Roflumilast Cream, a Once-Daily, Potent Phosphodiesterase-4 Inhibitor, in Chronic Plaque Psoriasis Patients: Efficacy and Safety From DERMIS-1 and DERMIS-2 Phase 3 Trials

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Introduction

- No novel nonsteroidal topical therapies for plaque psoriasis have been approved in more than 2 decades, and available topical treatments are less than ideal, necessitating a trade-off between efficacy and tolerability[1]
- Roflumilast is a highly potent phosphodiesterase-4 inhibitor being investigated as a once-daily, nonsteroidal, topical treatment for various dermatologic conditions
  - In a phase 2b, randomized, double-blind, vehicle-controlled trial, roflumilast cream provided significant and rapid improvement of psoriasis, including demonstrated efficacy for intertriginous plaques and rapid reduction of itch[2]
- This is the first report of the efficacy and safety results from DERMIS-1 and DERMIS-2, two identical phase 3, randomized, double-blind, vehicle-controlled studies of once-daily roflumilast cream 0.3% in patients with psoriasis

1. Elmets CA, et al. J Am Acad Dermatol. 2021;84:432-70; 2. Lebwohl MG, et al. N Engl J Med. 2020;383:229-39.

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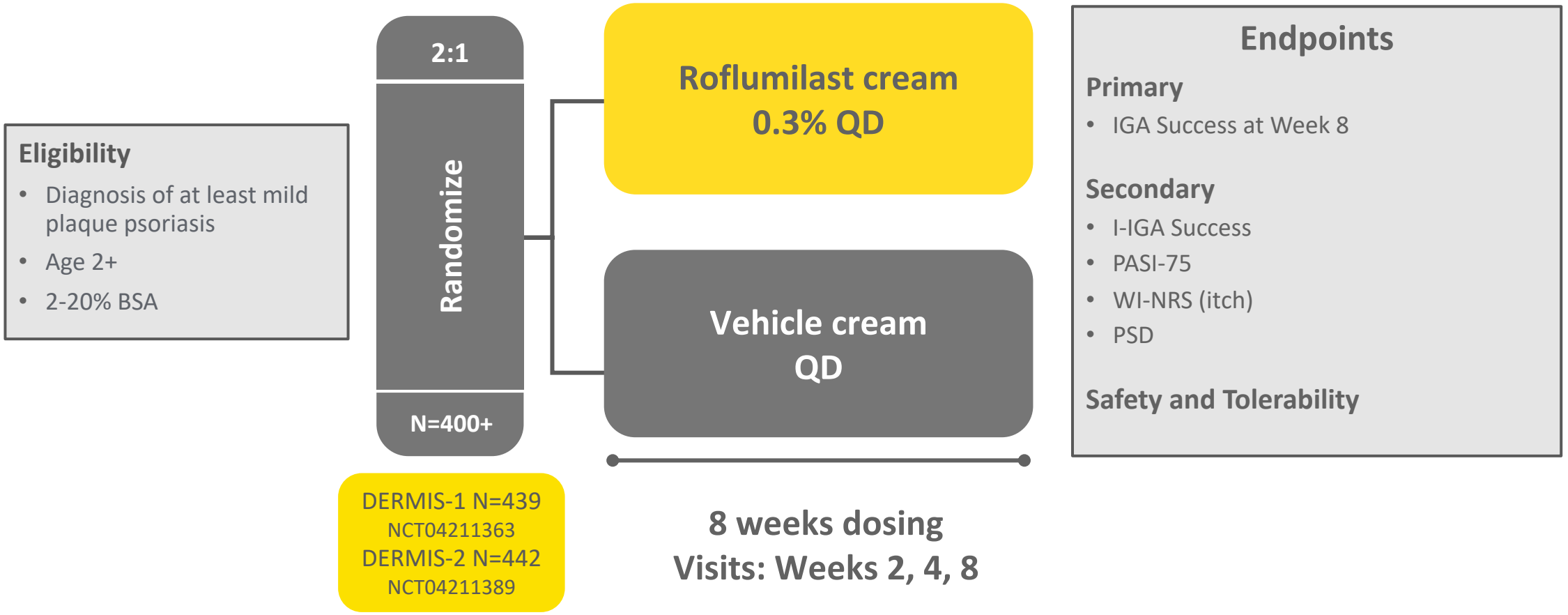
DERMIS-1 & DERMIS-2: Identical Study Design and Endpoints

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



BSA: body surface area; IGA: Investigator's Global Assessment; I-IGA: intertriginous-IGA; PASI-75: Psoriasis Area and Severity Index-75% reduction; PSD: Psoriasis Symptom Diary; QD: once daily; WI-NRS: Worst Itch Numeric Rating Scale

