverse event. There were two treatment-related serious adverse events in INTEGUMENT-2 (0.4% of subjects treated with roflumilast cream 0.15%).

Corporate Presentation

In connection with the announcement, the Company posted an updated corporate presentation to include information regarding the INTEGUMENT-1 and INTEGUMENT-2 trials to the investor section of the Company’s website. A copy of this presentation is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in the slides is summary information that is intended to be considered in the context of the more complete information included in the Company’s filings with the U.S. Securities and Exchange Commission (the "SEC") and other public announcements that the Company has made and may make from time to time by press release or otherwise. The Company undertakes no duty or obligation to update or revise the information contained in the presentation in this Current Report on Form 8-K, although it may do so from time to time as its management believes is appropriate. Any such update may be made through the filing of other reports or documents with the SEC.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Company presentation dated December 15, 2022.
104	Cover Page Interactive Data File, formatted in inline XBRL.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ARCUTIS BIOTHERAPEUTICS, INC.

Date: December 16, 2022 By: /s/ Scott Burrows
Scott Burrows
Chief Financial Officer

Exhibit 99.1

ARCUTIS
BIOTHERAPEUTICS

Bioscience applied to the skin.

Corporate Overview

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, current and future commercialization 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 roflumilast cream and roflumilast foam; 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; current and 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.

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.

For further information with respect to Arcutis, we refer you to our most recent annual report on Form 10-K, as amended, and our most recent quarterly report on Form 10-Q, filed with the SEC. In addition, we are subject to the information and reporting requirements of the Securities Exchange Act of 1934 and, accordingly, we file periodic reports, current reports, proxy statements and other information with the SEC. These periodic reports, current reports, proxy statements and other information are available for review at the SEC's website at http://www.sec.gov.

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2022: A Transformational Year for Arcutis Continues

- FDA approval of ZORYVE® (roflumilast) in plaque psoriasis is the realization of our efforts to bring meaningful innovation to patients with immune-mediated skin diseases
- Topical roflumilast is a unique "pipeline-in-a-product" opportunity across four development programs
- We announced positive topline data from our Phase 3 pivotal studies in atopic dermatitis, seborrheic dermatitis and scalp & body psoriasis in 2022 with regulatory next steps progressing.
- Acquisition of Ducentis broadens our robust immuno-dermatology pipeline with the addition of ARQ-234, our first biologic
- The strength of our balance sheet enables robust launch investment for ZORYVE and continued pipeline advancement

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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 optimize drug efficacy, safety, and tolerability

Developing potential best-in-class

and innovative topical dermatology therapies against validated biological targets

World-class leadership team

>50 FDA-approved products

Rapidly advancing

a broad, innovative pipeline with strong IP protection for clinical assets

FDA = U.S. Food and Drug Administration; IP = intellectual property

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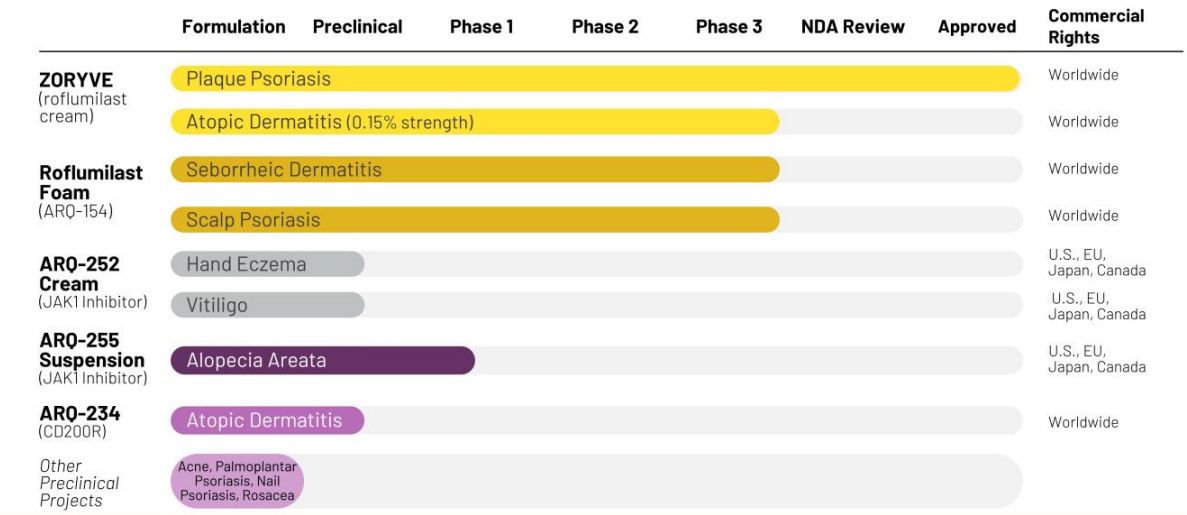
Broad and Deep Pipeline Continues to Progress



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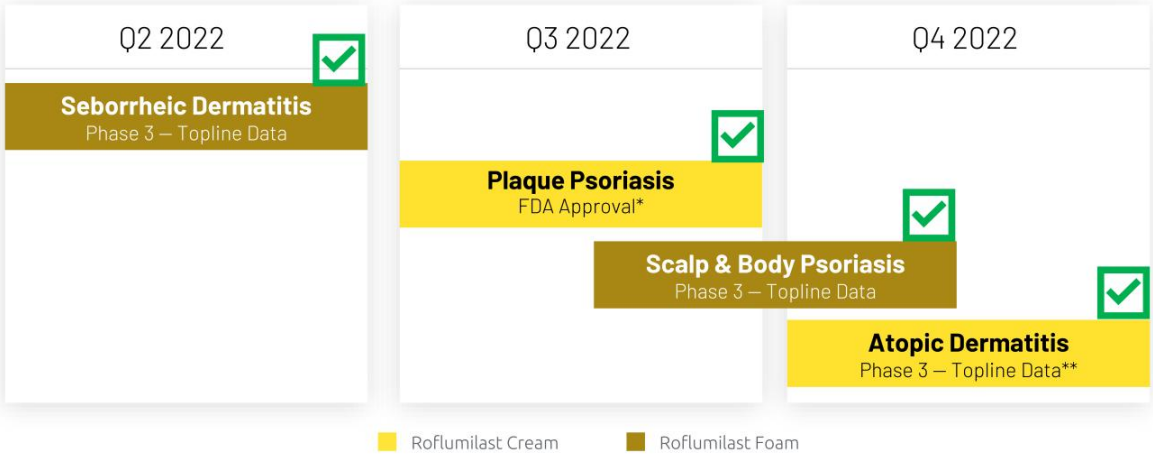
Arcutis Continues to Execute Without Fail



*Approved by the FDA for topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older; ** Phase 3 topline for INTEGUMENT-1 and -2 with 0.15% strength; INTEGUMENT-PED expected in 2023

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Topical Roflumilast Opportunity: ~7 million Dermatologist-Treated Patients in the U.S. Alone

	Psoriasis	Atopic Dermatitis	Seborrheic Dermatitis
Prevalence	~9M	~26M	~10M
Topical Rx treated in Derm setting	**2.0M** *(mild-moderate-severe)*	**2.6M** *(mild-to-moderate)*	**2.2M** *(moderate-to-severe)*
Topically treated outside Derm	~1.2M *(mild-moderate-severe)*	~4.1M *(mild-to-moderate)*	~1.0M *(moderate-to-severe)*

Significant incremental opportunity

to access the millions of U.S. patients Rx treated by other specialties (e.g., PCPs or pediatricians) via partnership

Rx = Prescription; PCP = primary care physician

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ZORYVE (zor-eev) - Next Generation PDE4 Inhibitor Approved for Treatment of Plaque Psoriasis in Ages 12+

PDE4 = phosphodiesterase-4

Established, rapid efficacy

Significant clearance of plaques + itch in all affected areas of the body

Uniquely broad label

Once-daily treatment in mild, moderate, & severe plaque psoriasis, *including intertriginous psoriasis*

Very well-tolerated, steroid-free cream

Minimal adverse application site reactions; coupled with our proprietary HydroARQ™ technology

