



ARCUTIS
BIOTHERAPEUTICS

Bioscience applied to the skin.



ZORYVE™
(roflumilast) Cream 0.3%
FDA Approval Call
August 1, 2022

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 execution in commercializing ZORYVE (roflumilast) cream in its approved indication in plaque psoriasis; 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(s) and product candidates; the size and growth potential of the markets for our product(s) and 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(s) and 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-K filed with U.S. Securities and Exchange Commission (SEC) on February 22, 2022, 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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Today's Speakers



Frank Watanabe
President & CEO



Patrick Burnett, MD, PhD, FAAD
Chief Medical Officer



Ken Lock
Chief Commercial Officer



Speakers & Agenda



Frank Watanabe

President and CEO

Arcutis Overview

ZORYVE - Differentiated Clinical Profile

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Conclusions

Q&A



2022: A Transformational Year for Arcutis Continues



FDA approval of ZORYVE (roflumilast) in plaque psoriasis and imminent launch is the realization of our efforts to bring **meaningful innovation** to address the unmet needs of patients with immune-mediated skin diseases



Topical roflumilast is a **unique “pipeline-in-a-product” opportunity** across four development programs

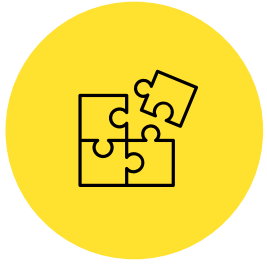


We **remain confident in continuing our track record of Phase 3 successes** in subsequent pivotal readouts in atopic dermatitis and scalp and body psoriasis later this year



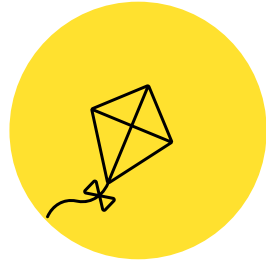
We will **further strengthen our balance sheet** by drawing an additional \$125 million from our debt facility; enables robust launch investment for ZORYVE and continued pipeline advancement

Strategic Milestone Today with Our Transition to Commercial-Stage 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

~7 million Dermatologist-Treated Patients Could Benefit From Topical Roflumilast in the U.S. Alone

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

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

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

Speakers & Agenda



Patrick Burnett,
MD, PhD, FAAD

Chief Medical Officer

Arcutis Overview

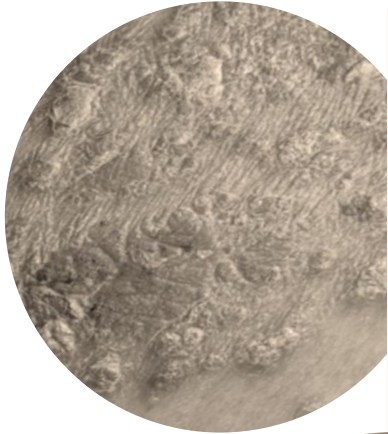
ZORYVE - Differentiated Clinical Profile

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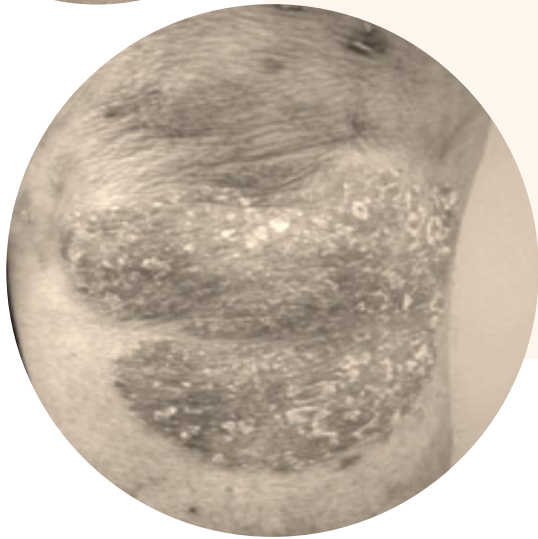
Q&A

Plaque Psoriasis - Significant Unmet Needs in Treatment Paradigm



~9M

individuals in the U.S. affected¹



>90%

of U.S. patients treated with topical drugs¹

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 steroids²

¹ 2021 Decision Resources Group [Psoriasis Landscape and Forecast + Psoriasis Epidemiology] reports; ² Skin Insights: Uncovering Psoriasis survey of >500 adults who use topicals, March 2022

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

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

Z 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)