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Patient Disposition: Few Patients Discontinued Due to Adverse Events

Patients, n (%)	DERMIS-1		DERMIS-2	
	Roflumilast cream 0.3% (n=286)	Vehicle (n=153)	Roflumilast cream 0.3% (n=290)	Vehicle (n=152)
Completed	255 (89.2)	133 (86.9)	264 (91.0)	131 (86.2)
Prematurely discontinued	31 (10.8)	20 (13.1)	26 (9.0)	21 (13.8)
Reason for discontinuation				
Withdrawal by patient	11 (3.8)	11 (7.2)	10 (3.4)	11 (7.2)
Physician decision	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)
Noncompliance	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)
Protocol violation	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
Lost to follow-up	12 (4.2)	4 (2.6)	15 (5.2)	7 (4.6)
Adverse event	5 (1.7)	2 (1.3)	1 (0.3)	2 (1.3)
Pregnancy	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
Other	1 (0.3)	2 (1.3)	0 (0.0)	0 (0.0)

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Baseline Demographics (ITT Population)

	DERMIS-1		DERMIS-2	
	Roflumilast cream 0.3% (n=286)	Vehicle (n=153)	Roflumilast cream 0.3% (n=290)	Vehicle (n=152)
Age in years, mean (SD)	47.6 (14.09)	48.7 (15.77)	46.9 (15.07)	47.1 (14.07)
Gender				
Male, n (%)	189 (66.1)	96 (62.7)	176 (60.7)	100 (65.8)
Female, n (%)	97 (33.9)	57 (37.3)	114 (39.3)	52 (34.2)
Race, n (%)				
American-Indian or Alaska Native	4 (1.4)	1 (0.7)	0 (0.0)	1 (0.7)
Asian	21 (7.3)	11 (7.2)	20 (6.9)	9 (5.9)
Black or African-American	8 (2.8)	8 (5.2)	13 (4.5)	9 (5.9)
Native Hawaiian or Other Pacific Islander	2 (0.7)	0 (0.0)	3 (1.0)	1 (0.7)
White	234 (81.8)	124 (81.0)	240 (82.8)	126 (82.9)
Not reported	4 (1.4)	3 (2.0)	5 (1.7)	2 (1.3)
Other	11 (3.8)	5 (3.3)	8 (2.8)	4 (2.6)
More than one race	2 (0.7)	1 (0.7)	1 (0.3)	0 (0.0)

ITT: intent-to-treat; SD: standard deviation

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Baseline Disease Characteristics (ITT Population)

	DERMIS-1		DERMIS-2	
	Roflumilast cream 0.3% (n=286)	Vehicle (n=153)	Roflumilast cream 0.3% (n=290)	Vehicle (n=152)
Psoriasis-affected BSA, mean % (SD)	6.3 (4.38)	7.4 (4.76)	7.1 (4.84)	7.7 (5.05)
PASI, mean score (SD)	6.3 (3.15)	6.8 (3.70)	6.5 (3.22)	7.0 (3.52)
WI-NRS, mean score (SD)	5.7 (2.75)	5.7 (2.84)	5.8 (2.61)	6.1 (2.75)
WI-NRS score ≥4, n (%)	218 (76.2)	115 (75.2)	229 (79.0)	116 (76.3)
PSD, mean total score (SD)	72.1 (42.75)	73.4 (41.29)	69.3 (40.66)	77.4 (41.24)
IGA score, n (%)				
2 (mild)	51 (17.8)	20 (13.1)	50 (17.2)	24 (15.8)
3 (moderate)	206 (72.0)	122 (79.7)	220 (75.9)	118 (77.6)
4 (severe)	29 (10.1)	11 (7.2)	20 (6.9)	10 (6.6)
I-IGA score ≥2, n (%)	n=63	n=32	n=53	n=31
2 (mild)	33 (52.4)	16 (50.0)	25 (47.2)	13 (41.9)
3 (moderate)	27 (42.9)	16 (50.0)	27 (50.9)	17 (54.8)
4 (severe)	3 (4.8)	0 (0.0)	1 (1.9)	1 (3.2)

BSA: body surface area; IGA: Investigator's Global Assessment; I-IGA: Intertriginous-Investigator's Global Assessment; ITT: intent-to-treat; PASI: Psoriasis Area Severity Index; PSD: Psoriasis Symptoms Diary; WI-NRS: Worst Itch-Numeric Rating Scale; SD: standard deviation

