Sol-Gel
Advanced Topical Therapy

EPSOLAY® PHASE 3 RESULTS

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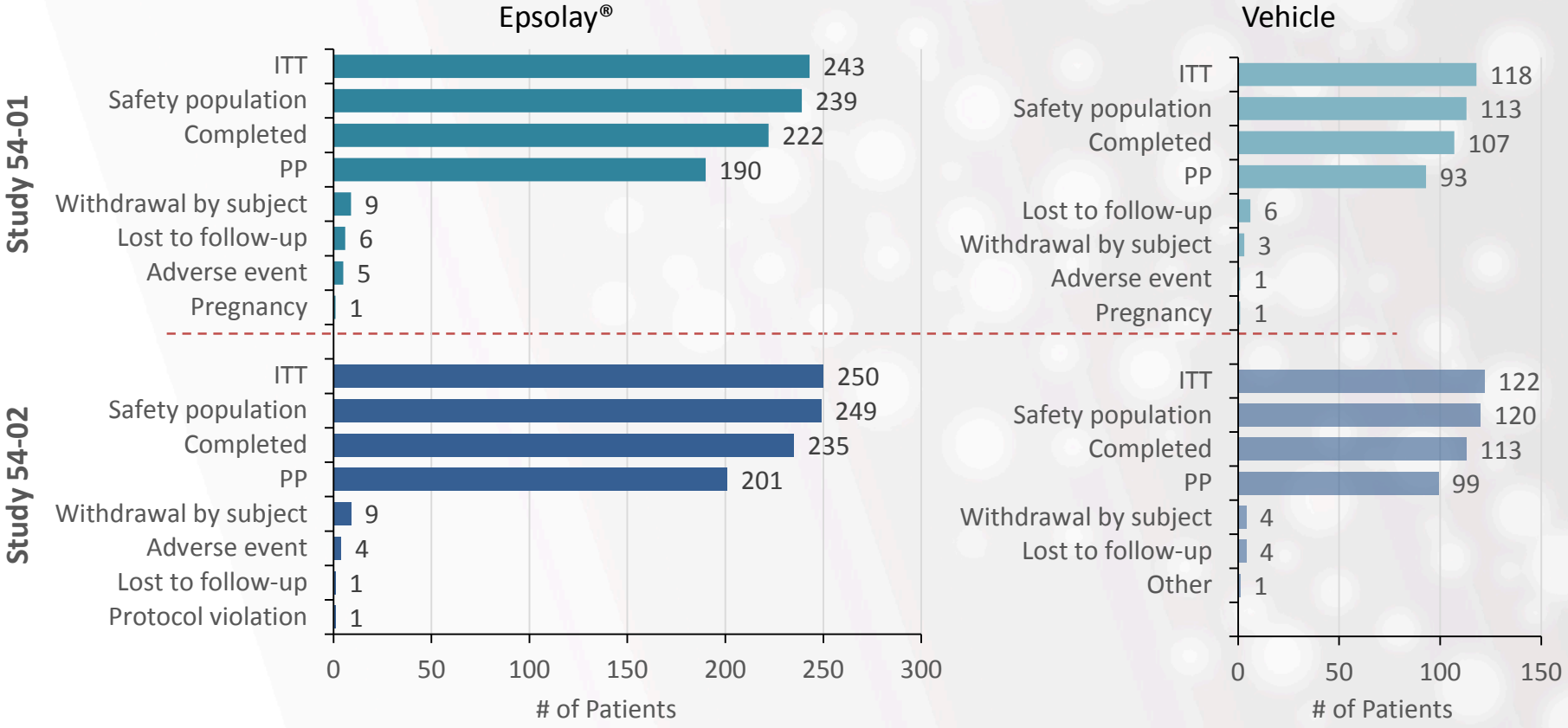
EPSOLAY® PHASE 3 STUDY DESIGN

- Multicenter, parallel, double-blind, randomized, vehicle-controlled, 2:1 ratio, QD
- Inclusion criteria:
  - Male & female ≥ 18 years of age
  - IGA score “moderate” to “severe”
  - ≥ 15 ≤ 70 inflammatory lesions
  - ≤ 2 nodules

- IGA Definition:
  - “Clear”: Skin clear of inflammatory papules or pustules
  - “Almost clear”: Very few small papules or pustules and very mild dull erythema is present
  - “Mild”: Few small papules or pustules and mild dull or light pink erythema is present
  - “Moderate”: Several to many small or larger papules or pustules and moderate light to bright red erythema is present
  - “Severe”: Numerous small and/or larger papules or pustules and severe erythema that is bright red to deep red is present