Efficacy & safety suitable for long-term use

No boxed warnings/limitations on duration of use

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Arcutis Enjoys Strong IP Protection[1]

13 **Issued U.S. and foreign patents on topical roflumilast cream and foam formulations**	**1** Pending U.S. patent application on novel restorative effect of the roflumilast cream vehicle
1 **Issued U.S. patent on topical roflumilast PK profile (plus 3 pending)**	**1** Pending U.S. patent application for method of use on a critical ingredient in the topical roflumilast formulations
1 **Issued foreign patent for use of a critical ingredient in topical roflumilast formulations**	**2** Pending U.S. patent applications for the Deep Dermal Drug Delivery (4D) Technology underlying ARQ-255
1 Pending U.S. patent application on anti-fungal properties of PDE4 inhibitors	**1** Pending U.S. patent application for novel JAK1 inhibitor formulation (ARQ-252)

[1]*As of 9/15/22; PK = pharmacokinetics;* PDE4 = phosphodiesterase 4; JAK = Janus Kinase

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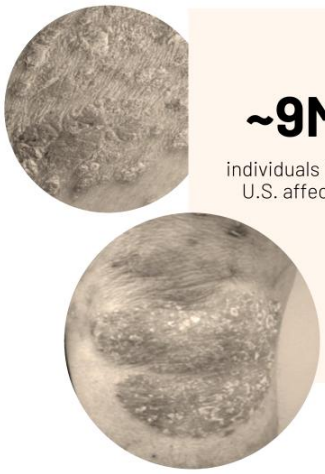
Plaque Psoriasis - Significant Unmet Needs in Treatment Paradigm



~9M

individuals in the U.S. affected

>90%

of U.S. patients treated with topical drugs

Past topical therapies have **numerous shortcomings**

Physicians and patients forced to trade-off between efficacy and safety/tolerability

81% Of patients wish they had more topical treatment alternatives to steroids[1]

[1] *Skin Insights: Uncovering Psoriasis survey of >500 adults who use topicals, March 2022*

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ZORYVE Cream – FDA-Approved U.S. Label in Psoriasis

Once-daily treatment in mild, moderate, & severe plaque psoriasis

ZORYVE™ (roflumilast) cream 0.3%

ZORYVE™ (roflumilast) cream, for topical use
Initial U.S. Approval: 2011

----------INDICATIONS AND USAGE----------
ZORYVE is a phosphodiesterase 4 inhibitor indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older. (1)

---------- DOSAGE AND ADMINISTRATION ----------
- Apply once daily to affected areas. (2)
- For topical use only. (2)
- Not for ophthalmic, oral, or intravaginal use. (2)

---------- DOSAGE FORMS AND STRENGTHS ----------
Cream, 0.3%: 3 mg of roflumilast per gram in 60-gram tubes. (3)

- Indication for treatment of intertriginous areas
- Indication for ages 12+
- Itch data (WI-NRS) included in label

WI-NRS: Worst Itch Numeric Rating Scale

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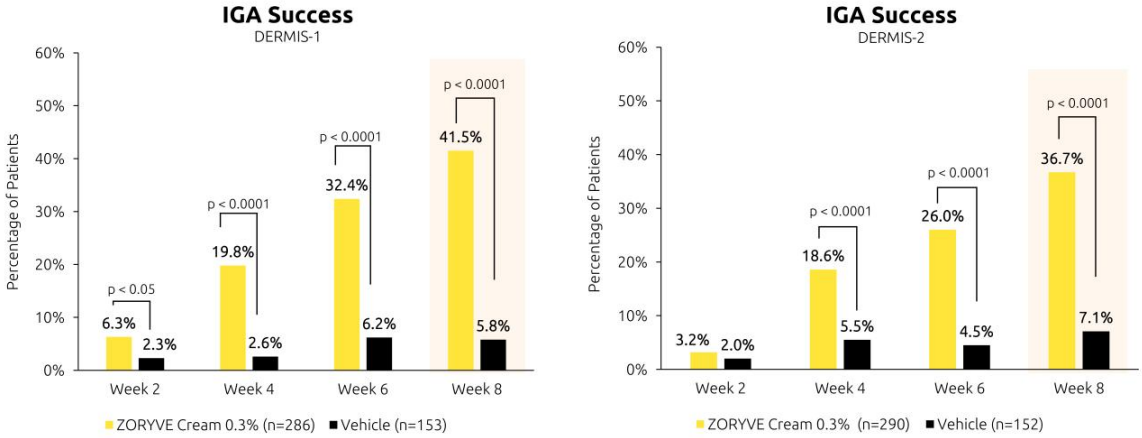
Rapid, Robust Efficacy on IGA Success in Both Phase 3 Plaque Psoriasis Trials



IGA = Investigator's Global Assessment; IGA Success = Clear or Almost Clear with at least a 2-grade improvement from baseline; ITT Population
Statistical analysis based on multiple imputation; Week 2, 4, and 6 consistent with label

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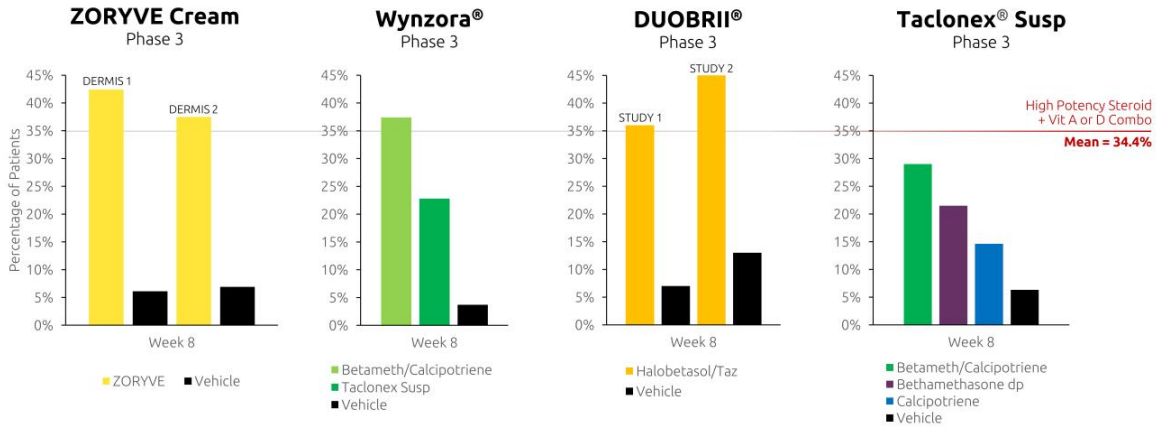
Efficacy at 8 Weeks Comparable to High-Potency Steroids & Vitamin D / Tazarotene Combo

Comparison of IGA success rates across separate topical psoriasis clinical trials



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

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.

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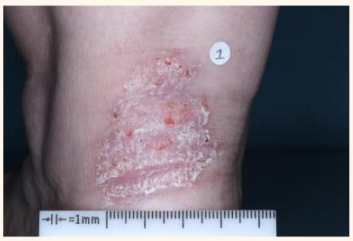
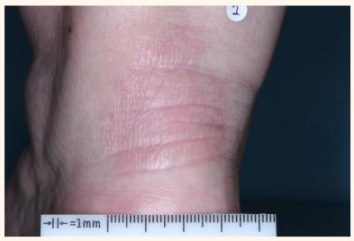
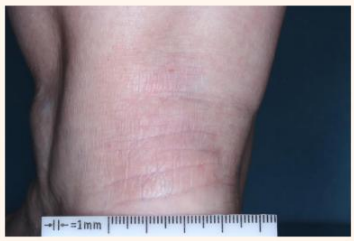
Significant and Rapid Clearance of Plaques in DERMIS Phase 3 Studies

Baseline (Heel)	Week 4	Week 8
		
IGA = 2	IGA = 0	IGA = 0

Demonstrated efficacy in tough-to-treat areas (knees/elbows) + intertriginous/sensitive areas