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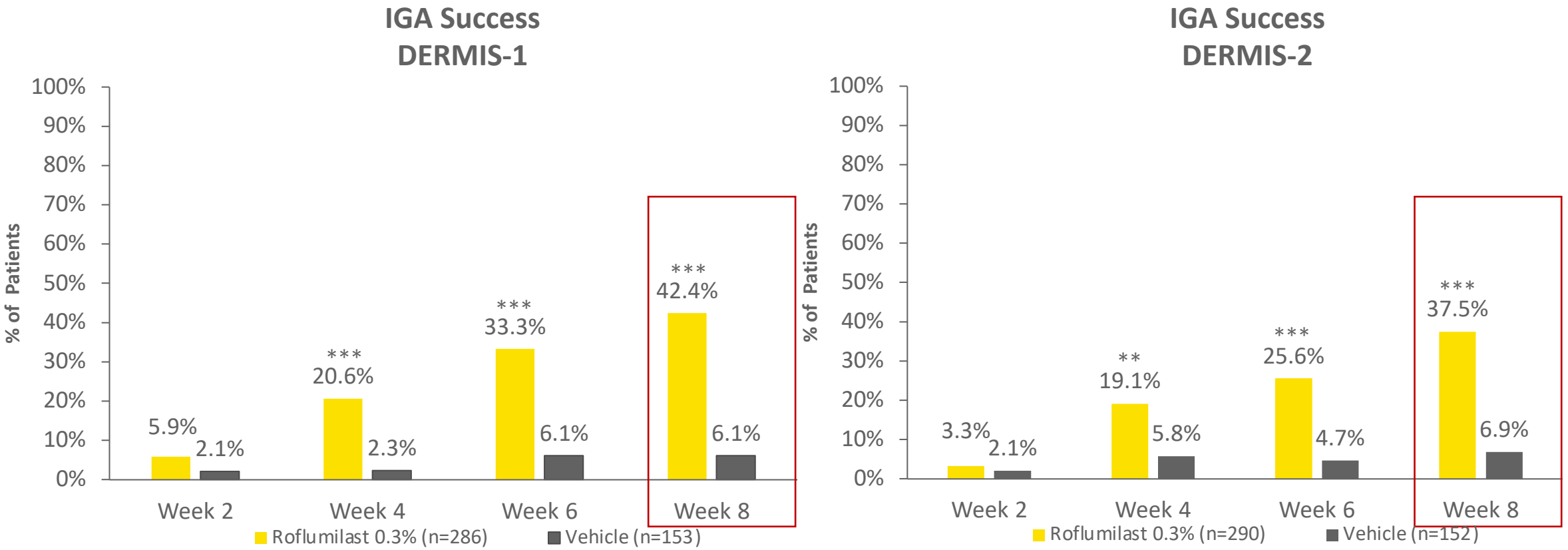
Robust Efficacy on IGA Success in Both Phase 3 Studies

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



* p<0.05; ** p<0.01; *** p<0.001

The primary endpoint was achieved in both DERMIS-1 and DERMIS-2

Intent-to-treat population; missing scores imputed using multiple imputations

IGA: Investigator's Global Assessment

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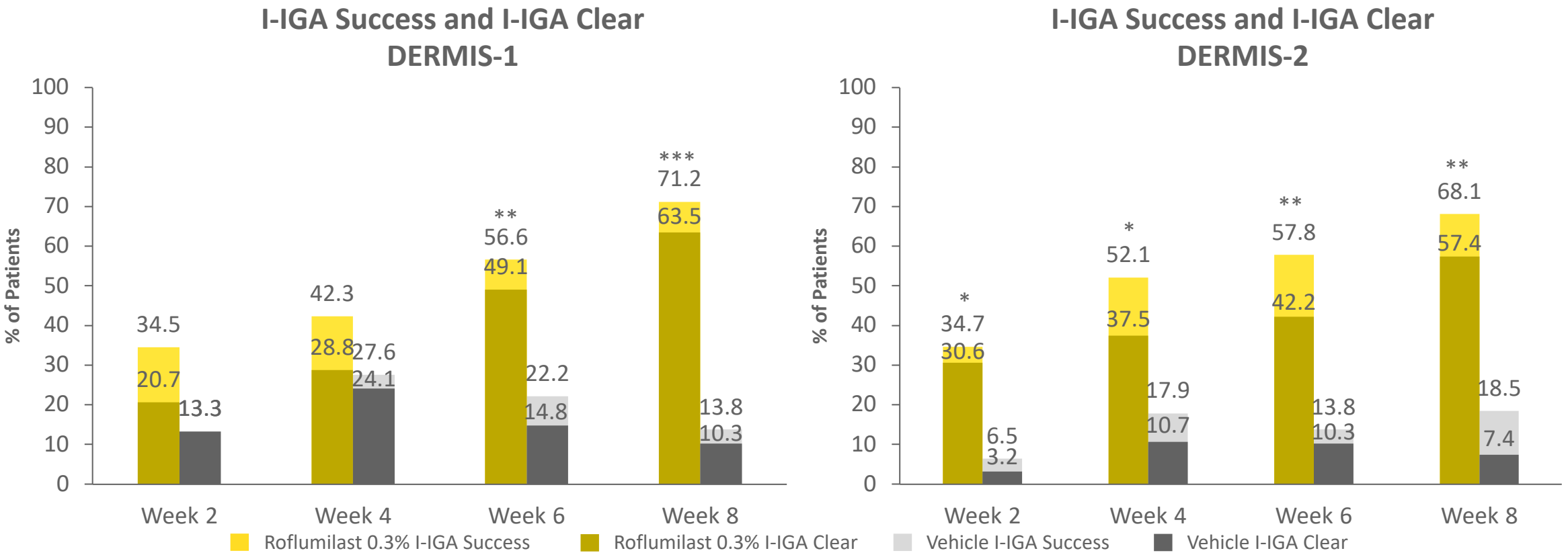
Roflumilast Was Highly Effective for Intertriginous Plaques in DERMIS-1 and DERMIS-2