STUDY POPULATION & DISCONTINUATION

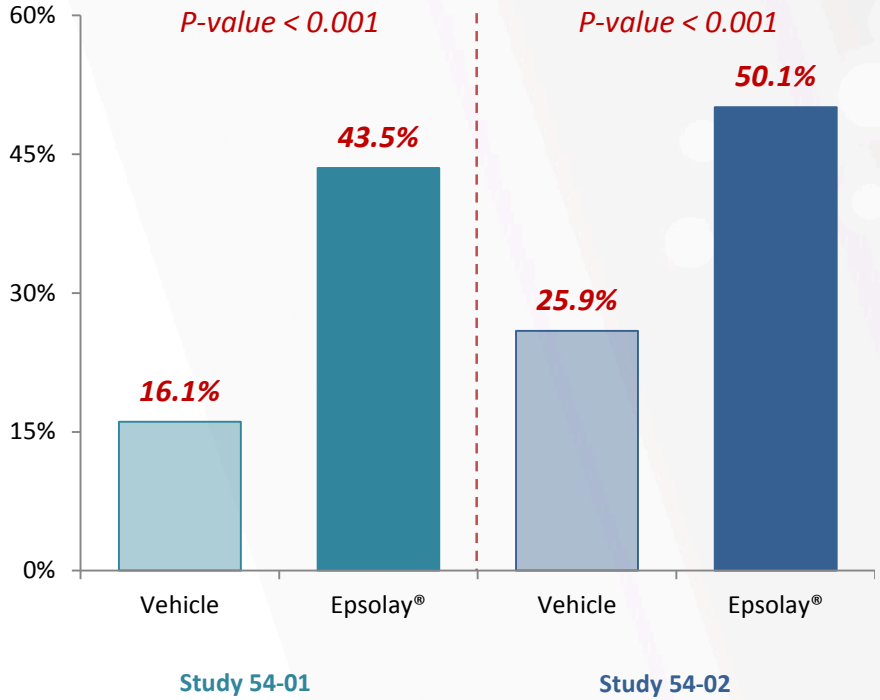


PATIENT SEVERITY AT BASELINE

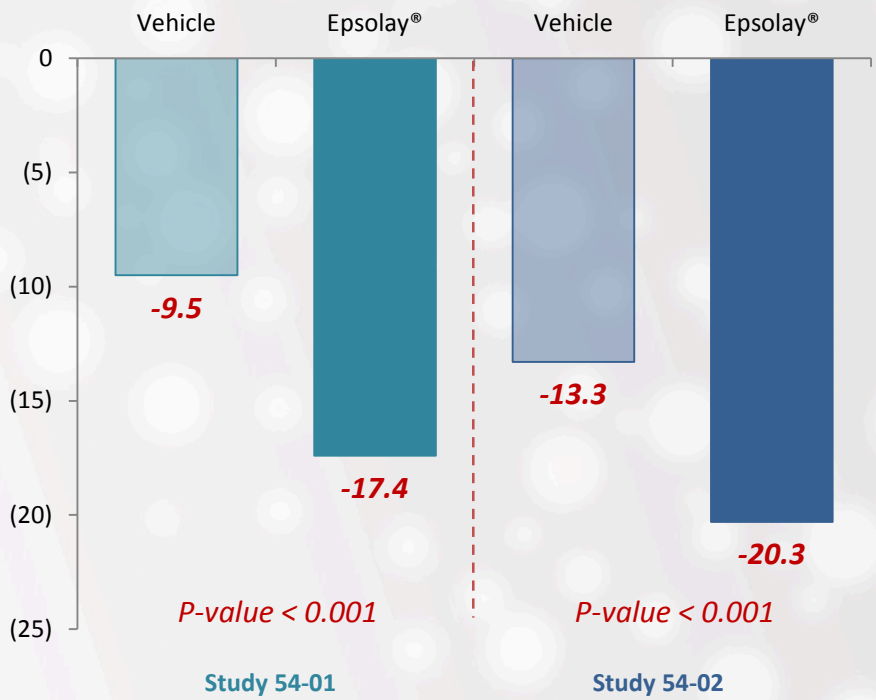
	Study 54-01		Study 54-02	
Characteristic	Epsolay®	Vehicle	Epsolay®	Vehicle
IGA “Moderate” IGA “Severe”	210 (86.4%) 33 (13.6%)	104 (88.1%) 14 (11.9%)	227 (90.8%) 23 (9.2%)	112 (91.8%) 10 (8.2%)
Mean lesion count (SD) Median lesion count (range)	25.7 (11.07) 22.0 (15-69)	26.3 (12.45) 21.0 (15-70)	29.8 (14.00) 25.0 (15-70)	27.5 (13.04) 22.5 (15-70)

PRIMARY ENDPOINTS (ITT)