Individual patient results may vary

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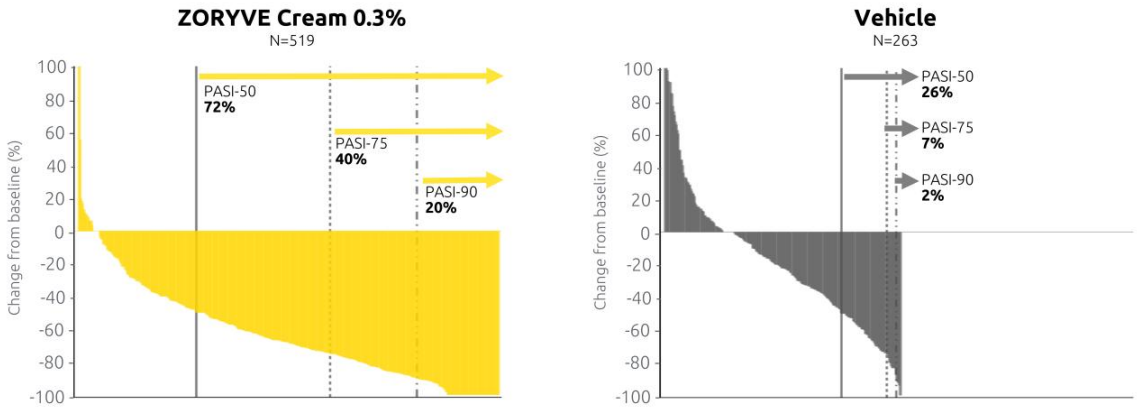
ZORYVE Delivered Clinically Meaningful Response in 3 out of 4 Patients

% Change in PASI Total Score at Week 8 - Pooled DERMIS Studies



PASI = Psoriasis Area and Severity Index

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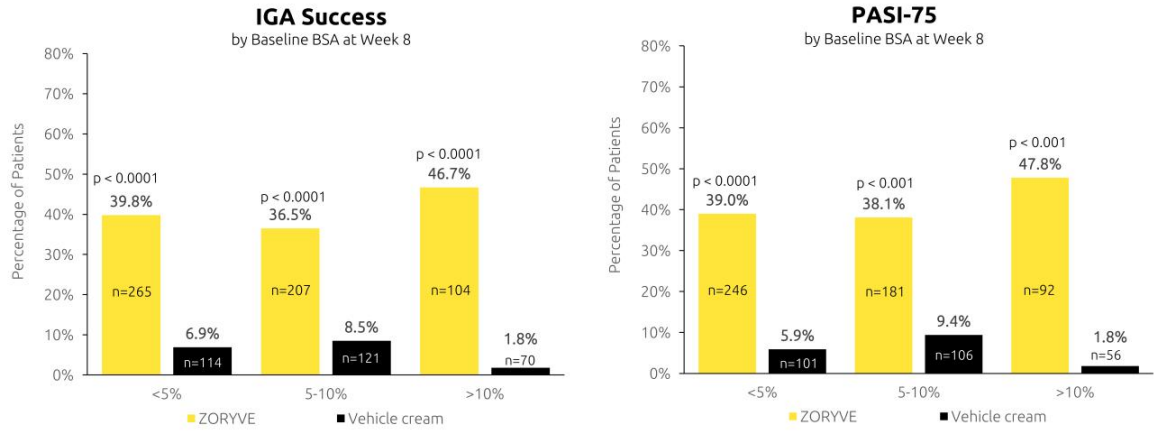
ZORYVE Demonstrates Consistent Clearance Regardless of Baseline Disease Severity



IGA Success = Clear or Almost Clear IGA status plus ≥2-grade improvement from baseline. PASI = Psoriasis Area and Severity Index; PASI-75 = ≥75% PASI improvement from baseline; Data are based on pooled data from DERMIS-1 and DERMIS-2. IGA results are from observed data from the Intent-to-treat population; Presented at American Academy Of Dermatology (AAD) Annual Meeting, March 25-29, 2022, Boston, MA, USA.

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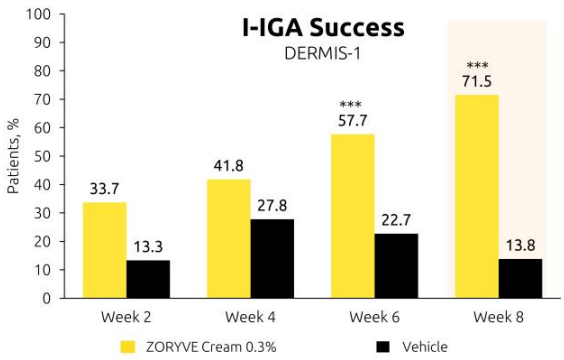
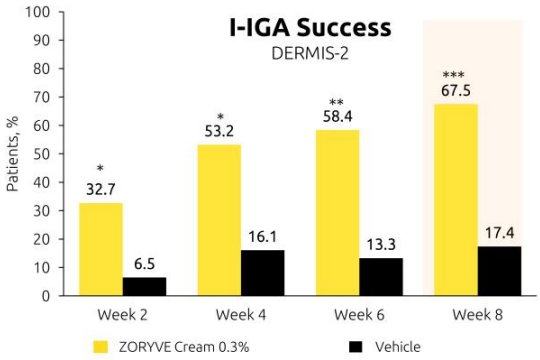
Demonstrated Efficacy and Favorable Safety and Tolerability in Treating Intertriginous Plaques

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





Survey Suggests ~2 in 3 Patients Have Exhibited Psoriasis in Intertriginous Areas[1]

**P<0.01; **P<0.001; ***P<=0.0001; I-IGA-intent-to-treat population: patients with intertriginous area involvement with severity of the intertriginous lesions at least mild (I-IGA ≥2) at baseline. Statistical analysis based on multiple imputation; Week 2, 4, and 6 consistent with label; I-IGA, Intertriginous-Investigator's Global Assessment. [1]Skin Insights: Uncovering Psoriasis survey of >500 adults who use topicals. March 2022*

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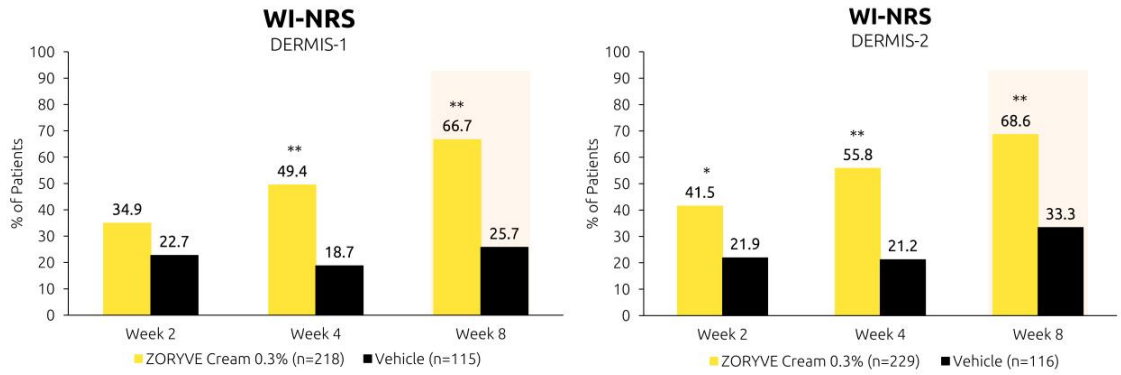
Rapid Reduction of Itch in DERMIS-1 and DERMIS-2

Proportion of patients who achieved a ≥4-point improvement in WI-NRS from baseline score of ≥4



Robust reduction in itch occurs early and consistently improves through Week 8

**P <0.001; ** P <0.0001: Evaluated in a subset of the intent-to-treat population of patients with WI-NRS pruritus score ≥4 at baseline; WI-NRS: Worst Itch Numeric Rating Scale*
Statistical analysis based on multiple imputation

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ZORYVE – Safe and Very Well-Tolerated

	DERMIS-1 and -2	
Adverse Reactions Reported in >=1% of Subjects for 8 Weeks [n (%)]	**ZORYVE** *(n=576)*	**Vehicle** *(n=305)*
Diarrhea	18 (3.1)	0 (0.0)
Headache	14 (2.4)	3 (1.0)
Insomnia	8 (1.4)	2 (0.7)
Nausea	7 (1.2)	1 (0.3)
Application site pain	6 (1.0)	1 (0.3)
Upper respiratory tract infection	6 (1.0)	1 (0.3)
Urinary tract infection	6 (1.0)	2 (0.7)