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



* p<0.05; ** p<0.01; *** p<0.001

About 60% of roflumilast-treated patients achieved clear intertriginous skin (I-IGA = 0) at Week 8

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. Observed data. P values for I-IGA success

I-IGA: Intertriginous-Investigator's Global Assessment

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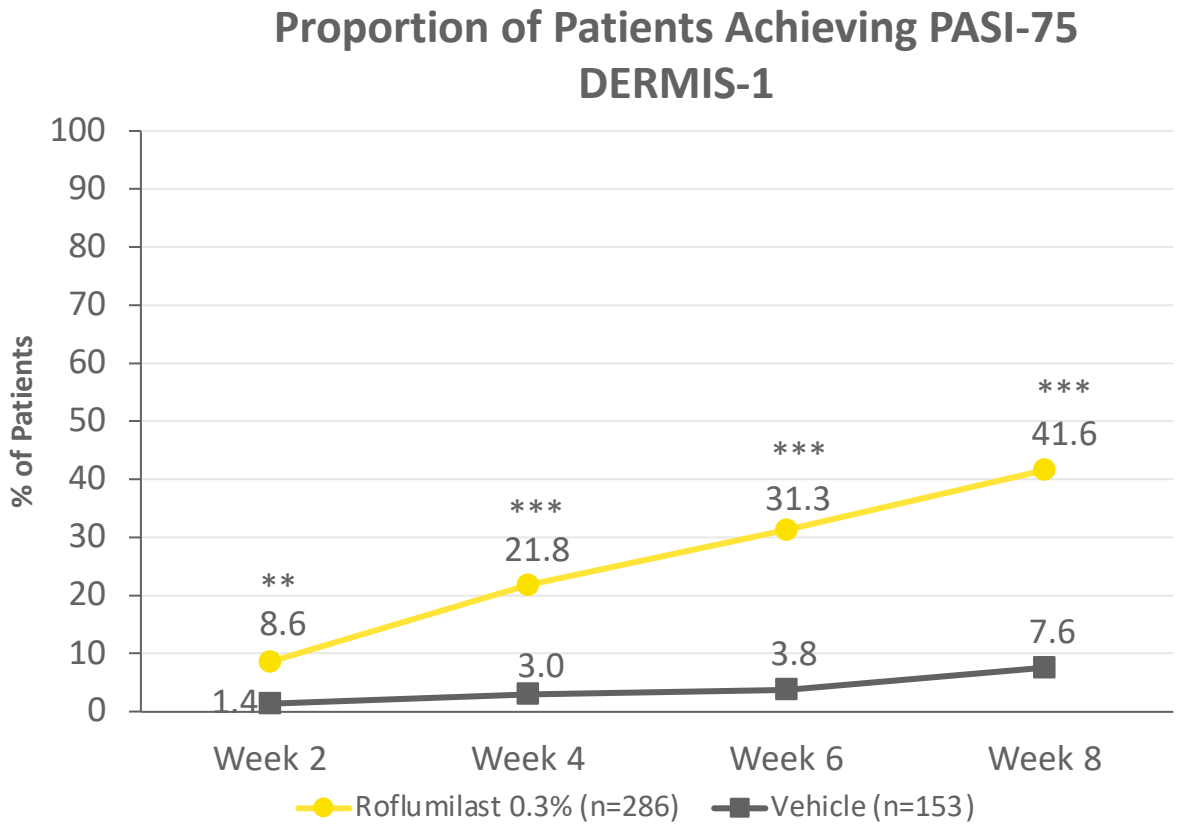
