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): February 1, 2021

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 February 1, 2021, Arcutis Biotherapeutics, Inc. (the "Company") announced positive topline results from its DERMIS-1 and DERMIS-2 pivotal Phase 3 studies evaluating roflumilast cream ("ARQ-151") as a potential topical treatment for plaque psoriasis. The studies were identical Phase 3 randomized, parallel, double-blind, vehicle-controlled, multi-national, multi-center studies in which subjects age 2 years and above with mild, moderate or severe chronic plaque psoriasis involving between 2% and 20% body surface area received 8 weeks of (i) roflumilast cream 0.3% once daily or (ii) matching vehicle once daily. DERMIS-1 enrolled 439 subjects and DERMIS-2 enrolled 442 subjects.

Results from the eight-week treatment period demonstrated statistically significant improvement compared to the matching vehicle on key efficacy endpoints. On the studies' primary efficacy endpoint of percentage of patients achieving Investigator Global Assessment ("IGA") success, which was defined as a score of "clear" or "almost clear" plus a 2-grade improvement from baseline at week 8, 42.4% of patients treated with roflumilast cream achieved IGA success, compared to 6.1% of patients treated with vehicle ($p < 0.0001$) in DERMIS-1, and 37.5% of patients treated with roflumilast cream achieved IGA success, compared to 6.9% of patients treated with vehicle ($p<0.0001$) in DERMIS-2. Roflumilast cream also demonstrated statistically significant improvements over vehicle on key secondary endpoints, including on Intertriginous IGA Success, Psoriasis Area Severity Index-75, reductions in itch as measured by the Worst Itch-Numerical Rating Scale, and patient perceptions of symptoms as measured by the Psoriasis Symptoms Diary.

Roflumilast cream was well-tolerated by the patient populations, with rates of treatment-emergent adverse events ("TEAEs") low and similar to vehicle, with most TEAEs assessed as mild to moderate in severity. Of the patients treated with roflumilast cream, five patients (1.7% of subjects) in DERMIS-1 and one patient (0.3% of subjects) in DERMIS-2 discontinued the study due to a TEAE. There were no treatment-related serious adverse events.

On February 1, 2021, the Company provided a corporate presentation relating to its topline results from its DERMIS-1 and DERMIS-2 pivotal Phase 3 studies of roflumilast cream as a potential topical treatment for plaque psoriasis by posting an additional corporate presentation 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 this report, 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 February 1, 2021.
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: February 1, 2021 By: /s/ John W. Smither
John W. Smither
Chief Financial Officer

ARCUTIS
BIOTHERAPEUTICS

DERMIS-1/DERMIS-2 Phase 3 Plaque Psoriasis Topline Data Review

February 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 relate data, our ability to obtain and maintain regulatory approval, the potential therapeutic benefits and economic value of our product candidates, competitive position, ind 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 applic 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 ou 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 potenti 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 intellectu property protection; our dependence on third party manufacturers; the success of competing therapies that are or may become available; our ability to attract and reta key scientific or management personnel; our ability to identify additional product candidates with significant commercial potential consistent with our commercial objecti 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 pre 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 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 inform 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) 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 for 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 m 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 degre uncertainty and risk.

Today's Speakers

Frank Watanabe
President and CEO

Mark Lebwohl, MD
Professor and Dean for Clinical Therapeutics, Icahn School of Medicine at Mount Sinai

Patrick Burnett, M.D., Ph.D., FAAD
Chief Medical Officer

Ken Lock
Chief Commercial Officer

Frank Watanabe

President & CEO

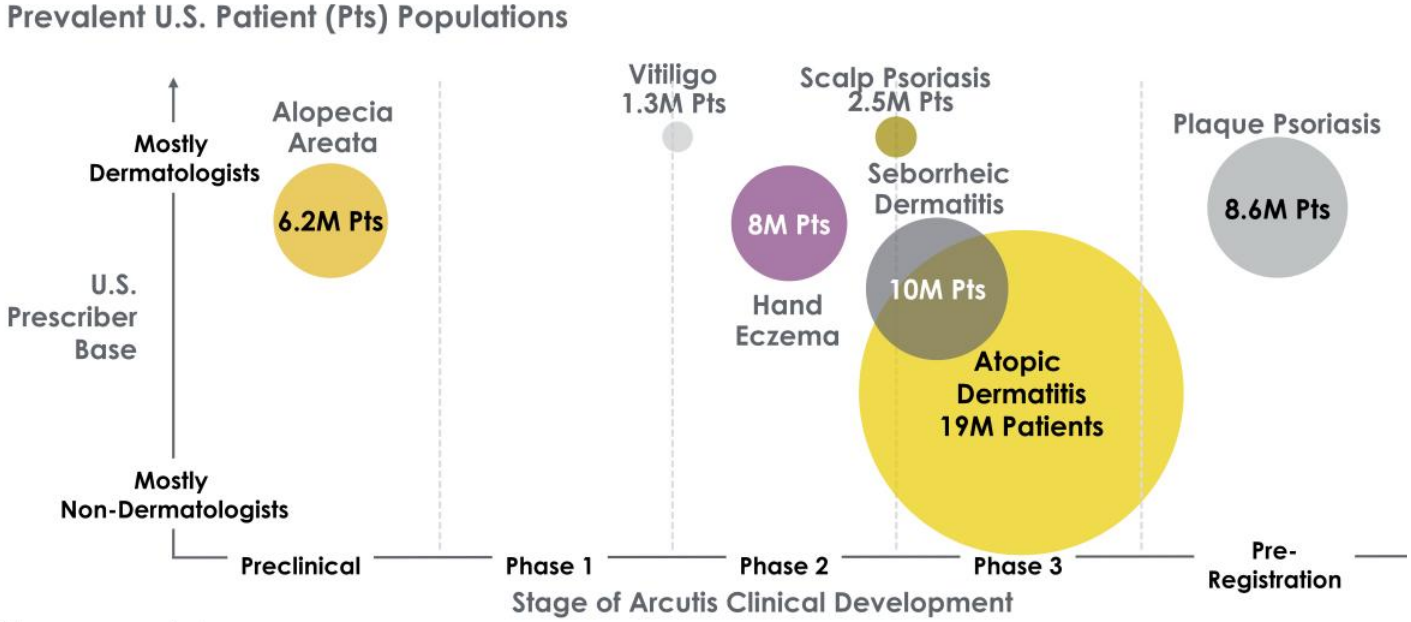
Arcutis Drivers of Value

- Focus on large dermatology markets with significant unmet medical needs
- Late-stage pipeline of differentiated products with significant near-term potential
- Topical roflumilast could become first-line therapy & transform treatment paradigm
- Leading dermatology development engine
- Experienced commercial team prepared to effectively launch our products