Success in IGA @ Week 12

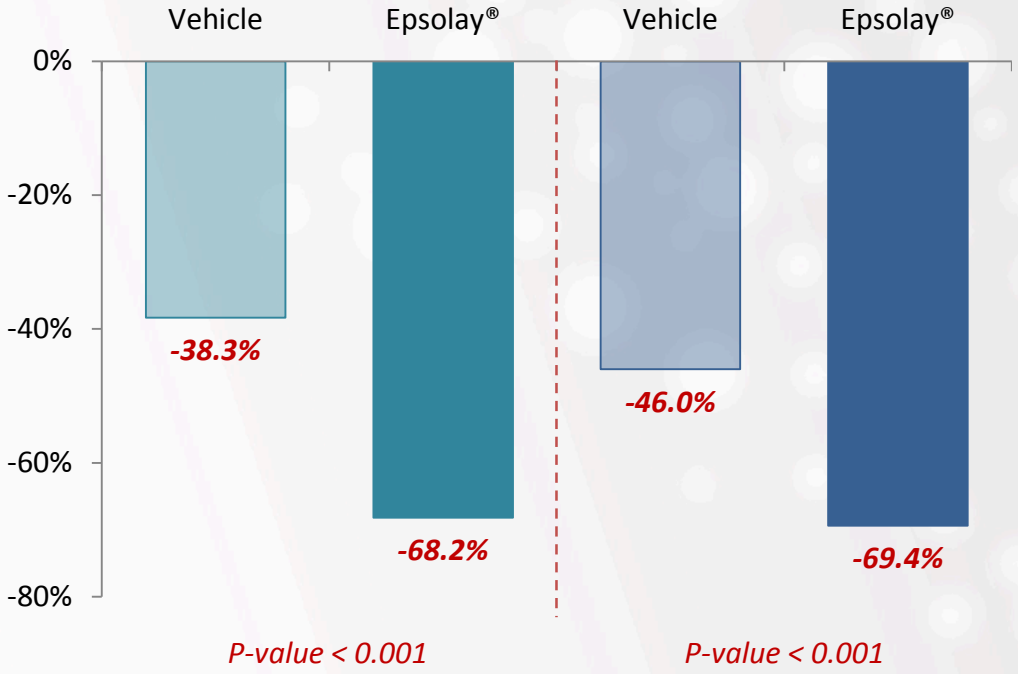


Inflammatory Lesion Count Change from Baseline @ Week 12



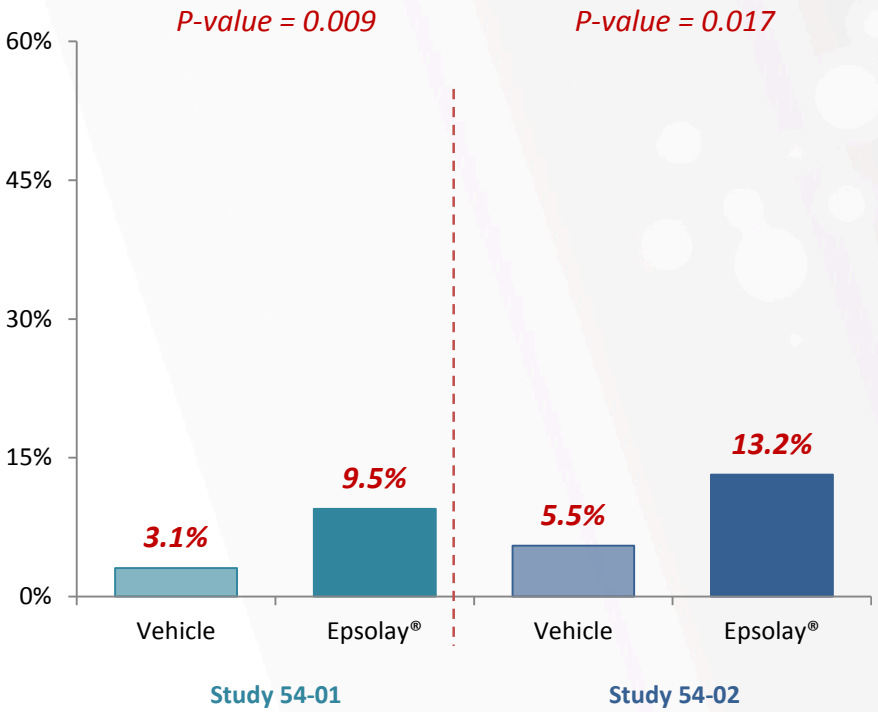
SECONDARY ENDPOINT (ITT)

Inflammatory Lesion Percent Change from Baseline @ Week 12

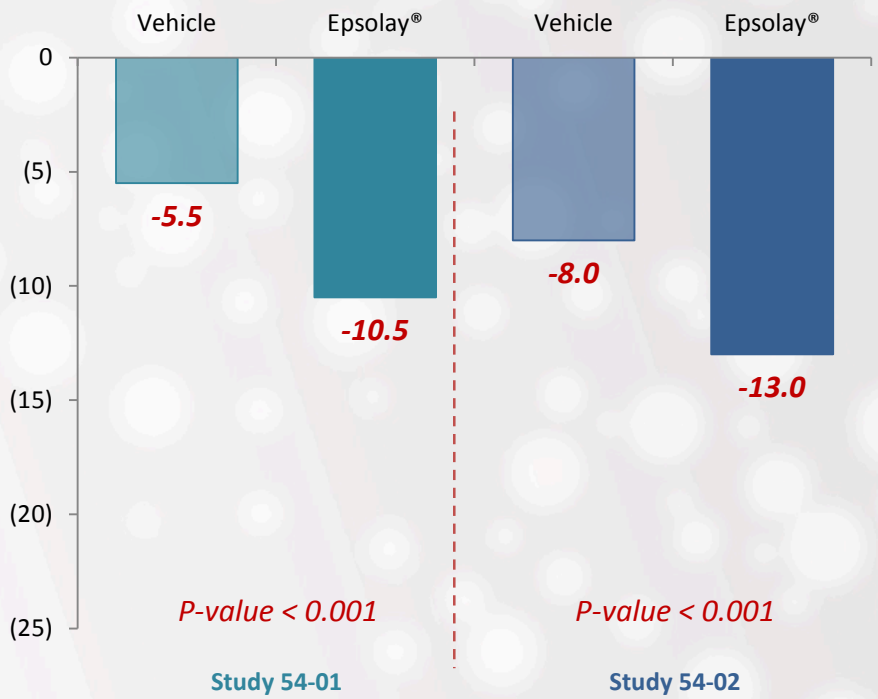


EXPLORATORY ENDPOINTS (ITT)