Data are presented for safety population

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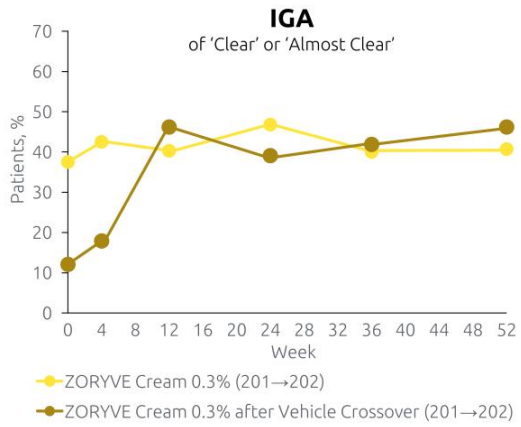
Durability of Response Maintained: Phase 2 Long-Term Data in Plaque Psoriasis



In 594 subjects who continued ZORYVE for up to 64 weeks in OLE trials, the adverse reaction profile was similar to that of vehicle-controlled vehicles

- **Durable efficacy over 52-64 weeks**
  - *Comparable to DERMIS-1/-2 8-week efficacy*
  - *Median duration of IGA of Clear or Almost Clear = 37 weeks*
- **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*

Observed data from ARQ-151-202 study; IGA = Investigator's Global Assessment; OLE = open label extension

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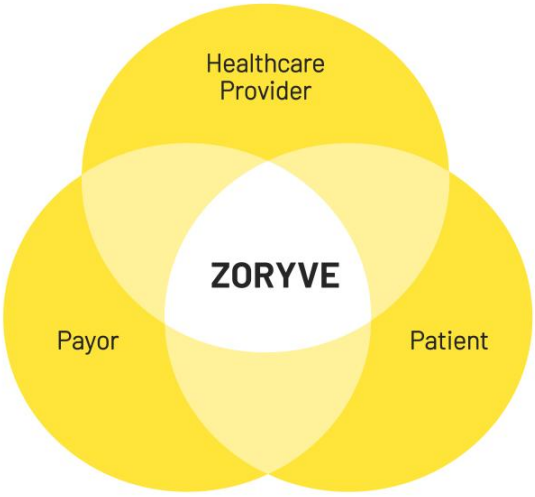
ZORYVE: Designed to Simplify the Treatment of Psoriasis



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ZORYVE Cream's Label in Psoriasis is Recognition of Our Differentiated Profile

In Label	DUOBRII®	ENSTILAR®	Wynzora®	VTAMA™	ZORYVE™
Intertriginous efficacy	⊖	⊖	⊖	⊖	⊕
Approved down to age 12	⊖	☑	⊖	⊖	⊕
Itch efficacy data	⊖	⊖	☑	⊖	⊕
Lack of warnings or precautions	⊖	⊖	⊖	☑	⊕
No limitations on duration of use	☑	⊖	⊖	☑	⊕

Comparison based on FDA-approved labels for referenced products. No head-to-head trials between these products have been conducted.

DUOBRII® : halobetasol propionate and tazarotene; ENSTILAR® : calcipotriene and betamethasone dipropionate; Wynzora® : calcipotriene and betamethasone dipropionate; VTAMA™ : tapinarof

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Patient Dynamics Are Favorable Towards Trial

~2M

Psoriasis patients currently Rx treated topically by U.S. dermatologists

Minimal behavioral change required to activate utilization

- 90% of U.S. patients treated with topicals

Highly dynamic market facilitates start/switch

- Steroids limited to short duration – frequent need to switch

Sparse competitive landscape for innovative topical therapies

- Synergy in activating non-steroidal market with two innovative topicals launching

Rx = prescription

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Our Access Strategy Remains Unchanged: Unlocking Broad, High-Quality Access to ZORYVE

Responsible pricing

Designed to obtain broad and rapid coverage

Reduced prescriber burden

Key to maximizing volume opportunity

Rapid follow-on indications

Allow for portfolio volumes across multiple indications

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Unlocking Broad, Quality Coverage of ZORYVE for Patients With Recent Formulary Wins

Our Access/Coverage Goals

- High-quality coverage for patients
- Faster formulary consideration/adoption
- Preservation of gross-to-net
- Optimizing for volume & franchise value

ZORYVE™ (roflumilast) cream 0.3%

Now Covered by a Top Pharmacy Benefit Manager (PBM) and a Large National Health Plan

- **Formulary Inclusion Effective 11/1**
- **Differentiated Access, Details Available Soon**

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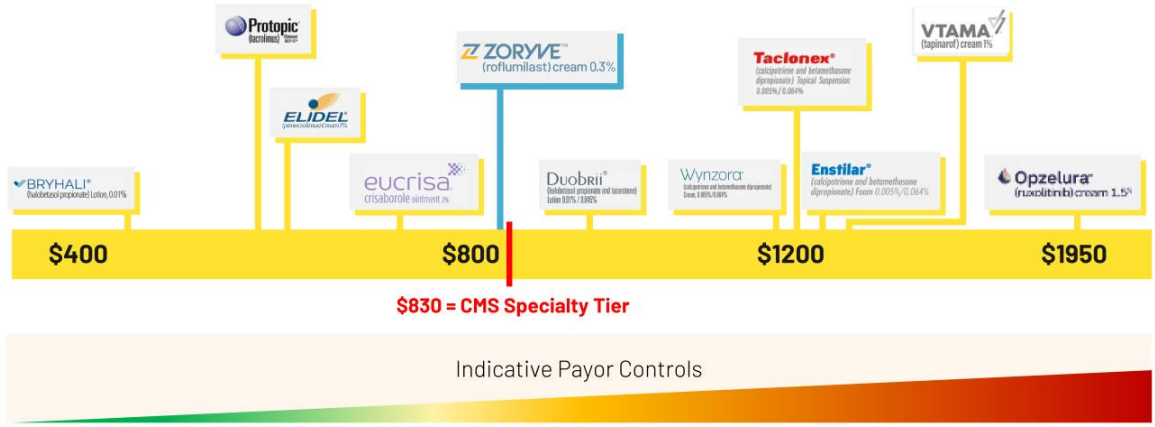
List Prices of Select Branded Topicals



Source: Analysource – 7/15/22

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Patients Are Supported via ZORYVE Direct

ZORYVE direct

Patient access support made easy

Savings Program*

Commercially insured patients with ZORYVE coverage	Commercially insured patients without ZORYVE coverage
$25	$75

For Financially Eligible Patients who are Uninsured or Underinsured, Arcutis Also Offers the Arcutis Cares™ Patient Assistance Program

*Uninsured patients and patients with government insurance are not eligible for the ZORYVE Direct savings program; Other terms and restrictions apply

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Atopic Dermatitis: Compelling Opportunity for Roflumilast Cream

Very large, established market

- ~26 million individuals in U.S. affected
- ~26 million total prescriptions in U.S.[1] (~2x of Psoriasis)
- 12% prevalence in children[2] → need for safe/effective therapy

Significant unmet need
for safe, effective non-steroidal therapy suitable for chronic use

Roflumilast Cream
Atopic Dermatitis Profile

Closely aligned with needs of:

1. Physicians
2. Patients
3. Parents
4. Payors

[1]Source: IQVIA FY 2021; [2]Silverberg JI, Dermatol Clin 35 (2017) 283-289

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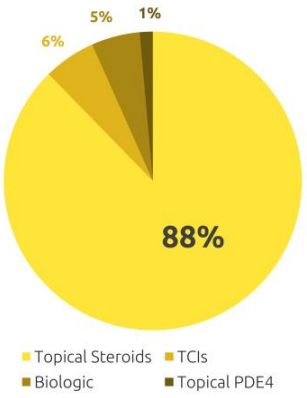
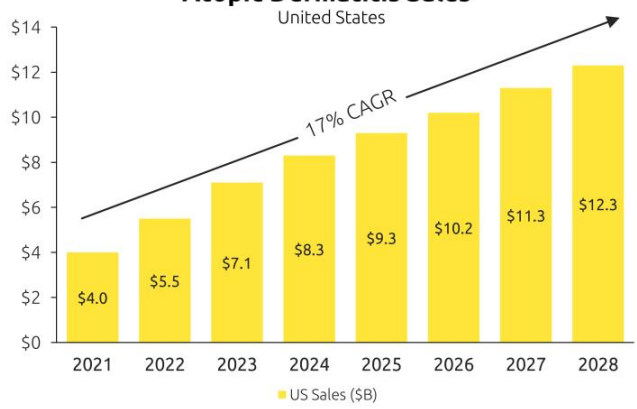
Topical Steroids Remain Standard of Care in Underserved, Rapidly Growing AD Market Segment