Portfolio could potentially generate ~$3-8 billion in U.S. annual sales by 2030[1]

1. Source: Company estimates, includes indications currently under development

Our Product Candidates Target Large Markets[1]



1. Source: company estimates

Roflumilast May Address Unmet Needs in Plaque Psoriasis

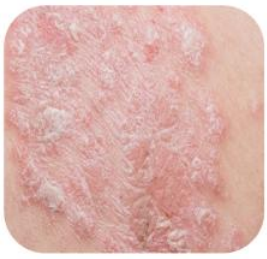
- Efficacy:
  - Symptomatic improvements similar to steroid/vitamin D combinati exceeding high-potency steroids or Otezla
  - Improvement on intertriginous plaques
  - Impact on itch associated with psoriasis
  - Rapid onset
  - Well tolerated
- Simple, easy to use once-a-day cream or foam

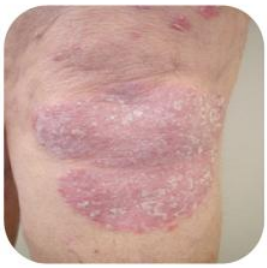
IGA = Investigator's Global Assessment (IGA) Scale

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

Chief Medical Officer

Significant Unmet Needs in Plaque Psoriasis





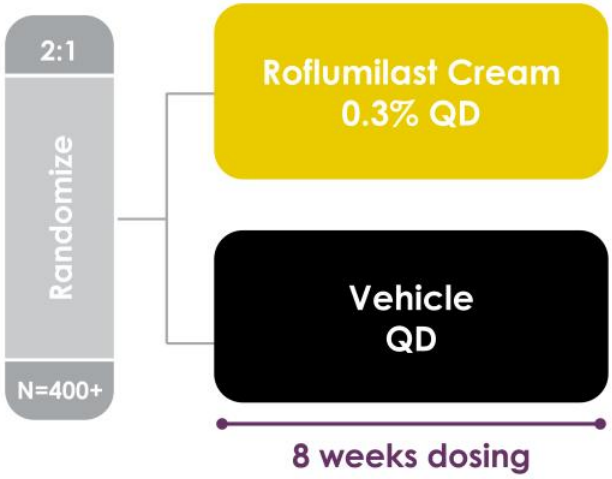
- > 90% of US patients treated with topical drugs
- Existing topical therapies have numerous shortcomings
  - Physicians and patients forced to trade off between efficacy and safety/tolerability
- Ideal topical: efficacy of high potency steroids, ability to use chronically, and ability to use in all body areas

DERMIS-1/2 Phase 3 Plaque Psoriasis Studie

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

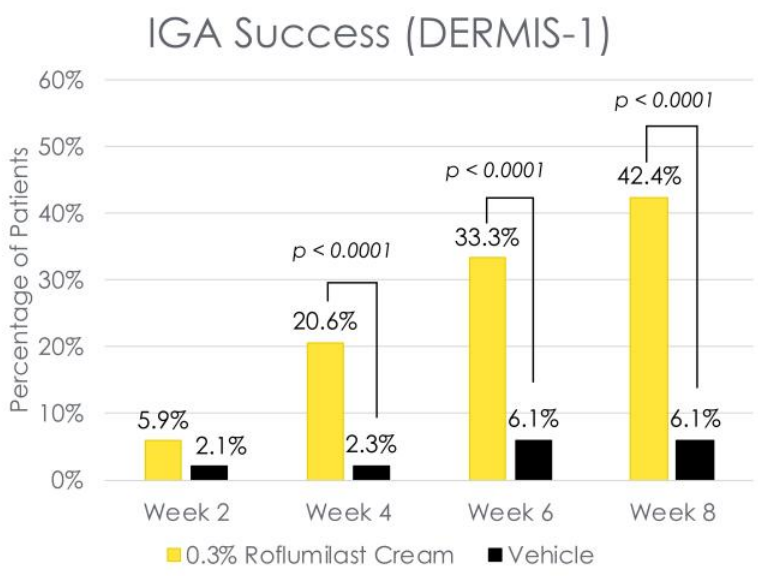
Secondary

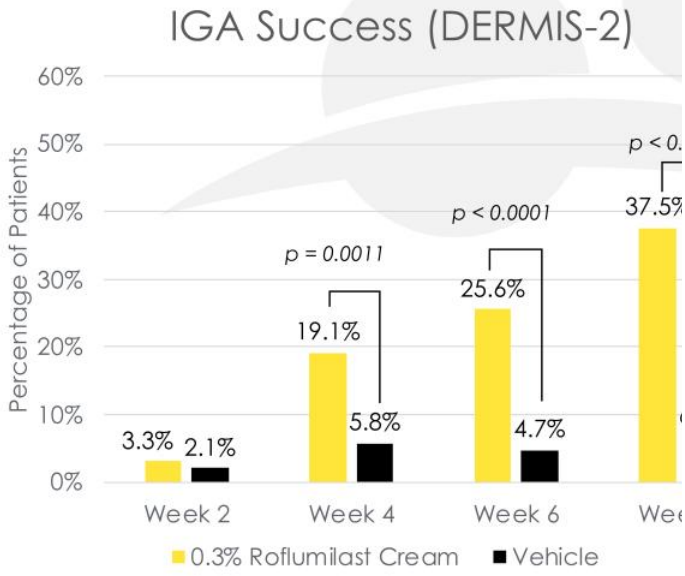
- PASI-50 and PASI-75
- Intertriginous-IGA (I-IGA) Succes
- WI-NRS (itch)
- Psoriasis Symptom Diary (PSD)