Success in IGA @ Week 2

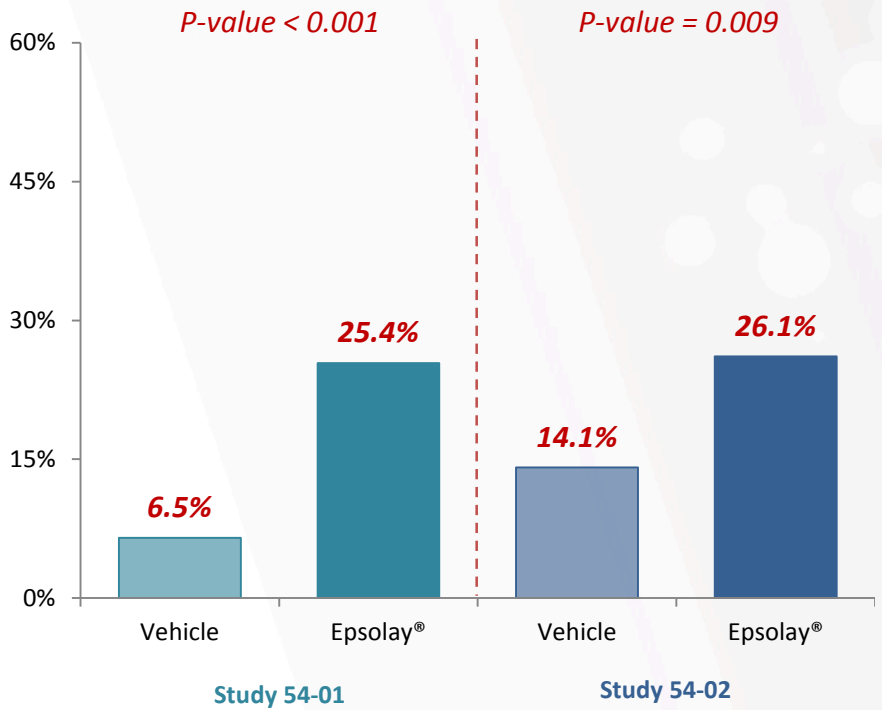


Inflammatory Lesion Count Change from Baseline @ Week 2

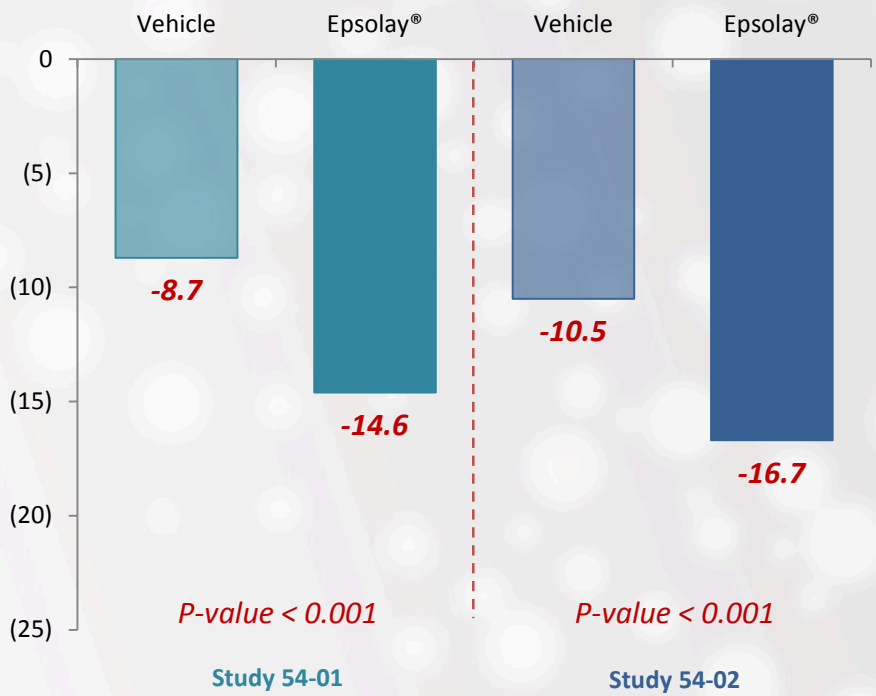


SECONDARY ENDPOINTS (ITT)