WI-NRS: Worst Itch Numeric Rating Scale



Indication for treatment of intertriginous areas

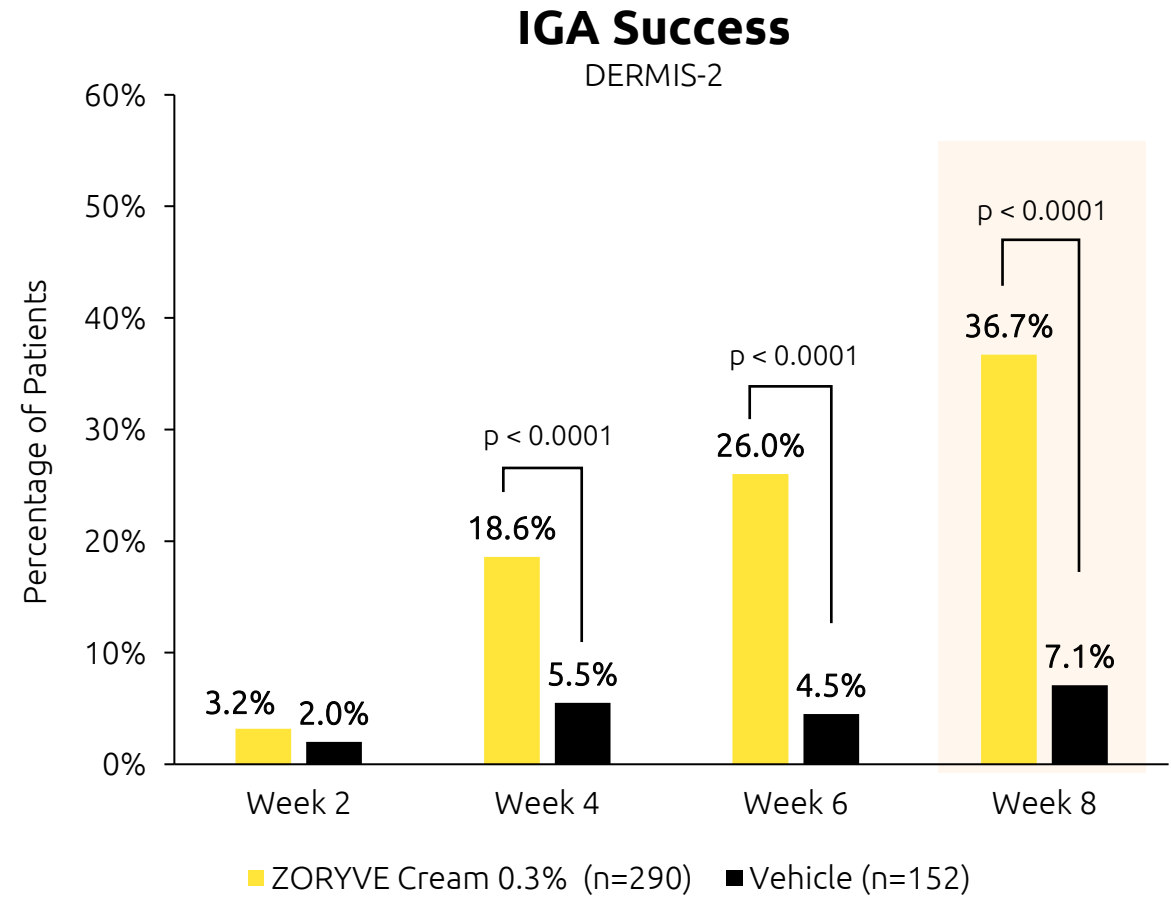
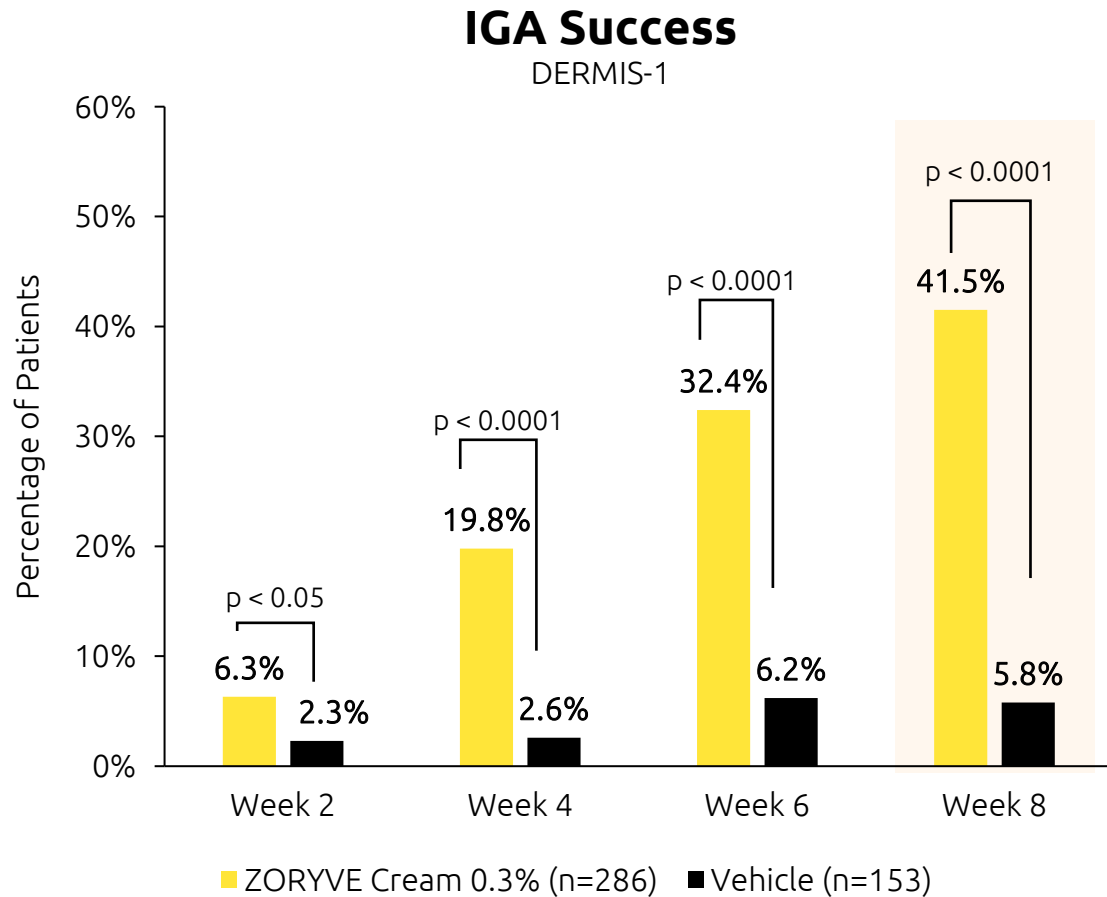