Safety and tolerability

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

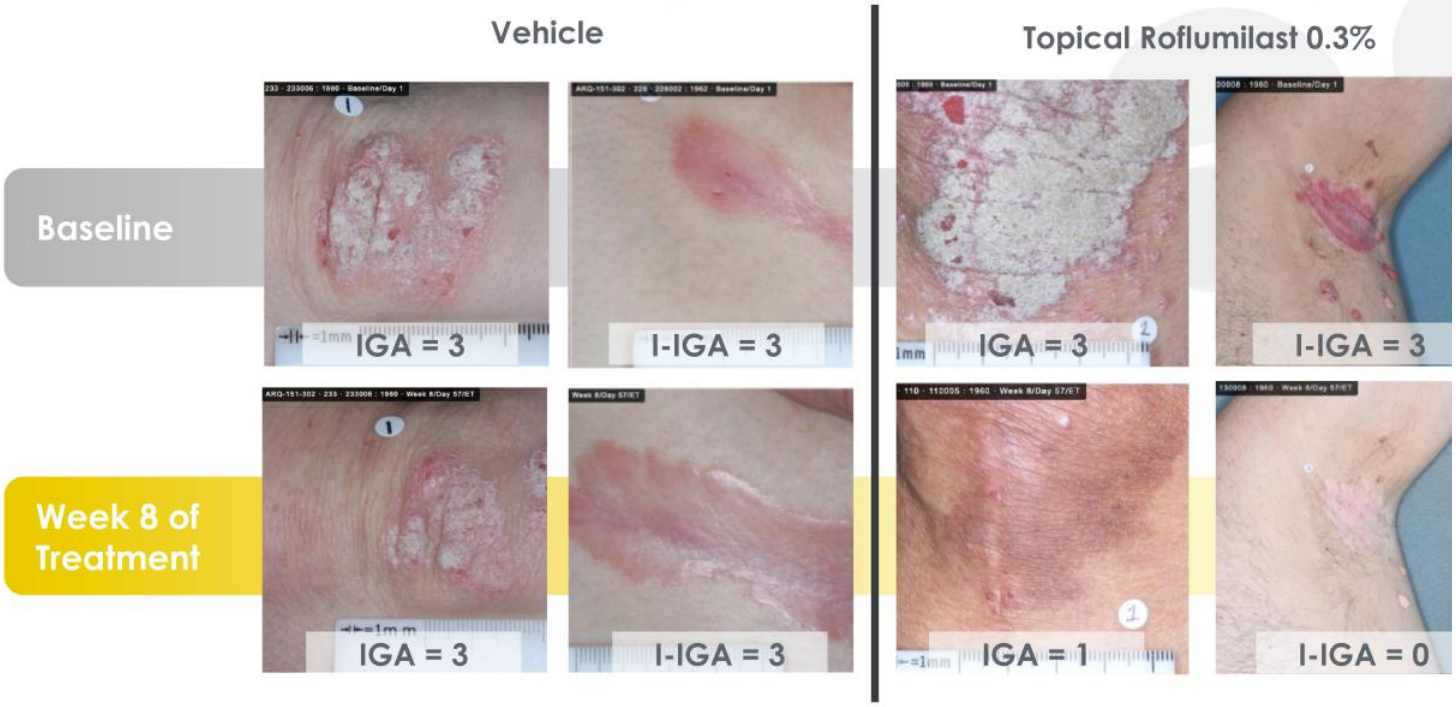
Robust Efficacy on IGA Success in Both Phase 3 Studies





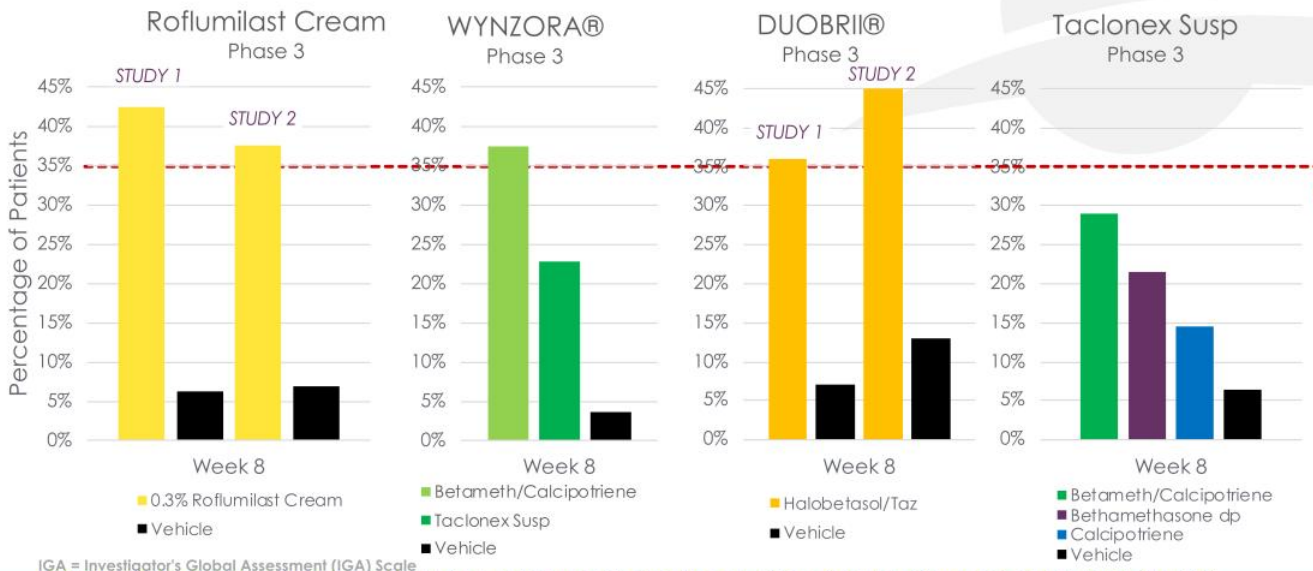
IGA Success = Clear or Almost Clear with at least a 2-grade improvement from baseline
ITT Population

DERMIS-1/2 Efficacy



IGA Success at 8 Weeks Comparable to Combo of High-potency Steroids & Vitamin D / Tazaroten