Success in IGA @ Week 4

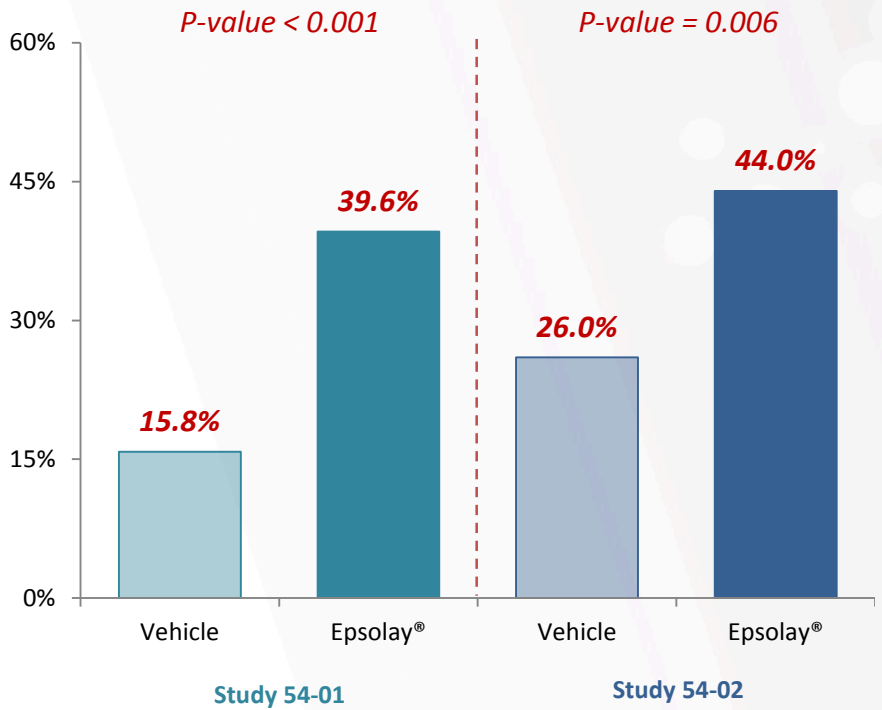


Inflammatory Lesion Count Change from Baseline @ Week 4

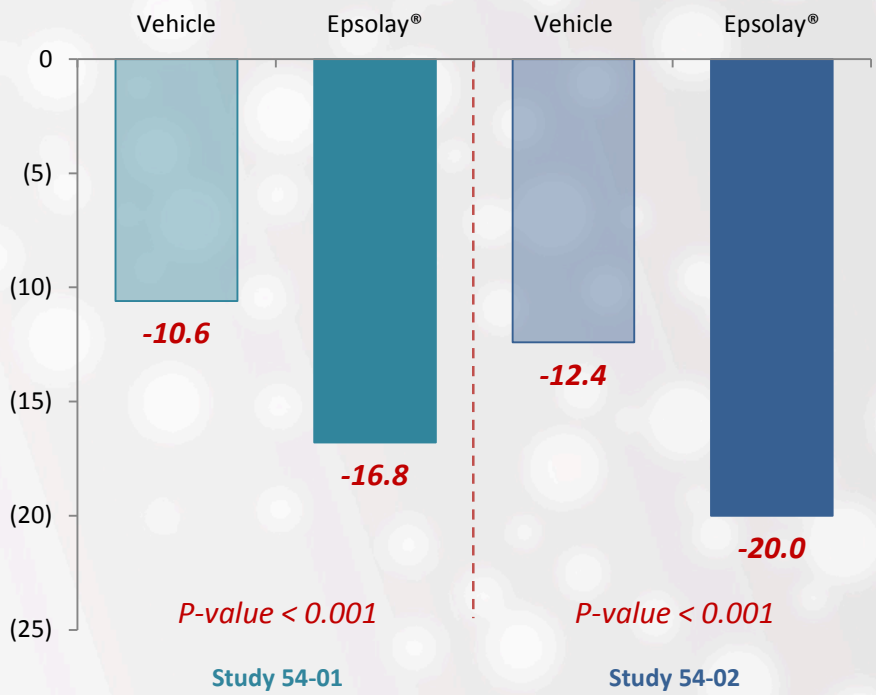


SECONDARY ENDPOINTS (ITT)