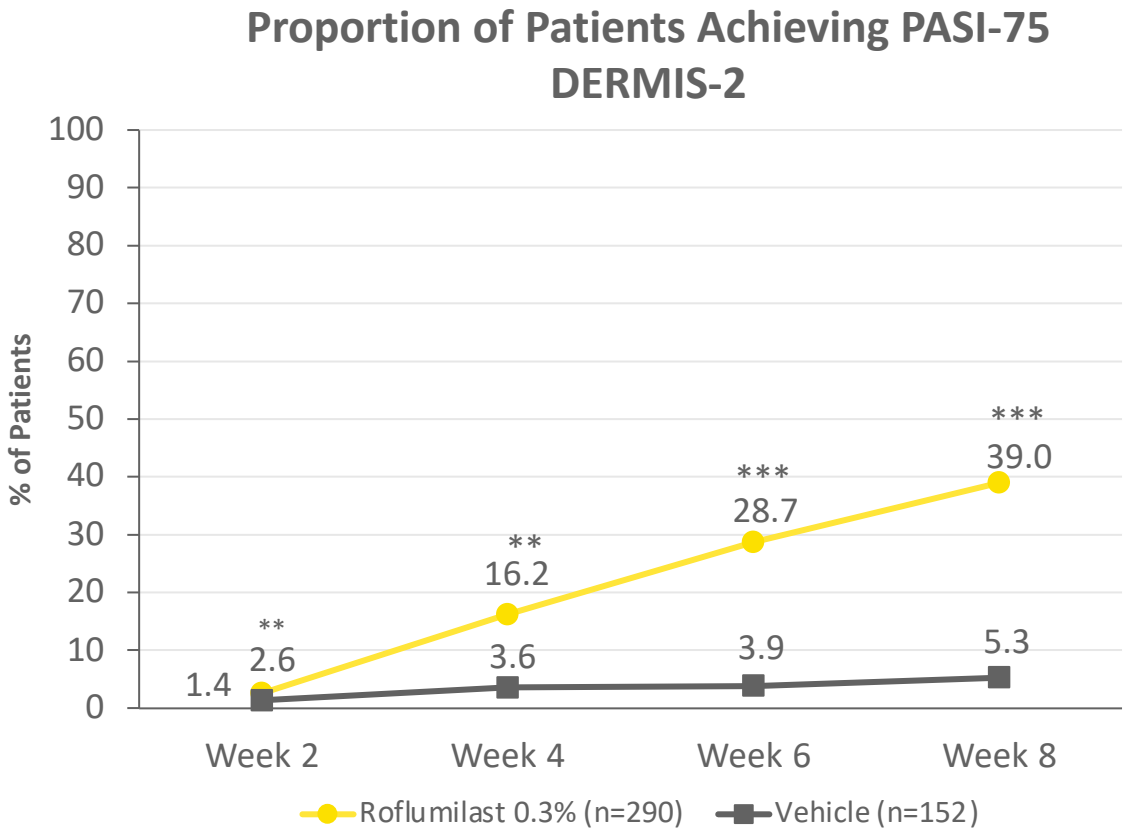
Roflumilast Was Statistically Superior to Vehicle for Improvement of Psoriasis (PASI-75) at All Timepoints





** p<0.01; *** p<0.001

Approximately 40% of patients demonstrated at least a 75% improvement in psoriasis by Week 8 as measured by PASI-75

PASI: Psoriasis Area Severity Index; PASI-75: 75% reduction in PASI total score from baseline
Intent-to-treat population; missing scores imputed using multiple imputations