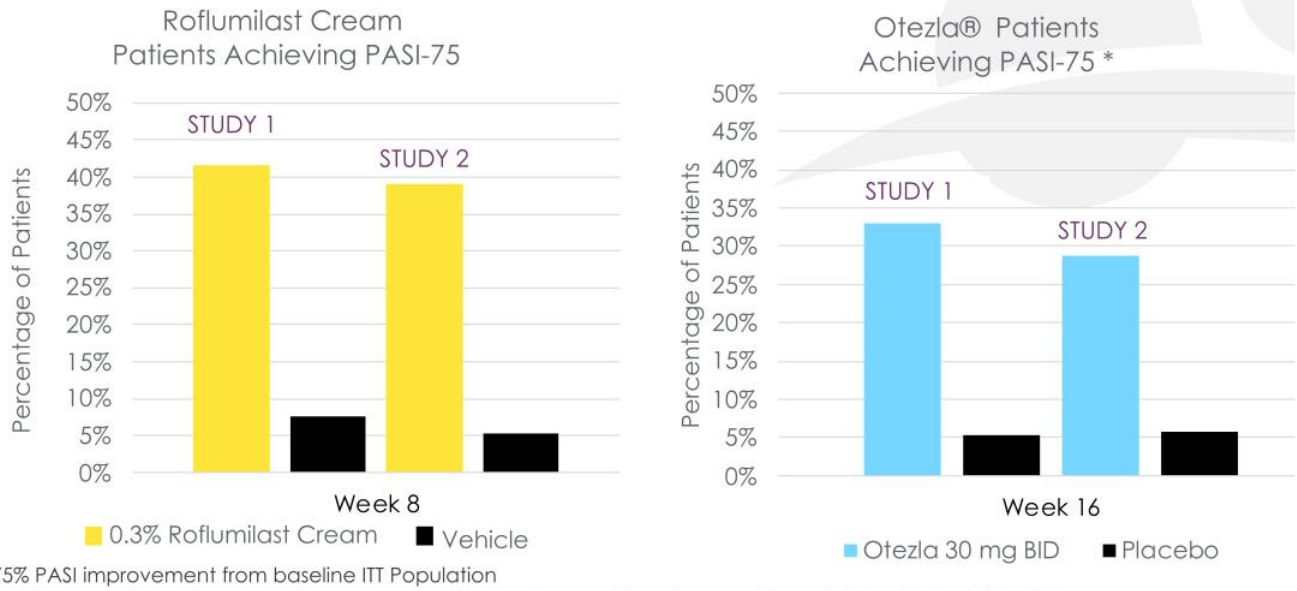
Comparison of IGA Success Rates Across Separate Topical Psoriasis Clinical Trials



IGA = Investigator's Global Assessment (IGA) Scale
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.

PASI-75 at 8 Weeks Surpasses Otezla 16-Week Data

Comparison of PASI-75 Across Separate Psoriasis Clinical Trials

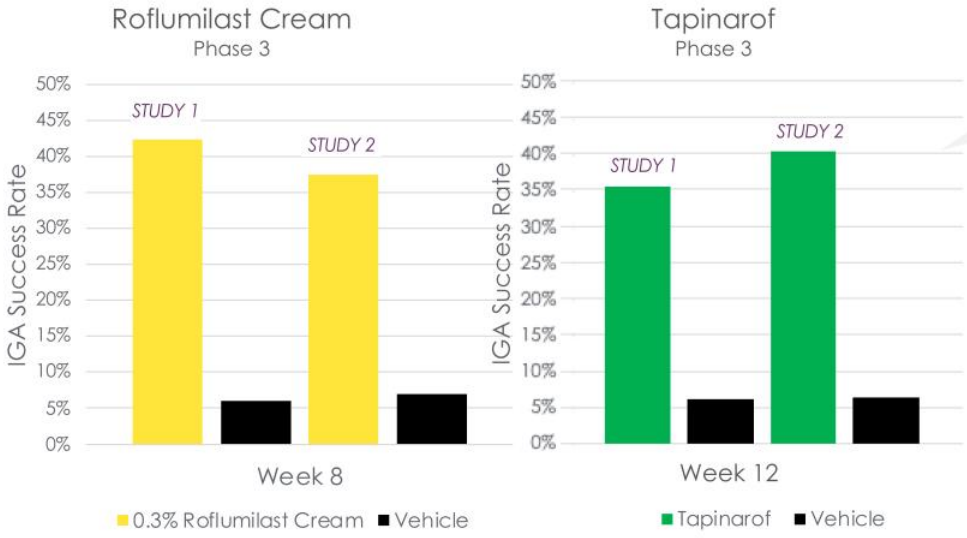


PASI-75 = ≥75% PASI improvement from baseline ITT Population

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.
*Otezla® trials were in moderate-to-severe patients

IGA Success Comparable to Tapinarof by Earlier Timepoint

Comparison of IGA Success Across Separate Topical Psoriasis Clinical Trials



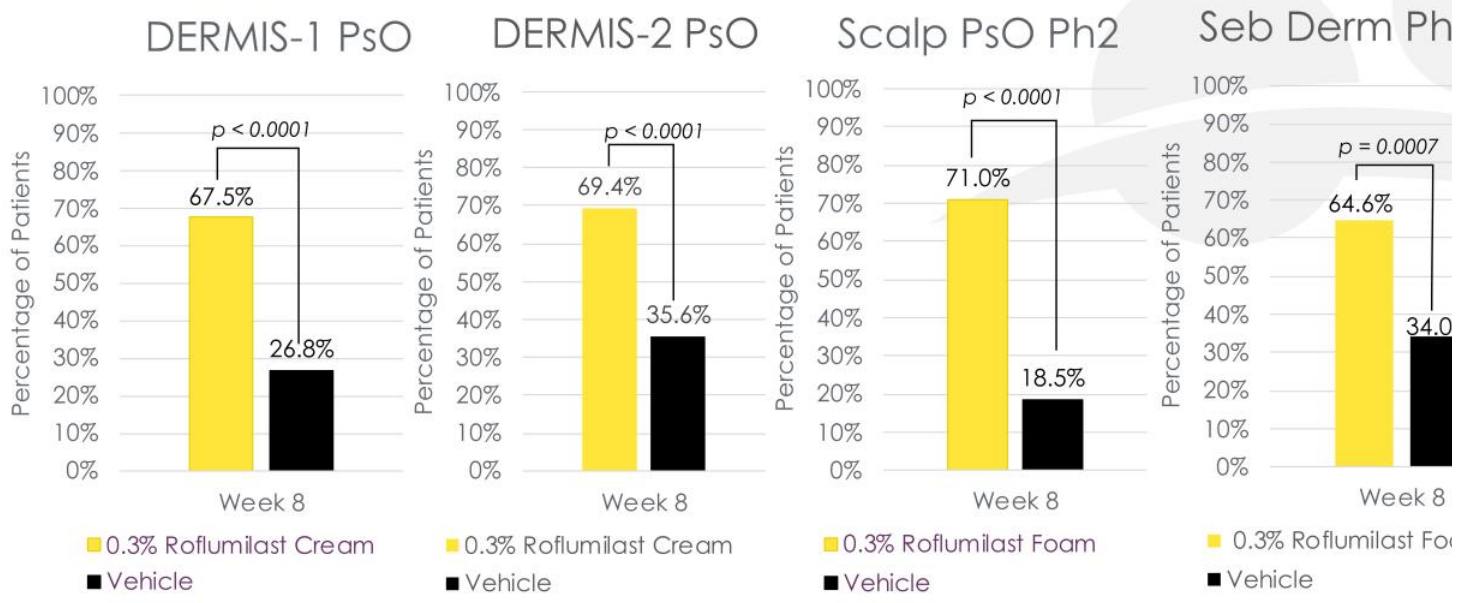
Roflumilast key advantag vs. tapinarof:

- **Local tolerability**
- **Impact on itch**
- **Week 8 vs. week 12 endpoint**

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

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.