Success in IGA @ Week 8

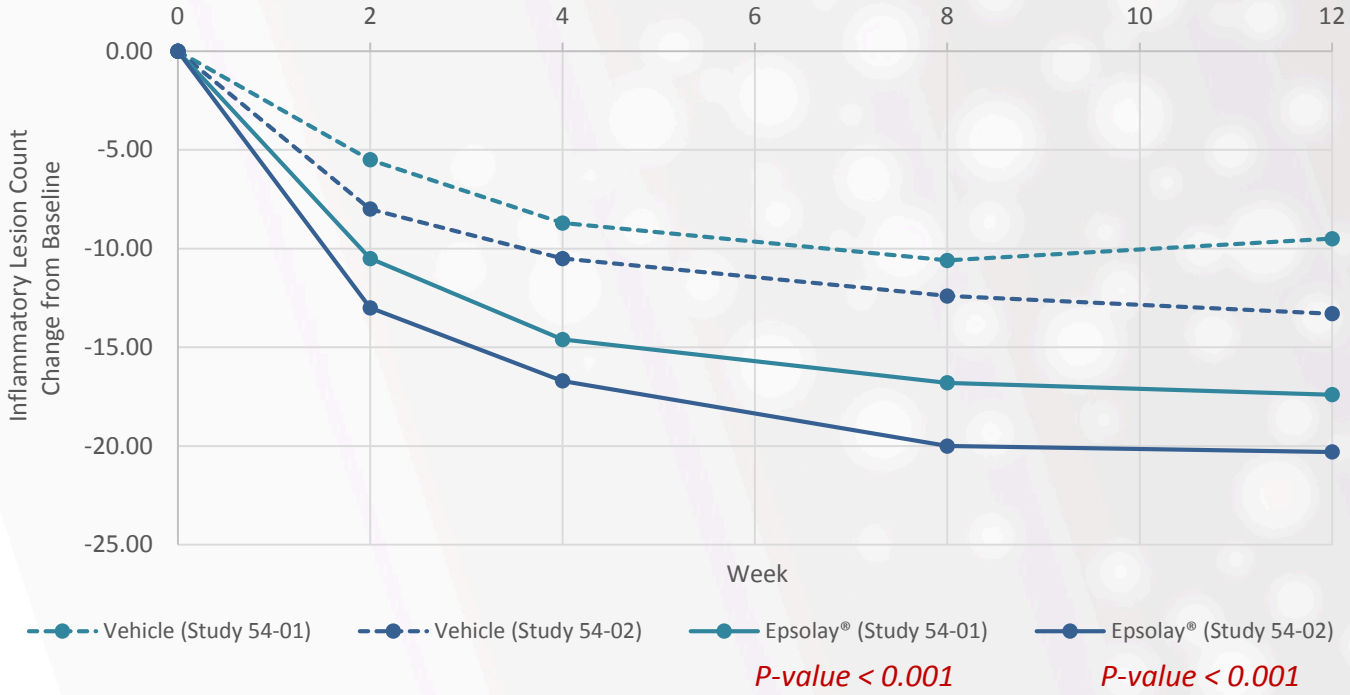


Inflammatory Lesion Count Change from Baseline @ Week 8



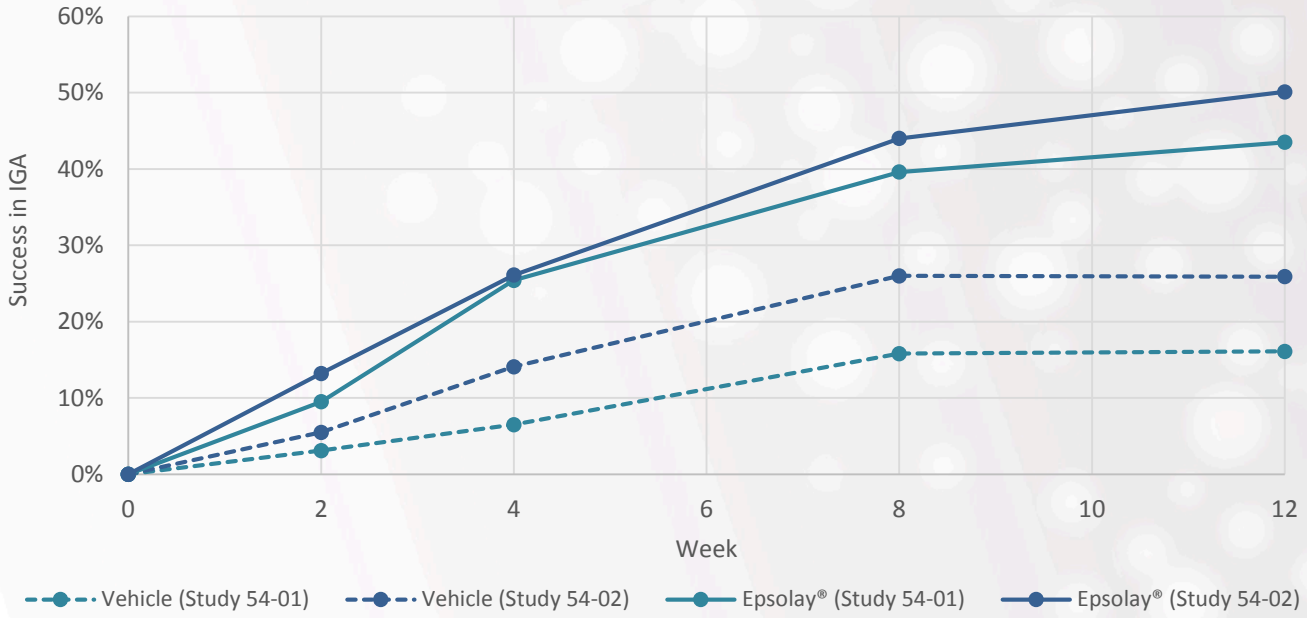
ABSOLUTE REDUCTION IN LESION COUNT OVER TIME

Statistical significant improvement in reducing inflammatory lesions as of Week 2



SUCCESS IN IGA OVER TIME (ITT)