Indication for ages 12+



Itch data (WI-NRS) included in label

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

Significant and Rapid Clearance of Plaques in DERMIS Phase 3 Trials

Baseline (Heel)



IGA = 2

Week 4



IGA = 0

Week 8



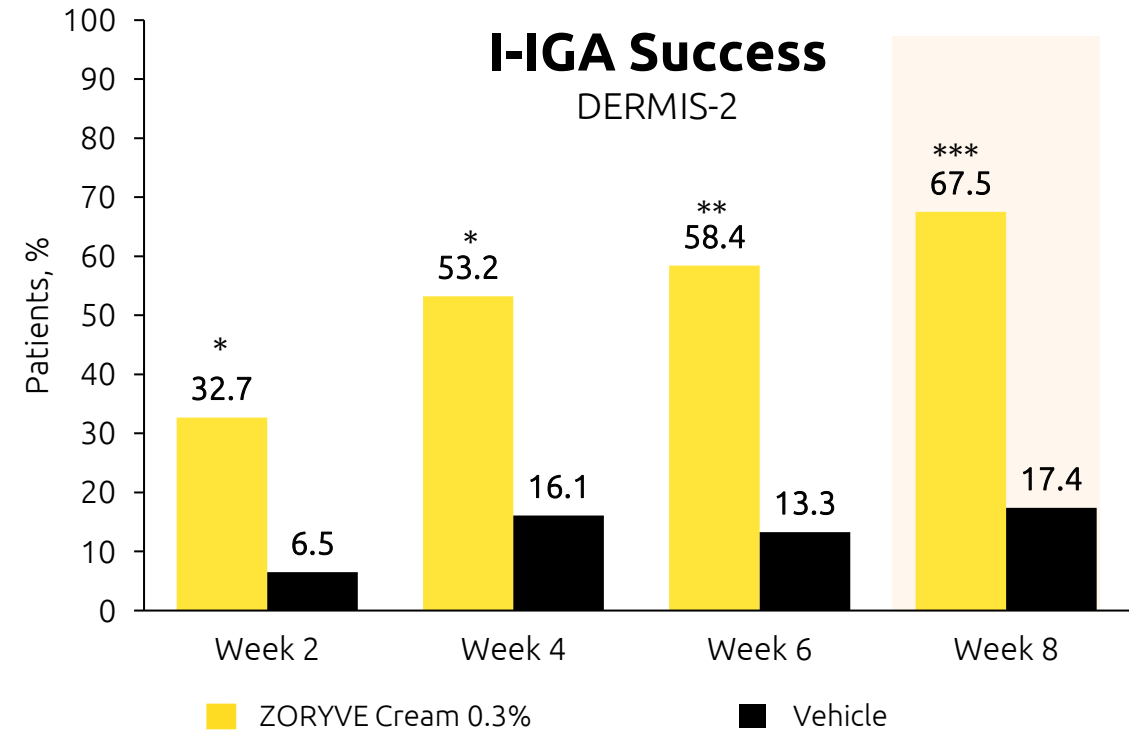
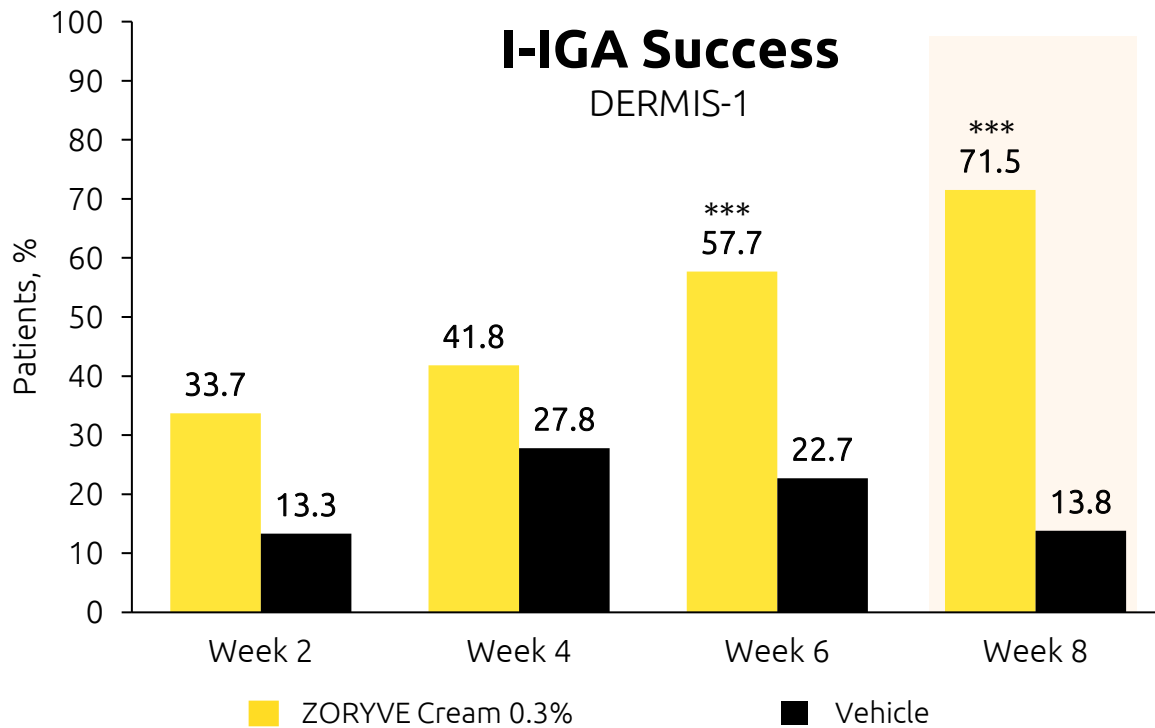
IGA = 0