Rapid, Robust and Consistent Effect on Itch Across Diseases



WI-NRS response = 4 point reduction in WI-NRS in patients with WI-NRS ≥ 4 at baseline

Topical Roflumilast Well Tolerated in Phase

	DERMIS-1		DERMIS-2	
	Roflumilast 0.3% (N=286)	Vehicle (N=153)	Roflumilast 0.3% (N=290)	Vehicle (N=152)
Subjects with any TEAE	72 (25.2%)	36 (23.5%)	75 (25.9%)	28 (18.4%)
Subjects with any Tx-Related TEAE	7 (2.4%)	3 (2.0%)	16 (5.5%)	8 (5.3%)
Subjects with any SAE	2 (0.7%)	1 (0.7%)	0	1 (0.9%)
Subjects with any Tx-Related SAE	0	0	0	0
Subjects who discontinued Study Drug due to AE	5 (1.7%)	2 (1.3%)	1 (0.3%)	2 (1.3%)

Most Common Adverse Events (≥2% in Any Group)

	DERMIS-1		DERMIS-2	
Subjects, n (%) Preferred Term	**Roflumilast 0.3% (n=286)**	**Vehicle (n=153)**	**Roflumilast 0.3% (n=290)**	**Vehicle (n=152)**
Hypertension	5 (1.7)	6 (3.9)	4 (1.4)	0
Headache	3 (1.0)	2 (1.3)	11 (3.8)	1 (0.7)
Diarrhea	10 (3.5)	0	8 (2.8)	0
Psoriasis	0	3 (2.0)	1 (0.3)	0
Nasopharyngitis	5 (1.7)	3 (2.0)	1 (0.3)	1 (0.7)

Hypertension includes synonymous terms (e.g., blood pressure increased)

Long-Term Data Supports Chronic Use in Plaque Psoriasis

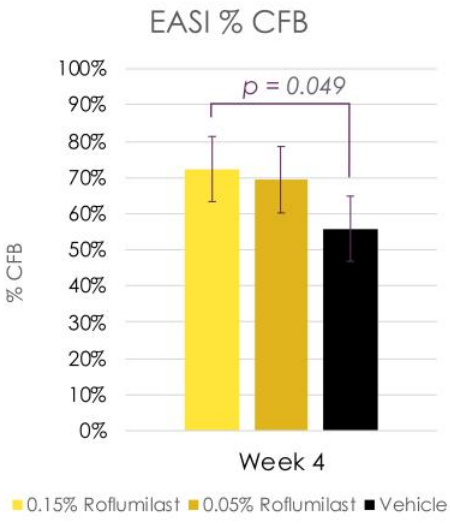
- 73.5% of patients completed 52-64 weeks of treatment
  - Only 0.9% discontinued due to lack of efficacy
  - Only 3.9% discontinued due to any adverse event
- Efficacy over 52-64 weeks comparable to DERMIS-1/-2 8-week efficacy

Roflumilast May Address Unmet Needs in Many Other Inflammatory Skin Diseases

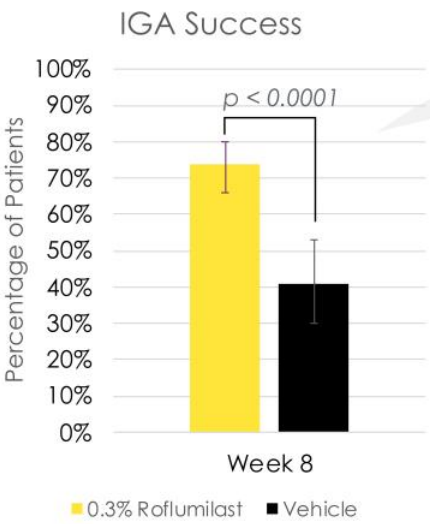
- Dermatologists and patients need topical therapies that:
  - Provide efficacy as good as or better than current standard-of-ca
  - Do not pose worrisome safety or tolerability issues
  - Don't force trade-offs in efficacy and safety
  - Available in patient-friendly formulations that support adherence

Topical Roflumilast Efficacy Across Multiple Other Inflammatory Skin Diseases

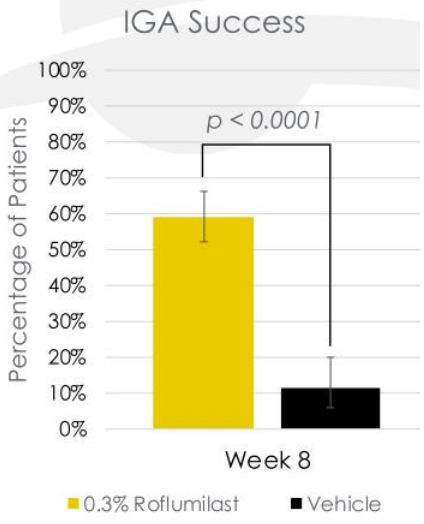
Atopic Dermatitis



Seborrheic Dermatitis



Scalp PsO



Tofacitinib MACE and Malignancy Data

Post-marketing safety study in 4,362 subjects with Rheumatoid Arthritis

	Tofacitinib 5 mg BID	Tofacitinib 10 mg BID	Tofacitinib Doses Combined	TNFi
Total number of subjects	1455	1456	2911	1451
Adjudicated MACE				
HR (95% CI) for tofa vs TNFi	1.24 (0.81, 1.91)	1.43 (0.94, 2.18)	1.33 (0.91, 1.94)	-
Adjudicated Malignancies Excluding NMSC				
HR (95% CI) for tofa vs TNFi	1.47 (1.00, 2.18)	1.48 (1.00, 2.19)	1.48 (1.04, 2.09)	-

BID=twice daily; CI=confidence interval; HR=hazard ratio; IR=incidence rate; NMSC=non-melanoma skin cancer; TNFi=Tumor Necrosis Factor inhibitor.

https://investors.pfizer.com/investor-news/press-release-details/2021/Pfizer-Shares-Co-Primary-Endpoint-Results-from-Post-Marketing-Required-Safety-Study-of-XELJANZ-tofacitinib-in-Subjects-with-Rheumatoid-Arthritis-RA/default.aspx

Consistently Favorable Tolerability Profile Across Indications

In psoriasis, AD, scalp and seb derm programs:

- > 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)
- Topical dosing avoids side effect profile 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 studie

Mark Lebwohl, MD

Professor and Dean for Clinical Therapeutics, Icahn School of Medicine at Mount Sinai