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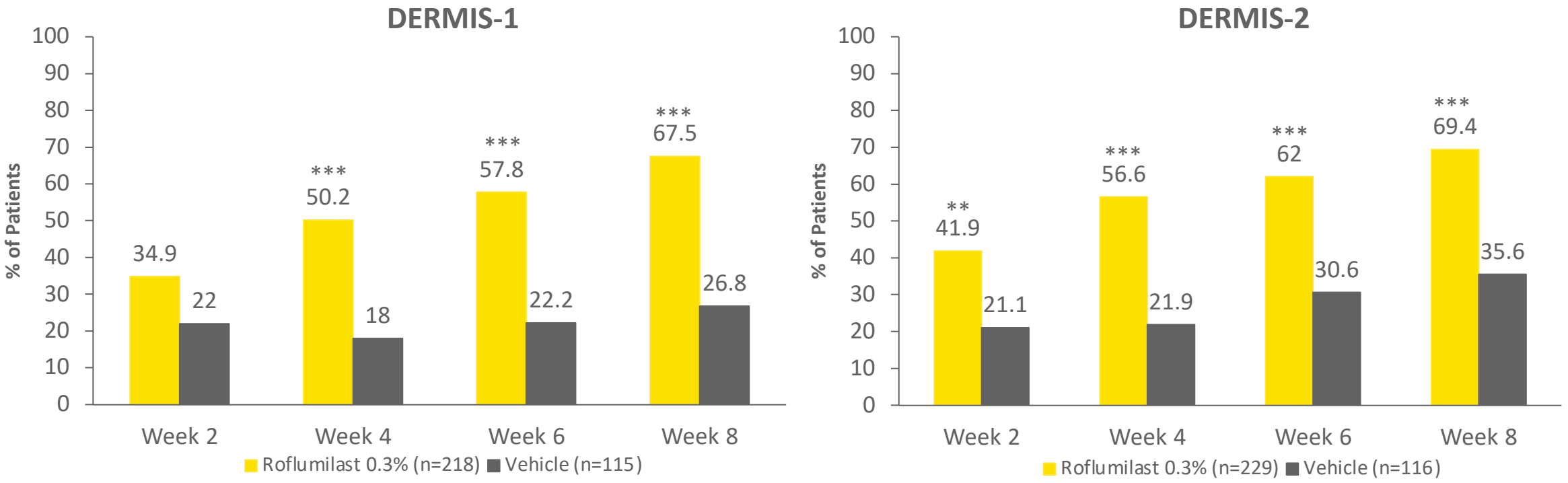
Rapid Itch Response in Both DERMIS-1 and DERMIS-2

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



Baseline mean (SD) WI-NRS: Roflumilast 0.3% 5.7 (2.75) and Vehicle 5.7 (2.84)

Baseline mean (SD) WI-NRS: Roflumilast 0.3% 5.8 (2.61) and Vehicle 6.1 (2.75)

** p<0.01; *** p<0.001

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

Evaluated in a subset of the intent-to-treat population of patients with WI-NRS pruritus score ≥4 at baseline; missing scores imputed using multiple imputations

SD: standard deviation; WI-NRS: Worst Itch Numeric Rating Scale

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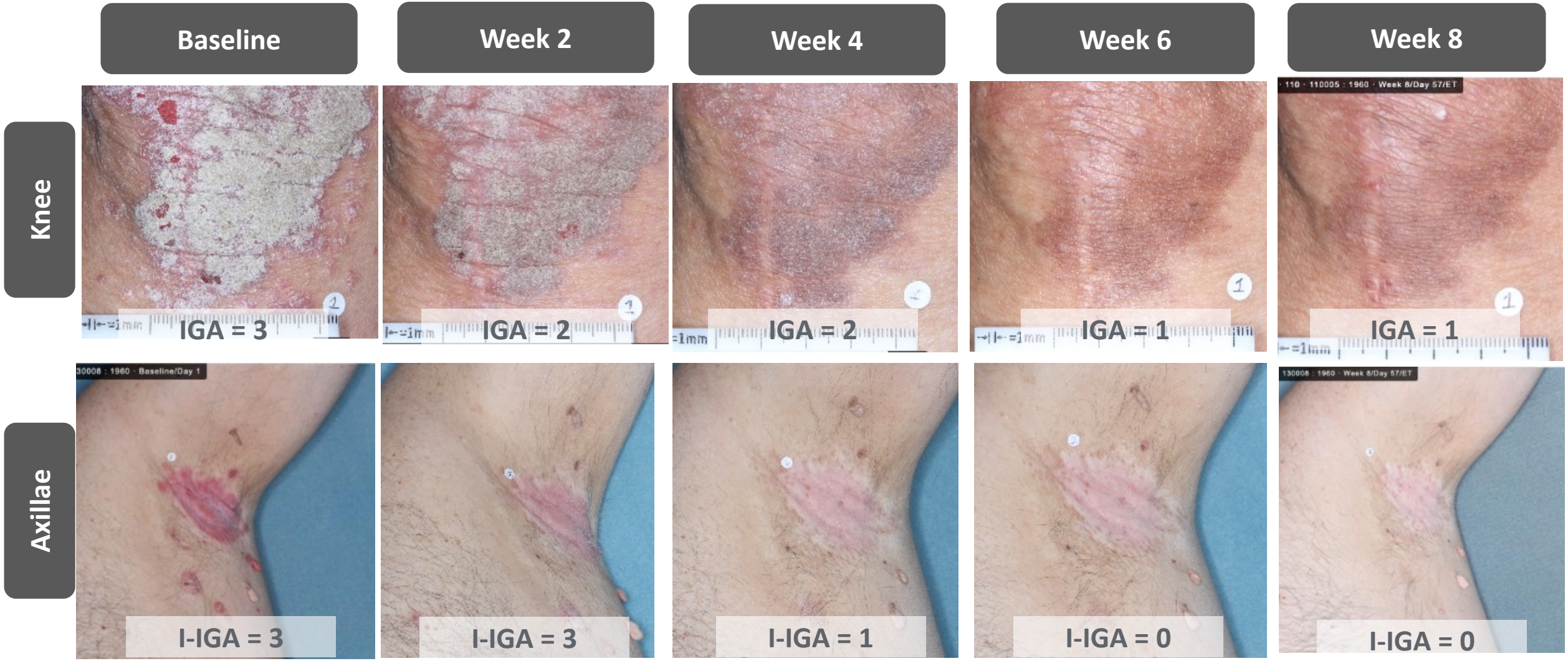
Patient Examples Illustrating Efficacy of Roflumilast Cream 0.3% From DERMIS-1 & DERMIS-2