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

Individual patient results may vary

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

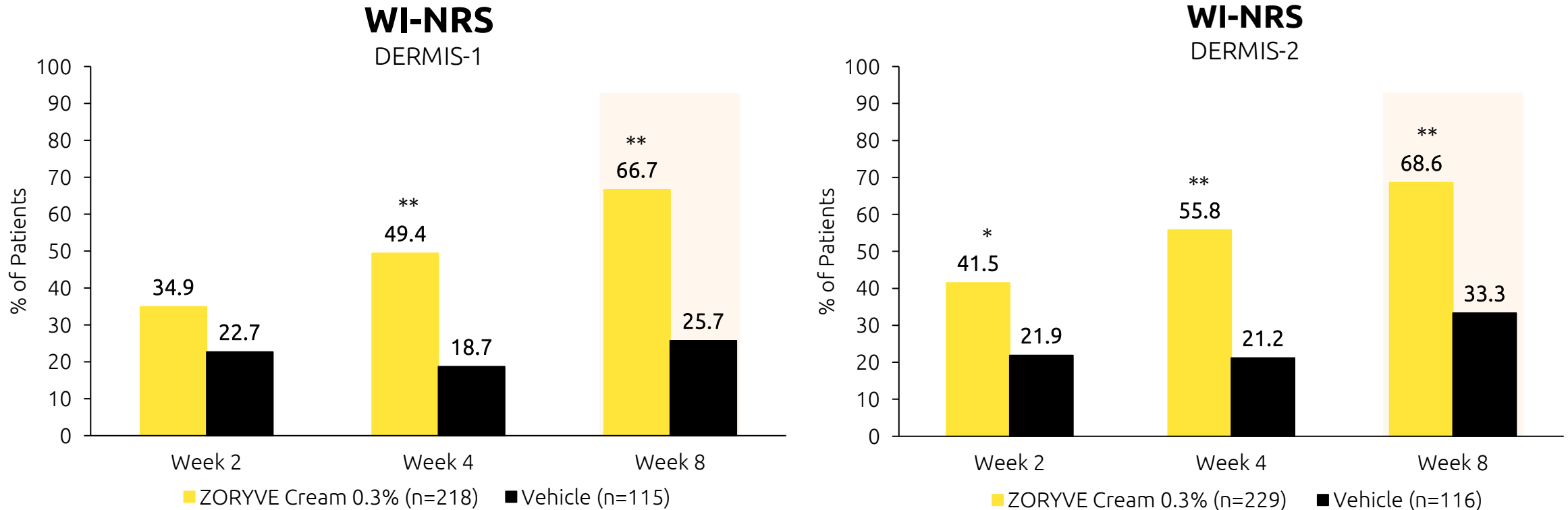


Survey Suggests ~2 in 3 Patients Have Exhibited Psoriasis in Intertriginous Areas¹

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

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

ZORYVE – Safe and Very Well-Tolerated

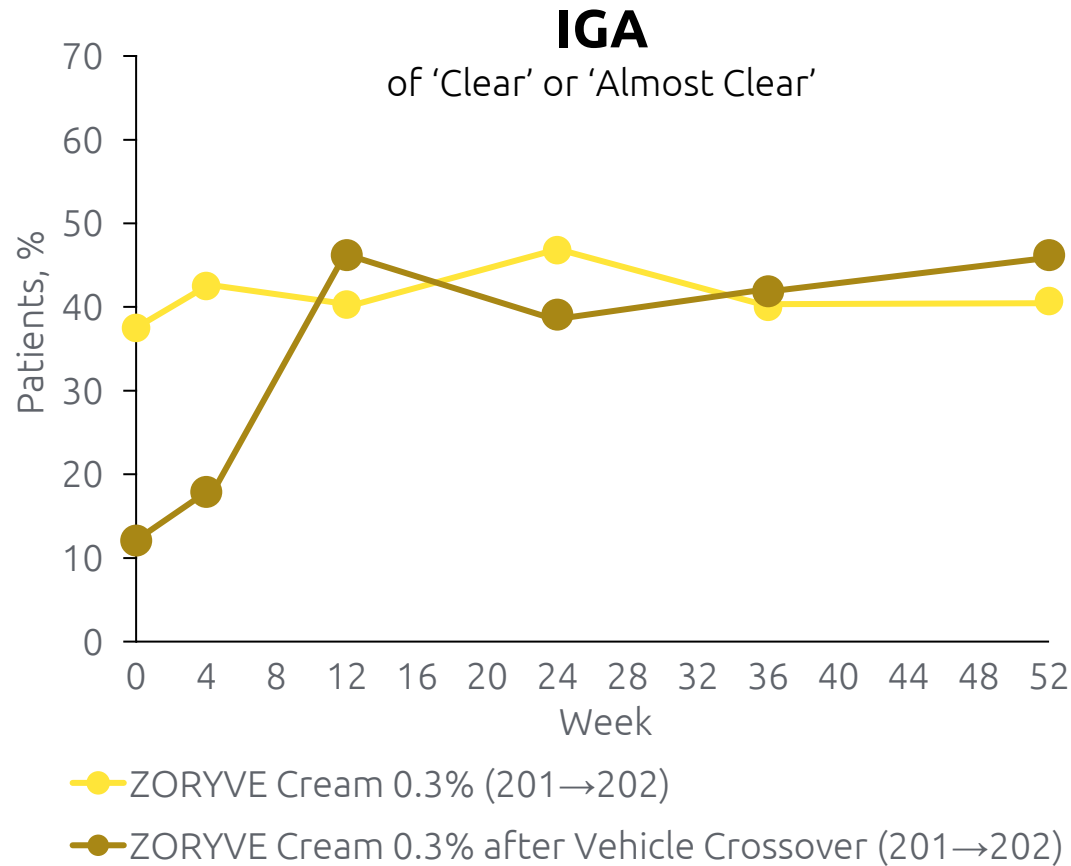
DERMIS-1 and -2

Adverse Reactions Reported in $\geq 1\%$ 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