Considerations of Topical Steroids

ADVERSE REACTIONS

The following local adverse reactions are reported infr
quently with topical corticosteroids, but may occur mo
frequently with the use of occlusive dressings. The
reactions are listed in an approximate decreasing order
occurrence:

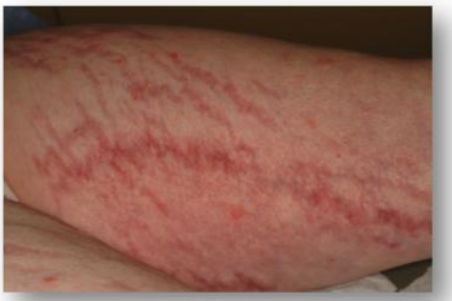
Burning	Perioral dermatitis
Itching	Allergic contact dermatitis
Irritation	Maceration of the skin
Dryness	Secondary infection
Folliculitis	Skin atrophy
Hypertrichosis	Striae
Acneiform eruptions	Miliaria
Hypopigmentation	

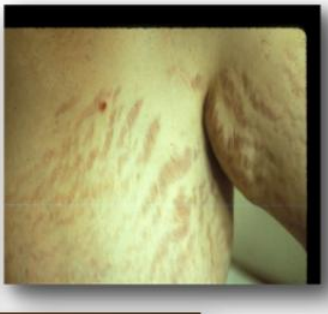
OVERDOSAGE

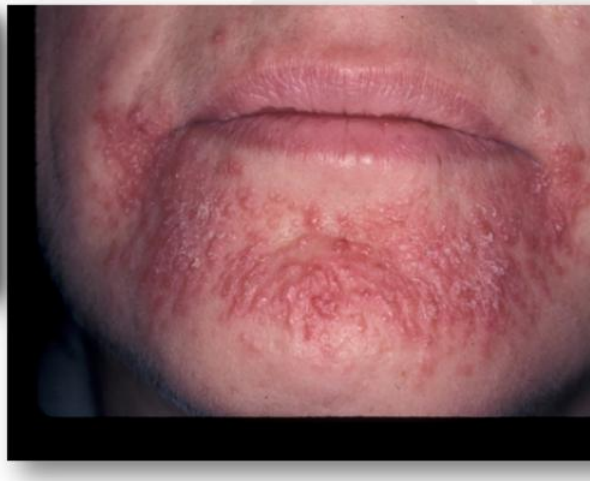
Topically applied corticosteroids can be absorbed
sufficient amounts to produce systemic effects (S

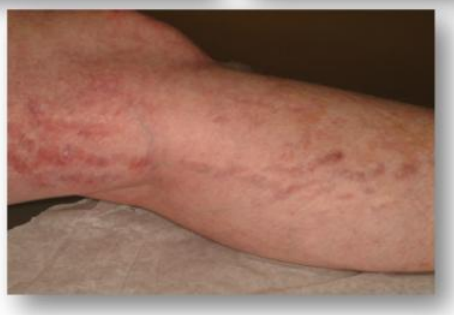
* PHOTOS COURTESY OF DR. MARK LEBWOHL

Striae and Perioral Dermatitis





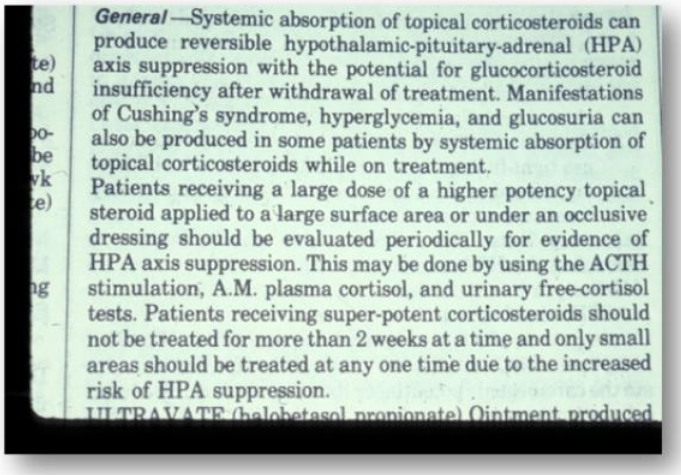




*PHOTOS REPRESENT SIDE EFFECTS FROM USE OF TOPICAL CORTICOSTEROIDS

* PHOTOS COURTESY OF DR. MARK LEBWOHL

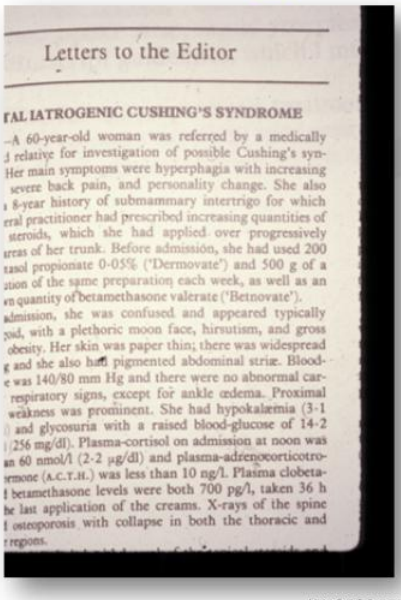
HPA Suppression & Cushing's Syndrome



General—Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycemia, and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment.

Patients receiving a large dose of a higher potency topical steroid applied to a large surface area or under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression. This may be done by using the ACTH stimulation, A.M. plasma cortisol, and urinary free-cortisol tests. Patients receiving super-potent corticosteroids should not be treated for more than 2 weeks at a time and only small areas should be treated at any one time due to the increased risk of HPA suppression.

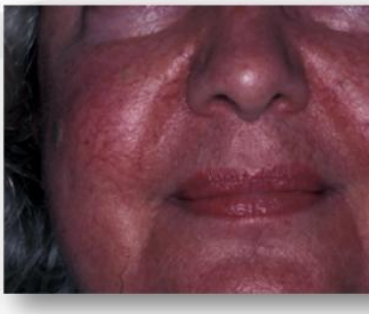
ULTRAVATE (halobetasol propionate) Ointment produced