Total 2021 TRx of ~26 Million[1]



[1]Source: IQVIA [Biologic = Dupixent; PDE4 = Eucrisa]; TCI = topical calcineurin inhibitor

Atopic Dermatitis Sales[2]



[2]Source: Evaluate Pharma; CAGR = compound annual growth rate

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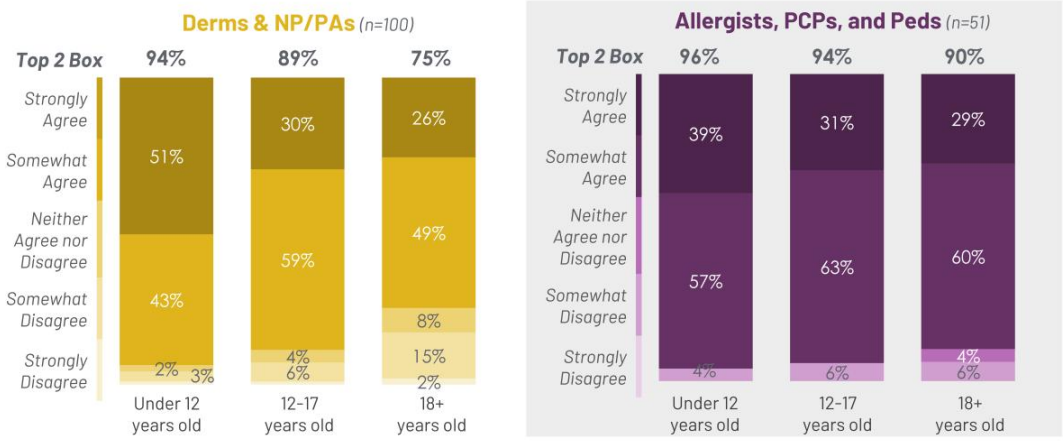
High Unmet Need for New Topical Therapies, Especially for Pediatric Patients

Unmet need with topical therapies for atopic dermatitis[1]



[1]Nov 2022 Quant Survey, The Link Group; NP = nurse practitioner; PA = physician assistant; PCP = primary care physician

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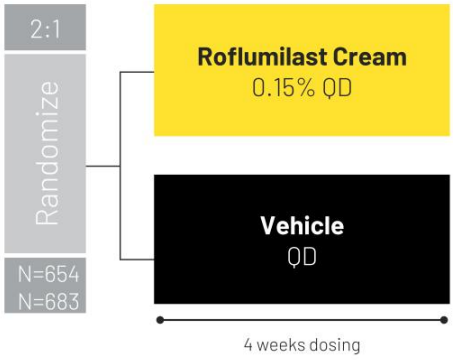
INTEGUMENT-1 & -2 Phase 3 Atopic Derm Studies

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

Eligibility

- Diagnosis of mild or moderate AD (vIGA = 2 or 3)
- Age 6+
- BSA ≥3%
- EASI ≥5



Endpoints

Primary

- vIGA-AD success at week 4

Secondary

- EASI-75
- WI-NRS (itch)
- vIGA = Clear (0) or Almost Clear (1)

Safety and tolerability

vIGA- Success = Clear or Almost Clear with at least a 2-grade improvement from baseline; BSA = body surface area; EASI = eczema area severity index; WI-NRS: Worst Itch Numeric Rating Scale; QD = once a day dosing

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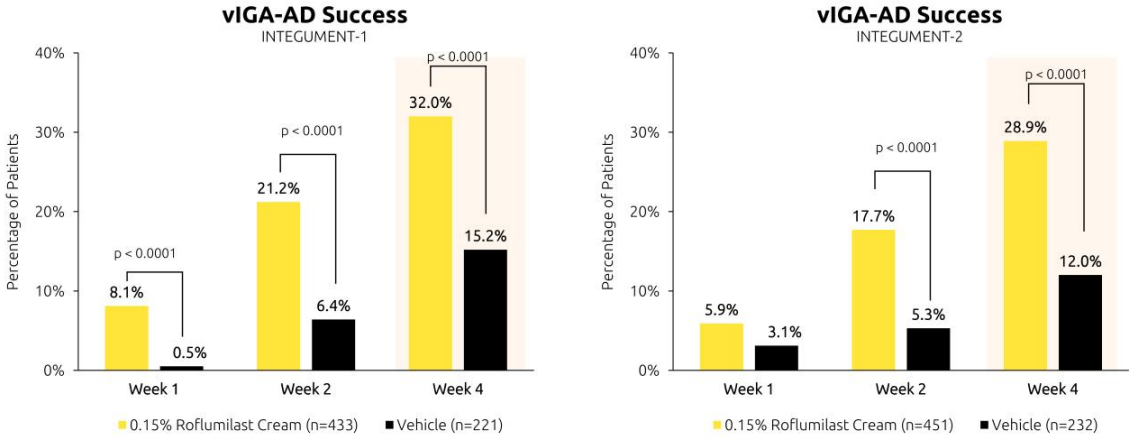
Rapid, Robust Efficacy on IGA Success Observed in Both Phase 3 Atopic Dermatitis Trials



vIGA = Validated Investigator's Global Assessment; IGA Success = Clear or Almost Clear with at least a 2-grade improvement from baseline; ITT Population
Statistical analysis based on multiple imputation

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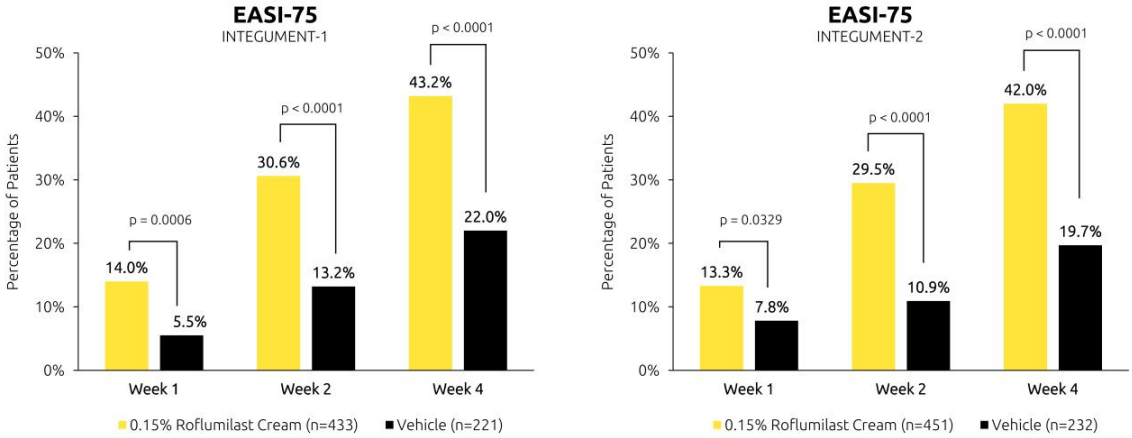
Over 40% of Patients Achieved EASI-75 at Week 4