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 trials

- **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

Speakers & Agenda



Ken Lock

Chief Commercial Officer

Arcutis Overview

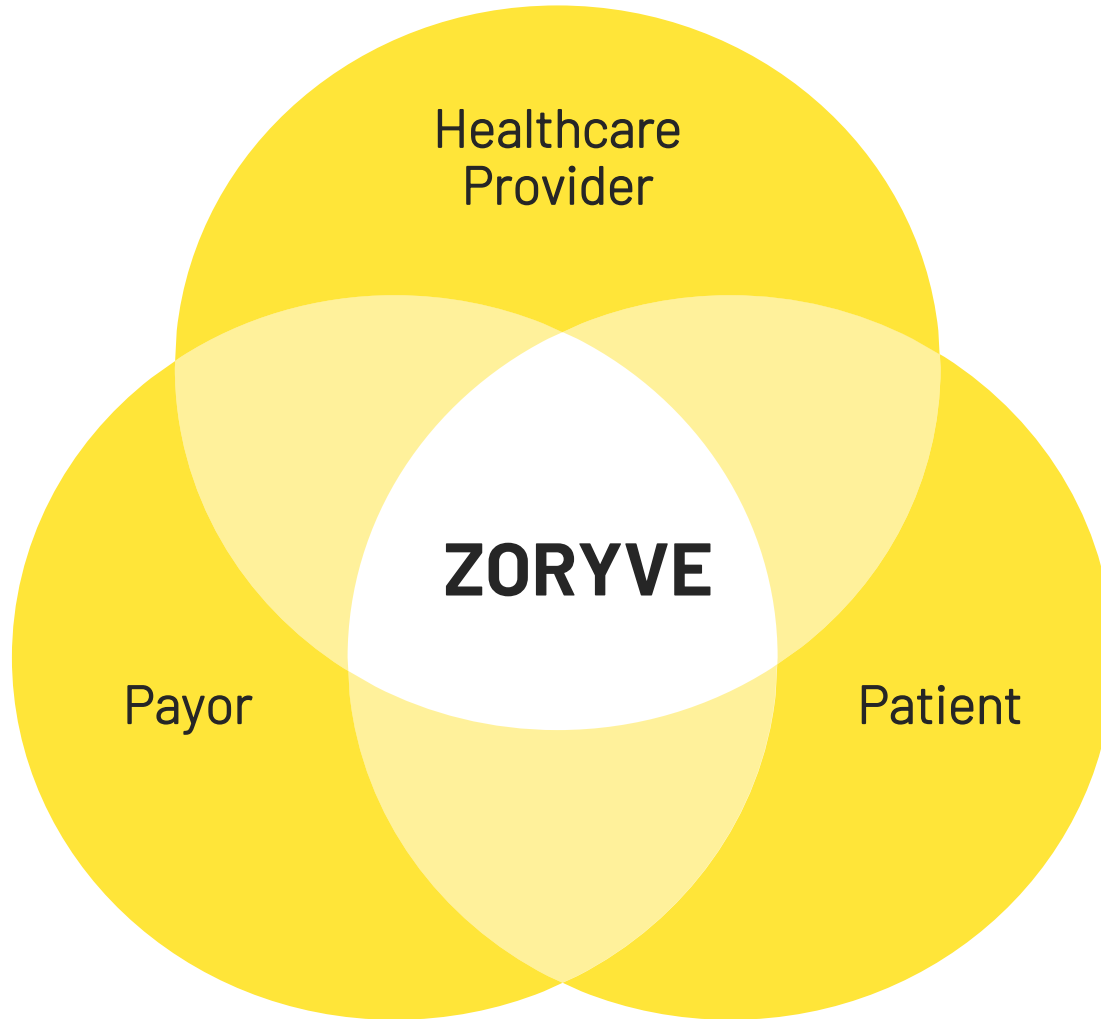
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ZORYVE: Designed to Simplify the Treatment of Psoriasis



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

<u>In Label</u>	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

ZORYVE - Patient-Friendly Formulation That Effectively Delivers Highly Potent PDE4



Once-daily dosing



Steroid-free



Uniquely featuring HydroARQ Technology

- Non-greasy, moisturizing cream
- Spreads easily, absorbs quickly
- No sensitizing excipients or irritants (e.g. propylene glycol, ethanol)



Patient Dynamics Are Favorable Towards Trial



~2M

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

Rx = prescription

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

Strong Patient Interest and Engagement in Innovation



9 in 10
Patients

- ✓ Wish there were more effective topical treatment options
- ✓ Wish topical treatments were a once daily application
- ✓ Wish they could use a single topical therapy anywhere on their body
- ✓ Are interested in trying a new topical treatment for their psoriasis