IGA: Investigator's Global Assessment; I-IGA: intertriginous-IGA

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Roflumilast Safety and Tolerability Were Similar to Vehicle

- Roflumilast cream demonstrated low rates of application site AEs, treatment-related AEs, and discontinuations due to AEs, comparable to vehicle
- There were no treatment-related SAE
- Roflumilast cream was well-tolerated with a low rate of application site reactions
- Local tolerability was highly favorable as reported by patient and investigator assessment of irritation, burning, and stinging

n (%)	DERMIS-1		DERMIS-2	
	Roflumilast cream 0.3% (n=286)	Vehicle (n=153)	Roflumilast cream 0.3% (n=290)	Vehicle (n=152)
Patients with any TEAE	72 (25.2)	36 (23.5)	75 (25.9)	28 (18.4)
Patients with any treatment-related TEAE	7 (2.4)	3 (2.0)	16 (5.5)	8 (5.3)
Patients with any SAE	2 (0.7)	1 (0.7)	0 (0.0)	1 (0.7)
Patients who discontinued study due to AE	5 (1.7)	2 (1.3)	1 (0.3)	2 (1.3)
Most common TEAE (>2% in any group), preferred term				
Hypertension	5 (1.7)	6 (3.9)	4 (1.4)	0 (0.0)
Headache	3 (1.0)	2 (1.3)	11 (3.8)	1 (0.7)
Diarrhea	10 (3.5)	0 (0.0)	8 (2.8)	0 (0.0)
Psoriasis	0 (0.0)	3 (2.0)	1 (0.3)	0 (0.0)
Nasopharyngitis	5 (1.7)	3 (2.0)	1 (0.3)	1 (0.7)

Data are presented for safety population. AE: adverse event; SAE: serious adverse event; TEAE: treatment-emergent adverse event

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Conclusions

- Once-daily roflumilast cream demonstrated robust and clinically meaningful efficacy based on IGA Success at the primary endpoint of 8 weeks
  - Results were reproducible across both phase 3 studies
- Roflumilast cream demonstrated statistically superior efficacy versus vehicle in patients with intertriginous area involvement, with most patients achieving I-IGA=0 (clear)
- Roflumilast cream significantly improved itch as early as 2 weeks (the earliest timepoint measured) using a clinically meaningful measure of a 4-point reduction in patients with WI-NRS ≥4 at baseline
- Roflumilast cream was well-tolerated with low rates of TEAEs, SAEs, and discontinuations due to AE
  - Occurrence of application site pain was low and comparable to vehicle
- These phase 3 studies demonstrated that investigational, once-daily roflumilast cream 0.3% has the potential to address many of the shortcomings of existing topical treatments for plaque psoriasis

AE: adverse event; IGA: Investigator's Global Assessment; I-IGA: Intertriginous-Investigator's Global Assessment; PASI: Psoriasis Area Severity Index; SAE: serious adverse event; TEAE: treatment-emergent adverse event; WI-NRS: Worst Itch Numeric Rating Scale