EASI-75 = 75% improvement from baseline

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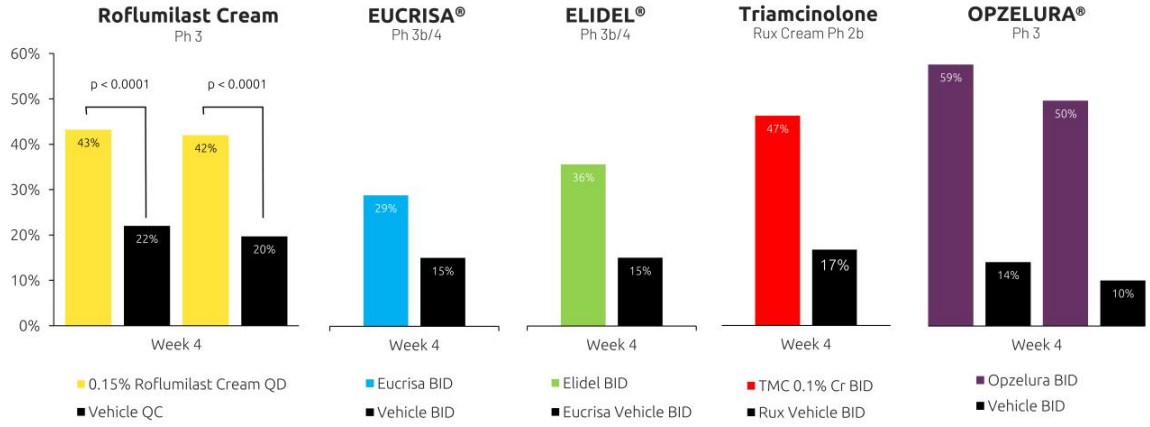
Roflumilast Cream vs. Current Approved Treatments in Atopic Dermatitis [EASI-75 Responders]



Note: The results of this retrospective post-hoc cross-trial comparison may not be directly comparable. Differences exist between trial designs and subject characteristics, and caution should be exercised when comparing data across unrelated studies. QD = once a day dosing; BID = twice a day dosing; EUCRISA = crisaborole; ELIDEL = pimecrolimus; OPZELURA = ruxolitinib cream

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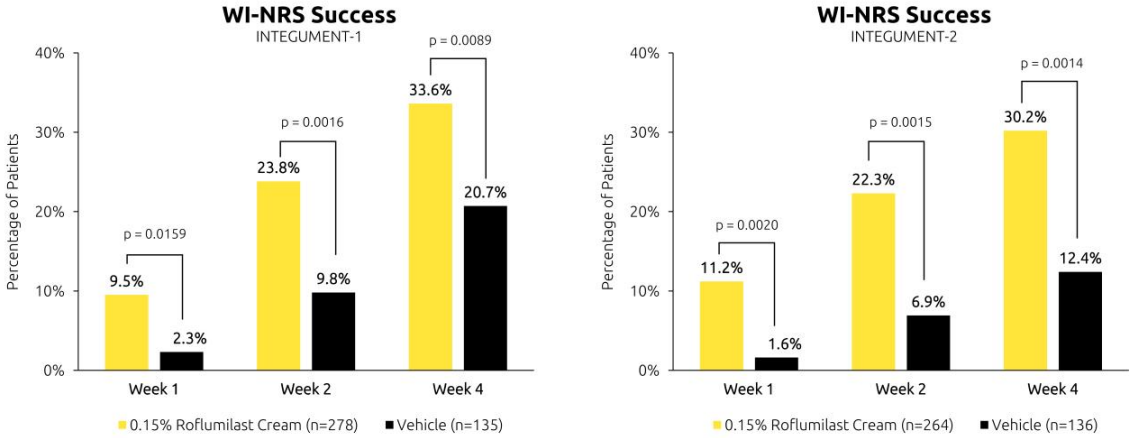
Robust and Rapid Itch Response Observed in Phase 3



WI-NRS: Worst Itch Numeric Rating Scale (only measured in the 12+ year old population in the study); WI-NRS response = 4 point reduction in WI-NRS in patients with WI-NRS >= 4 at baseline

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Roflumilast Cream Was Well-Tolerated in Phase 3

	INTEGUMENT-1		INTEGUMENT-2	
Subjects (%)	**Roflumilast 0.15%** (n=433)	**Vehicle** (n=221)	**Roflumilast 0.15%** (n=452)	**Vehicle** (n=230)
Subjects with any TEAE	92 (21.2%)	35 (15.8%)	102 (22.6%)	30 (13.0%)
Subjects with any Treatment-Related TEAE	27 (6.2%)	4 (1.8%)	26 (5.8%)	8 (3.5%)
Subjects with any SAE	4 (0.9%)	0	4 (0.9%)	0
Subjects with treatment-related SAE	0	0	2 (0.4%)	0
Subjects who discontinued Study due to AE	6 (1.4%)	3 (1.4%)	8 (1.8%)	2 (0.9%)

AE: adverse event; SAE: serious adverse event; TEAE: treatment-emergent adverse event

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Most Common Treatment-Emergent Adverse Events (≥1.0% in Any Group)

	INTEGUMENT-1		INTEGUMENT-2	
Preferred Term	**Roflumilast 0.15%** (n=433)	**Vehicle** (n=221)	**Roflumilast 0.15%** (n=452)	**Vehicle** (n=230)
Headache	10 (2.3%)	3 (1.4%)	16 (3.5%)	1 (0.4%)
Nausea	8 (1.8%)	2 (0.9%)	9 (2.0%)	0
Application site pain	9 (2.1%)	1 (0.5%)	4 (0.9%)	2 (0.9%)
Nasopharyngitis	8 (1.8%)	2 (0.9%)	0	1 (0.4%)
COVID-19	4 (0.9%)	5 (2.3%)	4 (0.9%)	3 (1.3%)
Diarrhea	6 (1.4%)	0	7 (1.5%)	2 (0.9%)
Vomiting	5 (1.2%)	0	8 (1.8%)	2 (0.9%)
Upper respiratory tract infection	0	1 (0.5%)	5 (1.1%)	1 (0.4%)

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Roflumilast Foam – Significant, Underappreciated Opportunity for Arcutis

Scalp

- 40% of plaque psoriasis sufferers have scalp involvement
- Competitive differentiation in psoriasis

Seb Derm

- As big a market as psoriasis, with no products promoted or in development

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Scalp Psoriasis - Roflumilast Foam May Address Unmet Needs

~40%

of Plaque Psoriasis sufferers have scalp involvement

Roflumilast foam ideal for scalp and body 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
- May be used near the eyes
- Rapid and robust impact on itch
- **Positive topline read-out from ARRECTOR Phase 3 Pivotal trial in September 2022**

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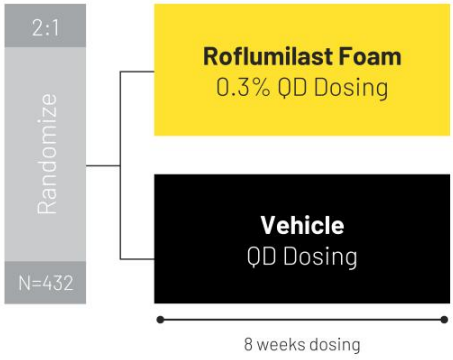
ARRECTOR Phase 3 Trial in Scalp & Body Psoriasis

Randomized, Double-blind, Vehicle-controlled Multicenter Study

Eligibility

- Diagnosis of scalp and body plaque psoriasis
- Age 12+
- At least moderate severity on scalp (S-IGA) and mild severity on body (B-IGA)
- ≤ 25% BSA; ≤ 20% non-scalp BSA
- Psoriasis Scalp Severity Index (PSSI) ≥ 6
- ≥ 10% of scalp involved
- PASI ≥ 2



Endpoints

Co-Primary

- Scalp IGA (S-IGA) success at week 8
- Body IGA (B-IGA) success at week 8

Secondary

- Scalp worst itch NRS (SI-NRS)
- WI-NRS
- PASI-75
- S-IGA = 0
- Psoriasis Symptom Diary (PSD)

Safety and tolerability

IGA = Investigator's Global Assessment; IGA Success = Clear or Almost Clear with at least a 2-grade improvement from baseline; WI-NRS: Worst Itch Numeric Rating Scale; QD = once a day; BSA = body surface area