2 in 3

Patients have exhibited psoriasis in intertriginous areas

9 in 10

Intertriginous patients would be more adherent if a single topical could be used everywhere on the body

Source: Skin Insights: Uncovering Psoriasis survey of >500 adults who use topicals, March 2022

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

WAC Price of \$825 Optimizes for Our Access Objectives, Helps More Patients, & Maximizes Total Franchise Value

Our Access/Coverage Goals

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

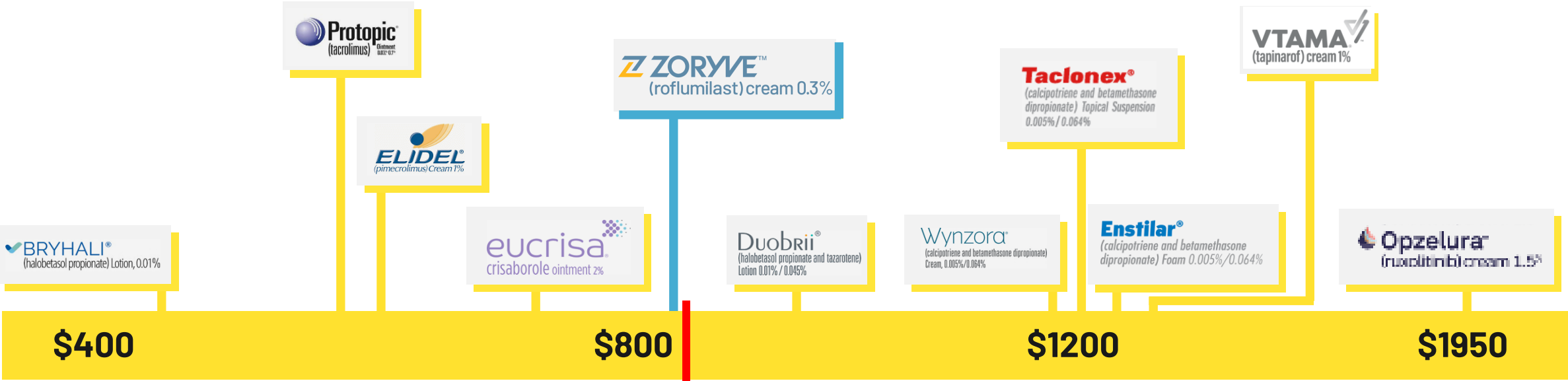
Topical Roflumilast

- Highly innovative
- Effective, safe, well-tolerated
- Potential 1st line treatment option
- Potential follow-on indications in AD & Seb Derm with varied patient mix

\$825/tube



List Prices of Select Branded Topicals



\$830 = CMS Specialty Tier

Indicative Payor Controls

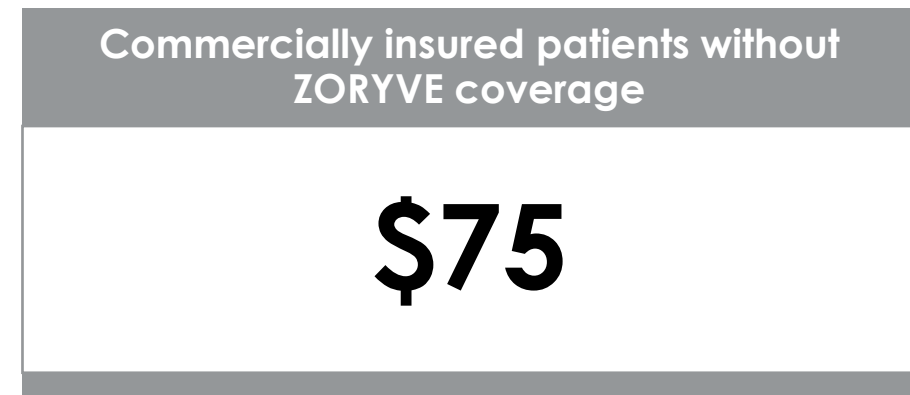
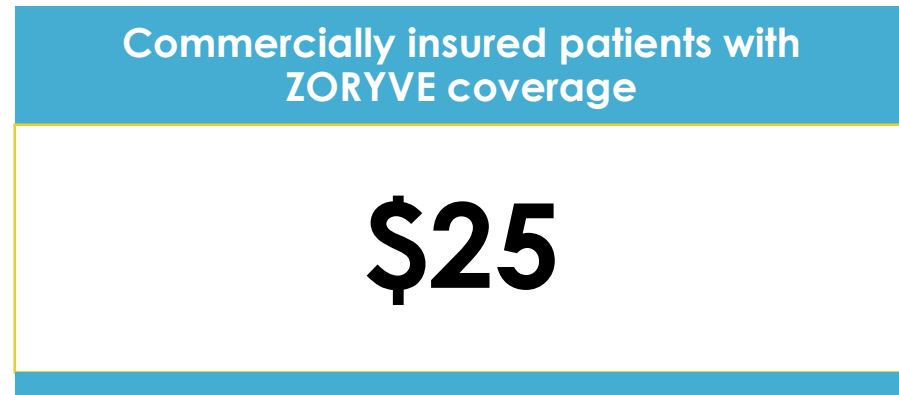
Source: Analysource - 7/15/22 ; CMS = Centers for Medicare & Medicaid Services