Letters to the Editor

IAL IATROGENIC CUSHING'S SYNDROME

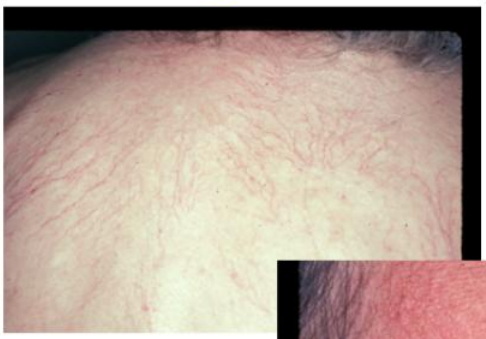
—A 60-year-old woman was referred by a medically relative for investigation of possible Cushing's syn- Her main symptoms were hyperphagia with increasing severe back pain, and personality change. She also 8-year history of submammary intertrigo for which eral practitioner had prescribed increasing quantities of steroids, which she had applied over progressively reas of her trunk. Before admission, she had used 200 asol propionate 0·05% ('Dermovate') and 500 g of a tion of the same preparation each week, as well as an n quantity of betamethasone valerate ('Betnovate'). admission, she was confused and appeared typically od, with a plethoric moon face, hirsutism, and gross obesity. Her skin was paper thin; there was widespread g and she also had pigmented abdominal striæ. Blood- e was 140/80 mm Hg and there were no abnormal car- respiratory signs, except for ankle œdema. Proximal weakness was prominent. She had hypokalæmia (3·1 and glycosuria with a raised blood-glucose of 14·2 (256 mg/dl). Plasma-cortisol on admission at noon was an 60 nmol/l (2·2 µg/dl) and plasma-adrenocorticotro- rmone (A.C.T.H.) was less than 10 ng/l. Plasma clobeta- betamethasone levels were both 700 pg/l, taken 36 h he last application of the creams. X-rays of the spine osteoporosis with collapse in both the thoracic and regions.

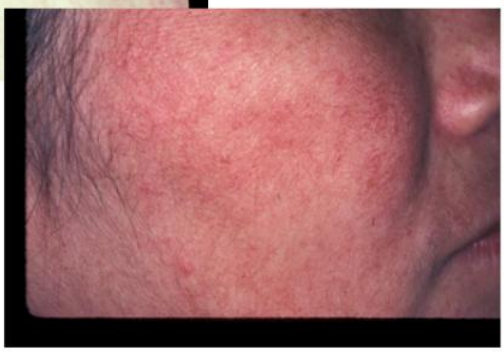


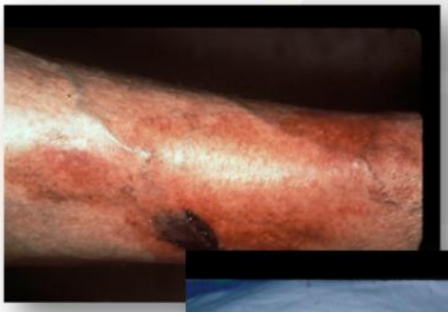
*PHOTOS REPRESENT SIDE EFFECTS FROM USE OF TOPICAL CORTICO

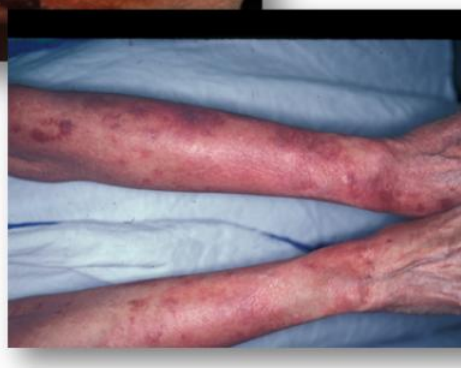
* PHOTOS COURTESY OF DR. MARK LEBWOHL

Telangiectasis and Skin Thinning









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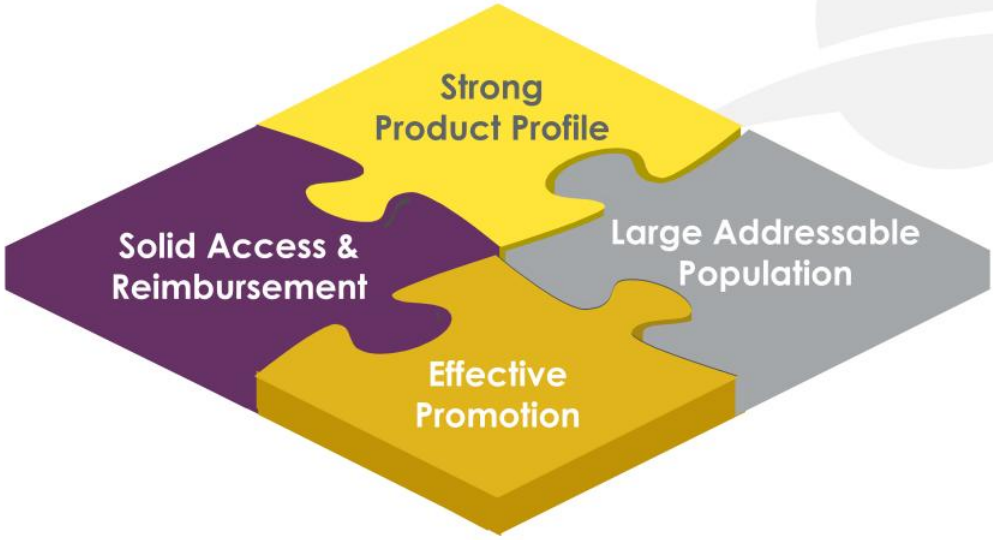
*PHOTOS REPRESENT SIDE EFFECTS FROM USE OF TOPICAL CORTICOSTERO

Ken Lock

Chief Commercial Officer

Keys to a Successful Launch



Topical Roflumilast Positioned to Have Differentiated and Compelling Profile

- Symptomatic improvements comparable to the combo of high-potency steroids and Vitamin D / Retinoid
- 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
- Not expected to have boxed warning

~5 Million PsO, AD, Seb Derm Patients Rx Topical Treated by Dermatologists in US

US Patient Populations (Millions)

	Psoriasis	Atopic Dermatitis	Seborrheic Dermati
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**