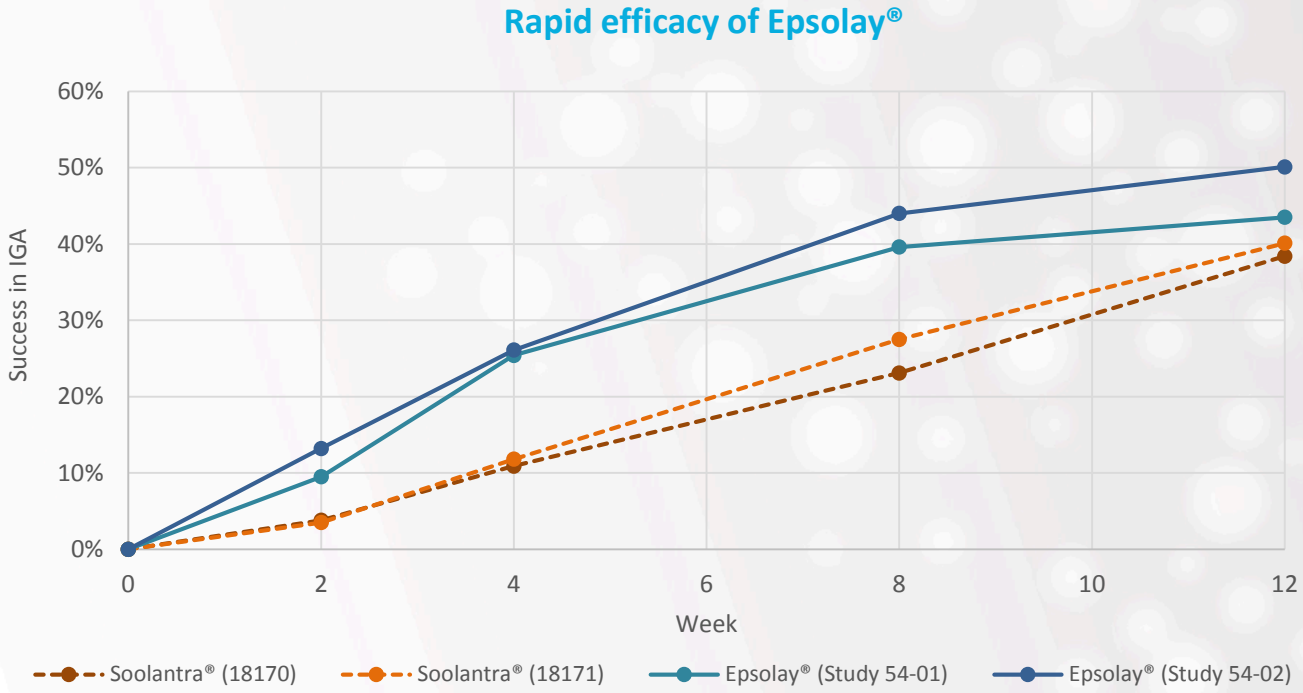
Statistical significant improvement in in getting patients to the stage of “clear” or “almost clear”



P-value < 0.001

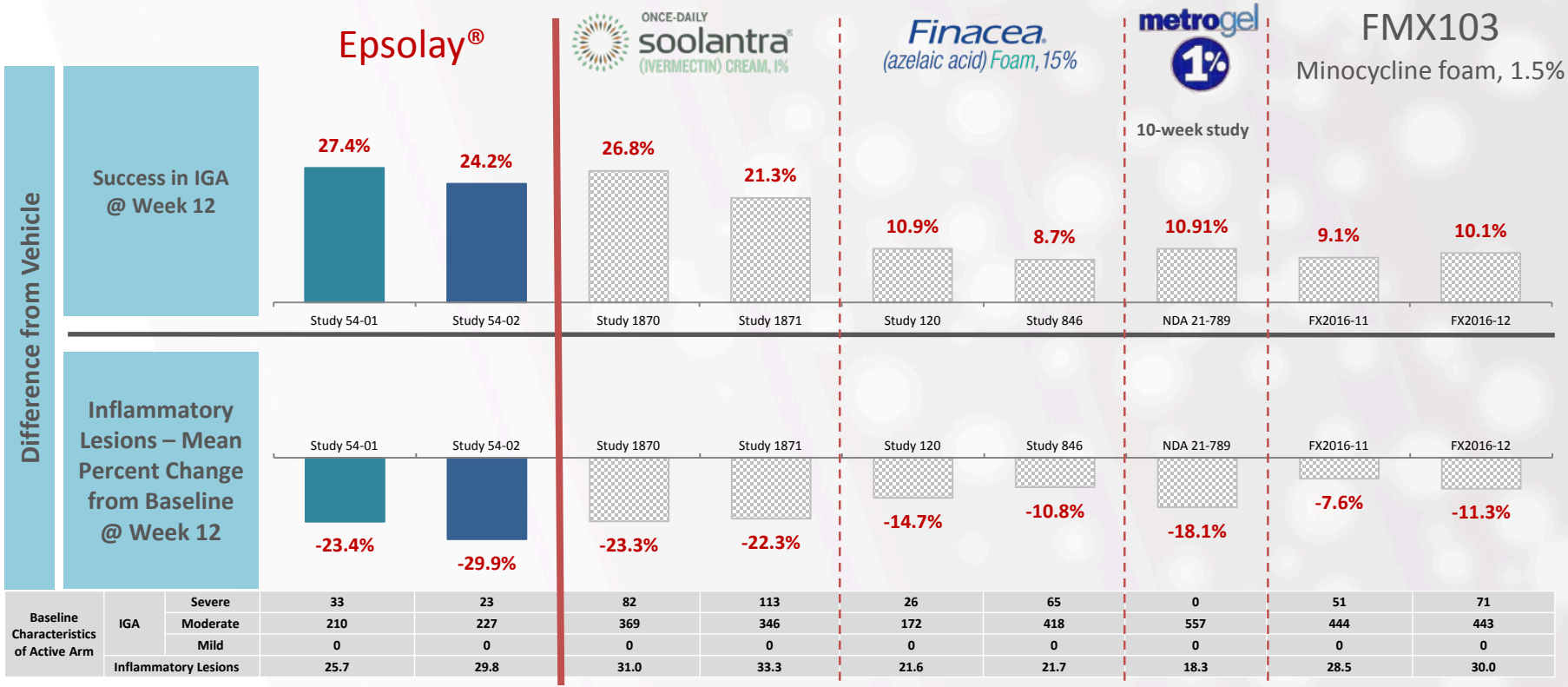
P-value < 0.001

SIDE-BY-SIDE WITH HISTORICAL SOOLANTRA® RESULTS(†)