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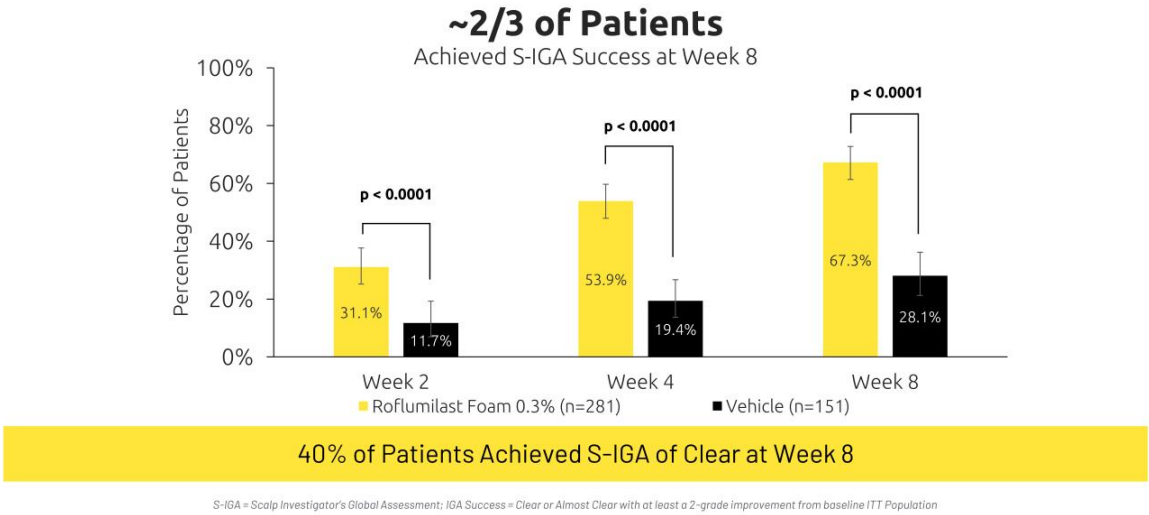
Robust Efficacy on Scalp IGA Success in ARRECTOR Trial



40% of Patients Achieved S-IGA of Clear at Week 8

S-IGA = Scalp Investigator's Global Assessment; IGA Success = Clear or Almost Clear with at least a 2-grade improvement from baseline ITT Population

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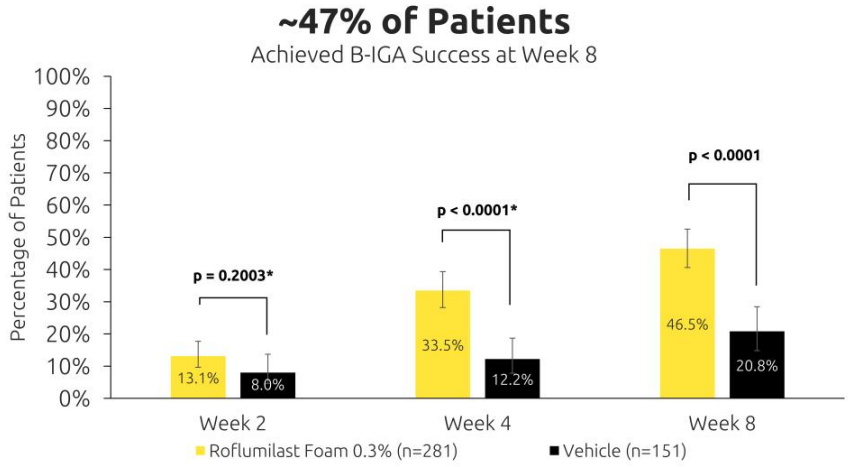
Demonstrated Efficacy on Body IGA Success in ARRECTOR Trial, Consistent with DERMIS Trials



*B-IGA = Body Investigator's Global Assessment; IGA Success = Clear or Almost Clear with at least a 2-grade improvement from baseline ITT Population; * Nominal p-values*

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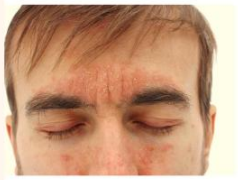
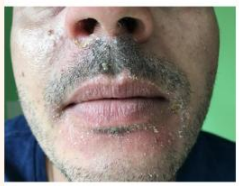
Seborrheic Dermatitis – Significant Unmet Needs in Treatment Paradigm

~10 million

Individuals in the U.S. affected

- Itchy red patches covered by greasy / flaking scales on scalp, face and chest
- Topicals dominate treatment, but options pose challenges:
  - Steroids pose safety issues, especially with chronic use
  - Proximity to eyes/thin skin on face exacerbates safety concerns
  - Topical antifungals offer only modest efficacy
  - Polypharmacy





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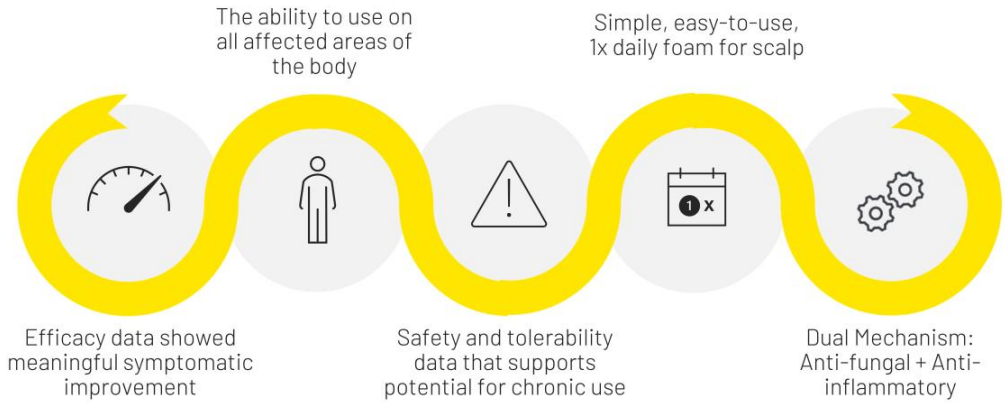
Roflumilast Foam Could Become Standard of Care in Seborrheic Dermatitis



Efficacy data showed meaningful symptomatic improvement

Safety and tolerability data that supports potential for chronic use

Dual Mechanism: Anti-fungal + Anti-inflammatory

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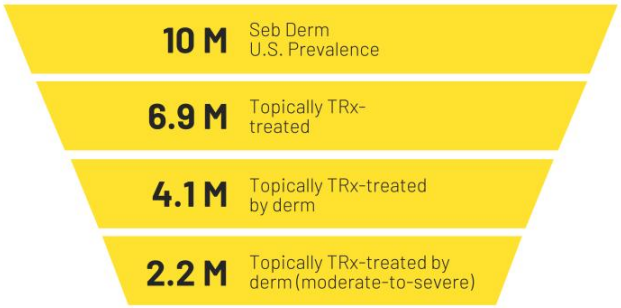
Seborrheic Dermatitis: Opportunity Comparable in Size to Psoriasis



75

Average # of seborrheic dermatitis patients seen in a typical month

	Mild	**Moderate**	**Severe**
Patients receiving a prescription treatment 1st line[1]	71%	**92%**	**97%**

[1] *Arcutis Quantitative Seb Derm Research August 2020, n=100 Dermatology HCPs: TRx = prescription*

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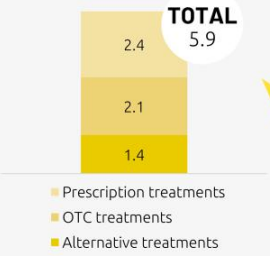
Patients Require Complex and Onerous Treatment Regimens

Actively Using Treatments[1]
Per Week, Mean



9 in 10 AGREE[1]
"I would be more likely to stick with a treatment plan if it meant using fewer treatments."

Patients ready for new options

"I am interested in trying new treatment options."