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Disclosures

Mark Lebwohl is an investigator and/or consultant for AbbVie, Aditum Bio, Allergan, Inc., Almirall, AltruBio Inc., Amgen, AnaptysBio, Arcutis, Inc., Aristea Therapeutics, Arrive Technologies, Avotres, Inc., BiomX Ltd., BirchBioMed, BMD Skincare, Inc., Boehringer Ingelheim, Bristol-Myers Squibb, Cara Therapeutics, Castle Biosciences, Inc, Corrona, Inc., Dermavant Sciences, Dr. Reddy, Eli Lilly and Company, EMD Serono, Evelo Biosciences, Inc., Evommune, Inc., Facilitation of International Dermatology Education, Forte Biosciences, Foundation for Research & Education of Dermatology, Helsinn Healthcare, Hexima Ltd., Incyte Corporation, Inozyme Pharma, Janssen Research & Development, LLC, Kyowa Kirin, Leo Pharma Inc, LEO Pharma, US, Meiji Seika Pharma Co., Ltd, Menlo Therapeutics, Mindera, Mitsibushi Pharma, Neuroderm LTD, Ortho Dermatologics, Pfizer Inc., Regeneron, Seanergy, Theravance Biopharma, UCB, Verrica Pharmaceuticals Inc.; **Leon H Kircik** is a speaker for Galderma Laboratories, L.P., Genentech, Inc., Johnson & Johnson Consumer Products Company, Leo Pharma Inc, 3M Pharmaceuticals, Onset Dermatologics, Pharmaderm, Merck Serono, SkinMedica, Inc., Stiefel a GSK company, Triax Pharmaceuticals, LLC, Valeant Pharmaceuticals International, Warner Chilcott; serves on an advisory board for Galderma Laboratories, Genentech, Inc., Intendis, Inc., Johnson & Johnson Consumer Products Company, NanoBio Corporation, Promius Pharma, LLC, SkinMedica, Inc., Stiefel a GSK company, Valeant Pharmaceuticals International, Warner Chilcott; is an investigator for Ferndale Laboratories, Inc., Galderma Laboratories, L.P., Genentech, Inc., GlaxoSmithKline, Healthpoint, Intendis, Inc., Johnson & Johnson Consumer Products Company, Leo Pharma Inc, 3M Pharmaceuticals, Medicis Pharmaceutical Corporation, NanoBio Corporation, Novartis Pharmaceuticals Corp., Nucryst, Obagi Medical Products, Onset Dermatologics, Othro Dermatologics, Promius Pharma, LLC, QLT Inc., Pharmaderm, Pfizer Inc., SkinMedica, Inc., Stiefel a GSK company, TolerRx, Triax Pharmaceuticals, LLC, Valeant Pharmaceuticals International, Warner Chilcott; is a consultant for Galderma Laboratories, L.P., Genentech, Inc., Intendis, Inc., Johnson & Johnson Consumer Products Company, Laboratory Skin Care, Inc., Leo Pharma Inc, Medical International Technologies, Merck & Co., Inc, Merz Pharmaceuticals, LLC, Novartis Pharmaceuticals Corp., Promius Pharma, LLC, PuraCap Pharmaceutical, SkinMedica, Inc., Stiefel a GSK company, Triax Pharmaceuticals, LLC, Valeant Pharmaceuticals International; **Angela Moore** is an investigator, consultant, speaker, and/or has served on advisory boards Abbvie, Arcutis, Boehringer Ingelheim, Bristol-Myers Squibb, Dermavant, Janssen, Leo, Lilly, Mayne Pharma, Novartis, Parexel, Pfizer, UCB; **Linda Stein Gold** is an investigator, consultant, speaker, and/or has served on advisory boards for Sol-Gel Technologies, Taro Pharm, La Roche-Posay Laboratorie Pharmaceutique, Aqua, Pfizer Inc., Promius Pharmaceuticals, Botanix Pharmaceuticals, Foamix, Allergan, Inc., Merz Pharmaceuticals, LLC, Lilly ICOS LLC, Pfizer Inc., AbbVie, Actavis, LEO Pharma, US, Novartis Pharmaceuticals Corp., Galderma Laboratories, L.P., Leo Pharma Inc., Topica, Valeant Pharmaceuticals International, Dermira, Dermavant Sciences, UCB, GlaxoSmithKline, Sun Pharmaceutical Industries Ltd., Incyte Corporation, VYNE Therapeutics, Cutera, Inc., AnaptysBio, Almirall, Sanofi/Regeneron, AbbVie, The Acne Store; **Zoe D Draelos** is an investigator and/or consultant for Bayer, L'Oreal USA Inc., Procter & Gamble Company, Novartis Pharmaceuticals Corp., Pfizer Inc., Merz Pharmaceuticals, LLC, Nuskin, Allergan, Inc., Neutrogena Corporation, Onset Therapeutics, Symrise, Avon Products, Inc., Pacific Biosciences, Signum Biosciences, Inc., Johnson & Johnson Consumer Products Company, Kao Brands, Dial Corporation, Amneal Pharmaceuticals, LLC, AstraZeneca, Boots, Elizabeth Arden, GlaxoSmithKline, Living Proof, Inc, Otsuka Pharmaceutical Co., Ltd., Ranbaxy Laboratories Limited, Tolmar, Mimetica Pty. 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