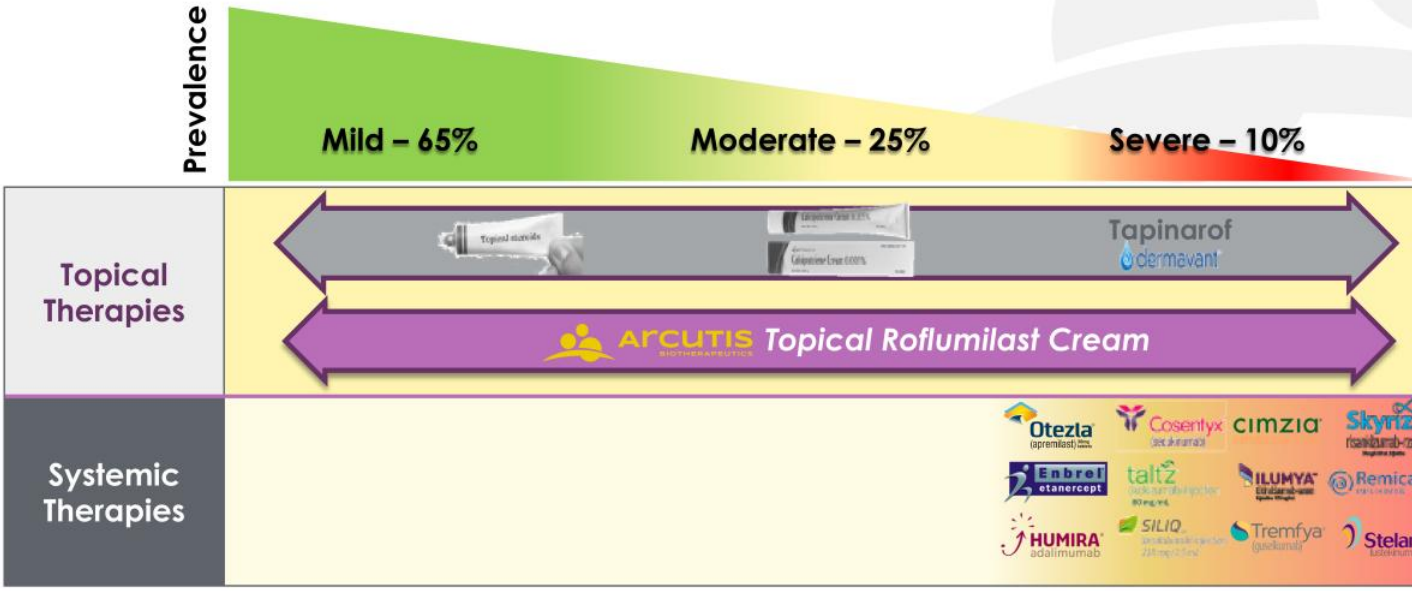
Additional opportunities to unlock value of our molecules:

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

Large Pool of Easily Accessible Patients

- **~ 6M patients** currently Rx treated by U.S. dermatologists
- **Concentrated prescribers** create sales force efficiencies
  - 75 – 80 sales reps required to cover most prescribers
- **Minimal behavioral change** required to activate utilization
  - Most patients in targeted diseases **already on Rx topical**
- **Highly dynamic market facilitates Start/Switch**
  - Steroids limited to short duration – frequent opportunities to switch
- **Sparse competitive landscape** for innovative topical therapie

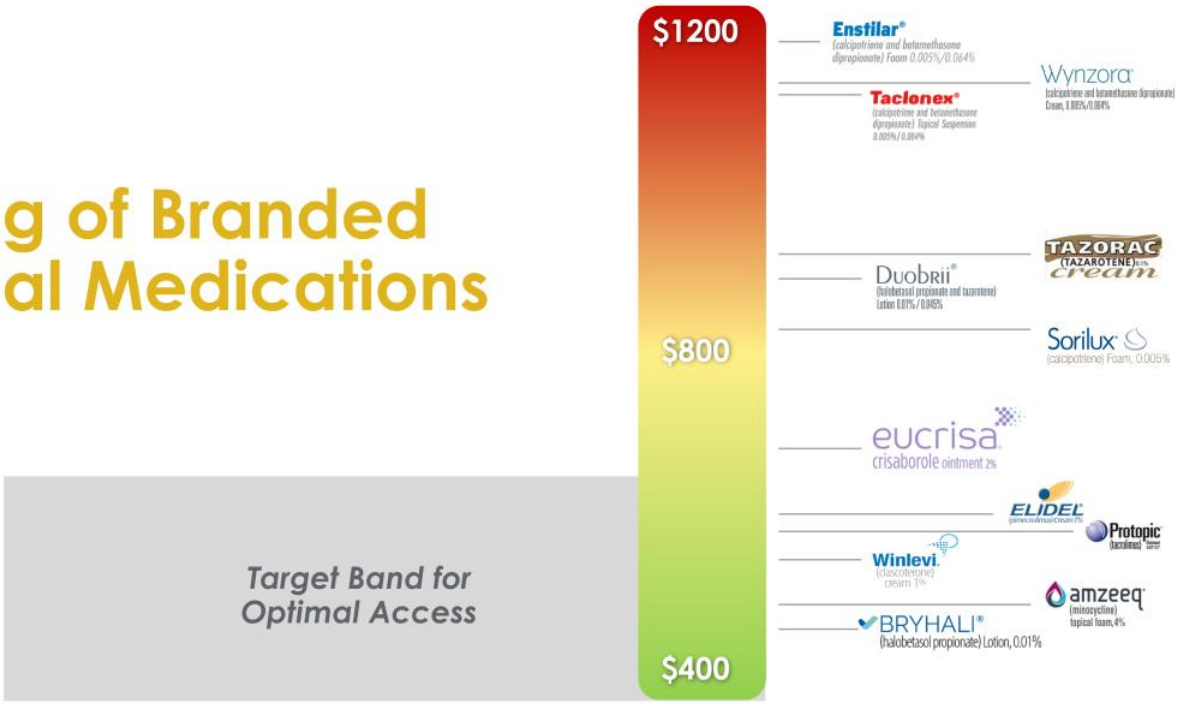
Psoriasis Landscape: Topical Roflumilast Positioned to Treat the Entire Spectrum



We Intend to Optimize Patient Access to Our Innovative Treatments

- Seek **broad access** and **reduced prescriber burden** to maximize volume opportunity
  - Highly innovative products at **appropriate pricing allow for broad and rapid adoption**
  - Ability for HCP to get drug when prescribed and **patient affordability** are as important as profile itself, hassle factor is anathema to prescribing
  - Rapid introductions of follow-on indications allow for **portfoli volumes across multiple indications** supporting payer value

Pricing of Branded Topical Medications



Source: Analysource – 1/11/21

Pipeline Could Generate 2030 Sales of ~$3B-$8B in U.S. Market Alone

U.S. Opportunity		Potential 2030 Sales
Dermatology market:	**Topical roflumilast (ARQ-151/154)**	**$1.3-3.7B**
	Plaque & scalp psoriasis	0.5-1.5B
	Atopic dermatitis	0.4-1.0B
	Seborrheic dermatitis	0.4-1.2B
	Topical JAK inhibitor (ARQ-252)	**0.5-1.6B**
Non-dermatologist market:		**1.0-2.6B**
Total Arcutis pipeline		**$2.8-7.9B**

Source: Company estimates, includes indications currently under development

Thank You