(†) Sol-Gel did not conduct a head-to-head comparison trial or study. The results described above are for illustrative purposes only and should not be construed as conclusions to be drawn as if we conducted a head-to-head comparison trial or study

SIDE-BY-SIDE WITH OTHER HISTORICAL TRIAL RESULTS(†)



Baseline Characteristics of Active Arm	IGA	Severe	33	23	82	113	26	65	0	51	71
		Moderate	210	227	369	346	172	418	557	444	443
		Mild	0	0	0	0	0	0	0	0	0
	Inflammatory Lesions		25.7	29.8	31.0	33.3	21.6	21.7	18.3	28.5	30.0

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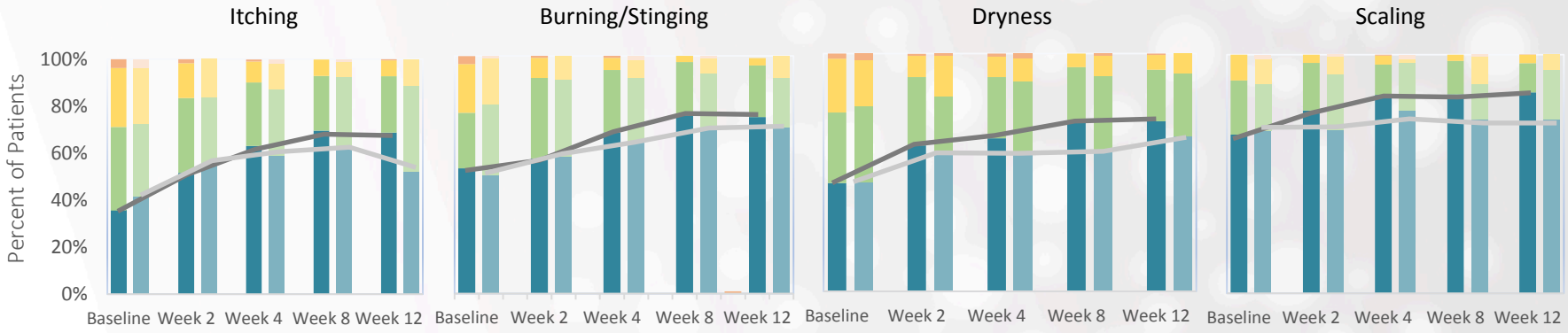
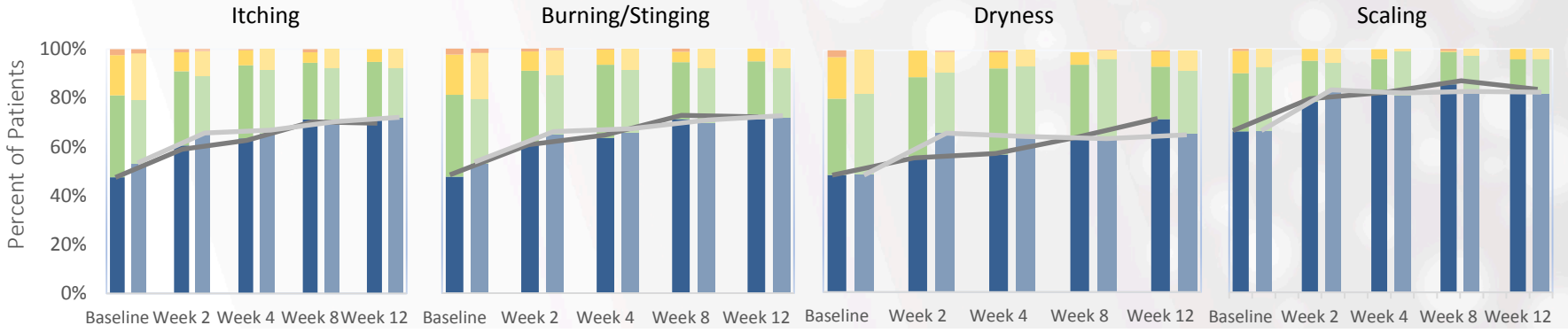
LESION COUNT IMPROVEMENT OVER TIME

SKIN TOLERABILITY (SAFETY POPULATION)

Study 54-01



Study 54-02



Epsolay® Vehicle

None Mild Moderate Severe

TEAEs (†) (SAFETY POPULATION)

No. (%) of Subjects	Study 54-01		Study 54-02	
	Epsolay®	Vehicle	Epsolay®	Vehicle
Subjects reporting any TEAE	49 (20.5%)	17 (15.0%)	50 (20.2%)	22 (18.2%)
Serious TEAE	1 (0.4%)[1]		1 (0.4%)[2]	
Severe TEAE	2 (0.8%)		2 (0.8%)[3]	
Discontinuation	5 (2.1%)	1 (0.9%)	4 (1.6%)	1 (0.8%)[4]
Treatment-related	14 (5.9%)	3 (2.7%)	9 (3.6%)	

[1] Femur fracture
[2] Spinal compression fracture
[3] One subject with spinal compression fracture
[4] Subject with urinary tract infection – Discontinuation defined as "other" reason

(†)TEAE = Treatment-Emergent Adverse Events

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