9 in 10
AGREE[1]

[1]*Harris Poll Seborrheic Dermatitis Survey (n>600 HCPs, n=300 patients)*

OTC = over the counter; HCP = healthcare professional

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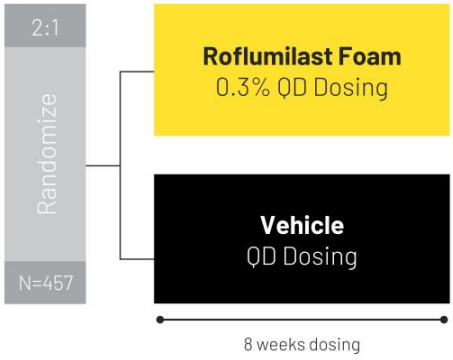
STRATUM Phase 3 Trial in Seborrheic Dermatitis

Randomized, Double-blind, Vehicle-controlled Multicenter Study

Eligibility

- Diagnosis of at least moderate seborrheic dermatitis (IGA ≥3)
- Age 9+
- Up to 20% BSA



Endpoints

Primary

- IGA success at week 8

Secondary

- IGA success at week 2 and 4
- IGA score of 0 at week 8
- Overall assessment of erythema/scaling
- WI-NRS (itch)

Safety and tolerability

Single STRATUM study should be sufficient basis for NDA

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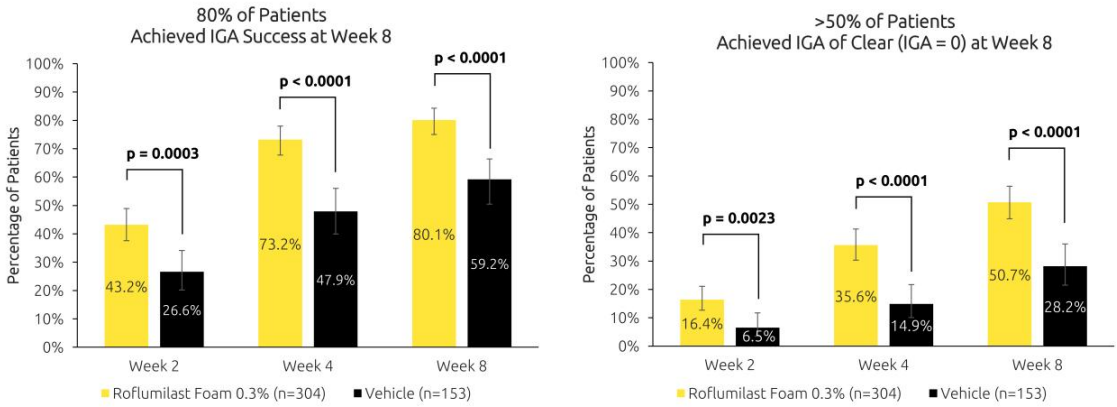
80% of Patients Achieved IGA Success & 50% Completely Clear at 8 Weeks in Seb Derm Phase 3



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

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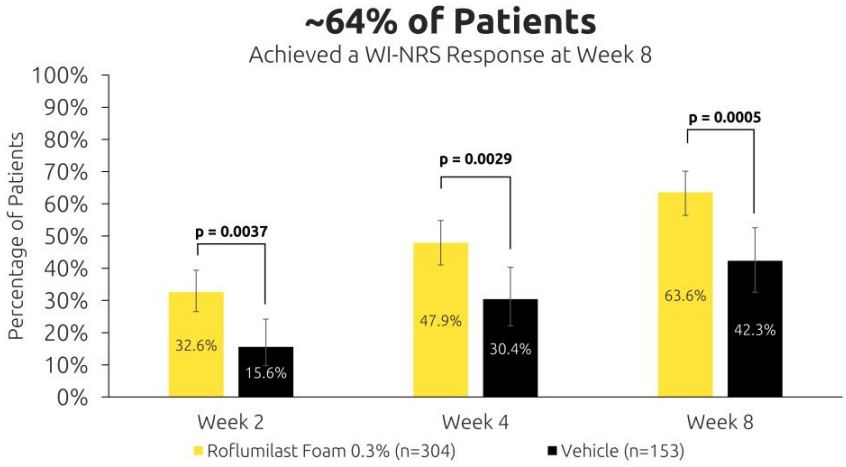
Robust Itch Response in Phase 3 in Pivotal Phase 3 STRATUM Trial



WI-NRS: Worst Itch Numeric Rating Scale; WI-NRS response = 4 point reduction in WI-NRS in patients with WI-NRS > 4 at baseline

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Roflumilast Foam Was Well-Tolerated in Pivotal Phase 3 STRATUM Trial

Subjects (%)	Roflumilast 0.3% (n=304)	Vehicle (n=153)	Overall (n=457)
Subjects with any TEAE	70 (23.0%)	33 (21.6%)	103 (22.5%)
Subjects with any Treatment-Related TEAE	8 (2.6%)	5 (3.3%)	13 (2.8%)
Subjects with any SAE	1 (0.3%)	0	1 (0.2%)
Treatment-related SAE	0	0	0
Subjects who discontinued Study Drug due to AE	2 (0.7%)	3 (2.0%)	5 (1.1%)
Subjects who discontinued Study due to AE	2 (0.7%)	3 (2.0%)	5 (1.1%)

AE: adverse event; SAE: serious adverse event; TEAE: treatment-emergent adverse event

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Most Common Treatment Emergent Adverse Events (>1.0% in Any Group) in Pivotal Phase 3 STRATUM Trial

Preferred Term	Roflumilast 0.3% (n=304)	Vehicle (n=153)	Overall (n=457)
COVID-19	11 (3.6%)	5 (3.3%)	16 (3.5%)
Urinary tract infection	4 (1.3%)	3 (2.0%)	7 (1.5%)
Nasopharyngitis	4 (1.3%)	1 (0.7%)	5 (1.1%)
Nausea*	5 (1.6%)	0	5 (1.1%)
Application site pain	1 (0.3%)	3 (2.0%)	4 (0.9%)
Sinusitis	0	2 (1.3%)	2 (0.4%)

*All graded as mild

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Advancing Multiple Preclinical Programs in Dermatology

Candidate	Program
ARQ-252 Cream (JAK1 Inhibitor)	• Chronic Hand Eczema • Vitiligo
ARQ-255 Suspension (JAK1 Inhibitor)	• Alopecia Areata
Other Preclinical Projects	• Acne • Palmoplantar Psoriasis • Nail Psoriasis • Rosacea

Strategic In-licensing / Business Development

- Best-in-class potential
- Validated targets
- Modality agnostic

Ducentis BioTherapeutics

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Alopecia Areata (AA) – No Approved Treatments and Significant Unmet Needs

Autoimmune, chronic, and relapsing hair loss
ranging from scattered patches to complete loss of hair

Significant psychosocial impact
on self-esteem, body image, and/or self-confidence

No FDA-approved therapies

- Standard of care includes topical steroids or steroid injections
- Most development focused on oral/systemic therapies targeting more severe disease
- Topical therapy well-positioned for more common mild-to-moderate disease

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Barriers to Topical Drug Delivery to the Hair Bulb

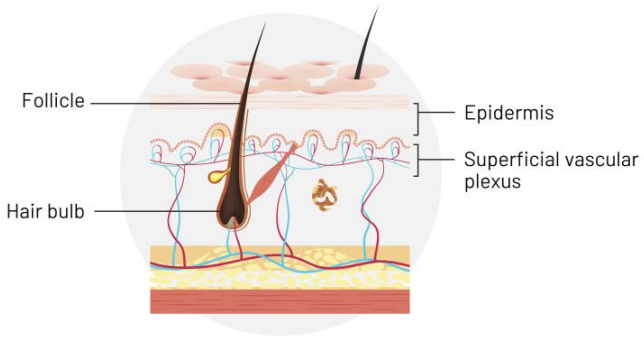
Drug delivery challenge
suggested by failure of topical JAKi approach, coupled with success of oral JAKs

Inflammation in AA
surrounds the hair bulb

Challenges to topical treatment

- Depth of inflammation
- Dense vasculature

ARQ-255
is designed to deliver drug to the site of inflammation deep in the hair follicle



Entered Clinic in December 2022 for ARQ-255

AA = alopecia areata

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Acquisition of Ducentis – Next Step Towards Evolution into Preeminent Immuno-Dermatology Company

- **Aligned to the Arcutis Strategy**
  (1) Atopic Derm (AD) is Large Market with High Unmet Need, (2) CD200R is a biologically-validated target, (3) ARQ-234 potentially best-in-class molecule
- Leverages Arcutis' Deep Dermatology & Biologics Expertise
- ARQ-234 Is Highly Complementary To Roflumilast Cream In AD
- Modest Investment to Acquire Biologic and Achieve Proof-of-Concept Against De-Risked Target in High-Value Indication

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