Patients Will be Supported via ZORYVE Direct

ZORYVE direct

Patient access support made easy

Savings Program*



For Financially Eligible Patients who are Uninsured or Underinsured, Arcutis Will Also Offer 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*

ZORYVE Launch Readiness



Sales force fully hired; detailing begins today



Product expected in channel in < 2 weeks



Broad sampling program ready to activate



ZORYVE Direct patient support active



ZORYVE
(roflumilast) cream 0.3%
direct
Patient access support made easy

Speakers & Agenda



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President and CEO

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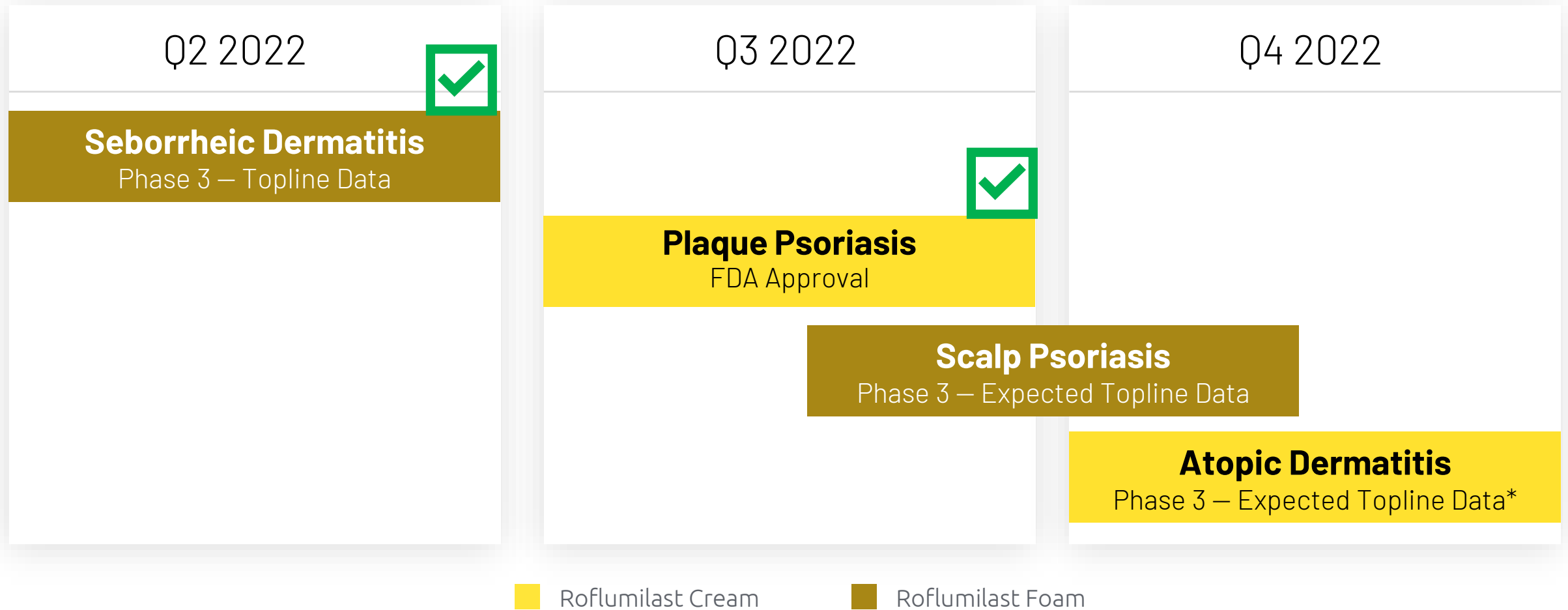
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Continued Execution Against Our Four Transformational Catalysts in 2022



*Phase 3 topline for INTEGUMENT-1 and -2; INTEGUMENT-PED expected in 2023

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Thank You



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