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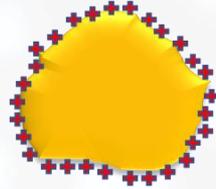
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# AGENDA

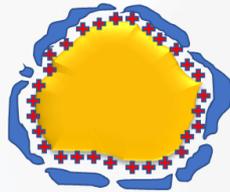


- Sol-Gel's topical microencapsulation system
- Challenges in treating papulopustular rosacea (PPR)
- EPSOLAY – the most effective treatment for PPR

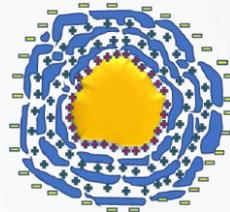
# MICROENCAPSULATION OF WATER DISPERSED APIS



Stage 1: Drug substance is dispersed in water with cationic surfactant

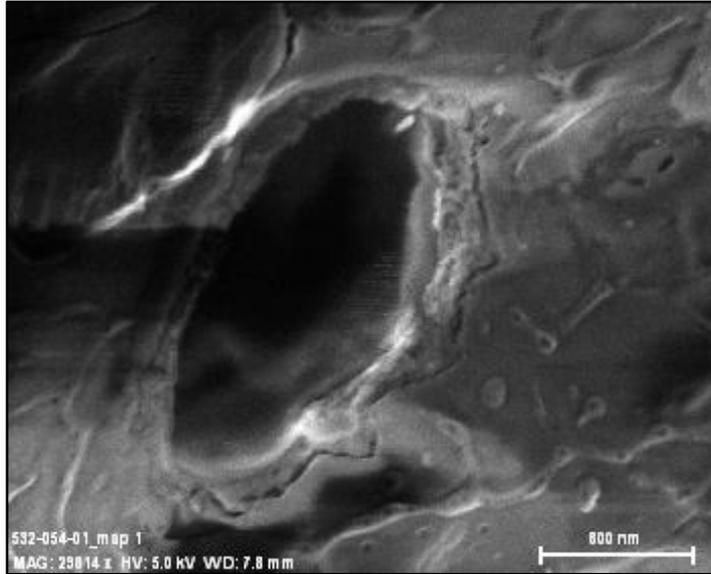


Stage 2: Silica monomers adsorb on the surface of the drug substance and polymerize to form silica layer

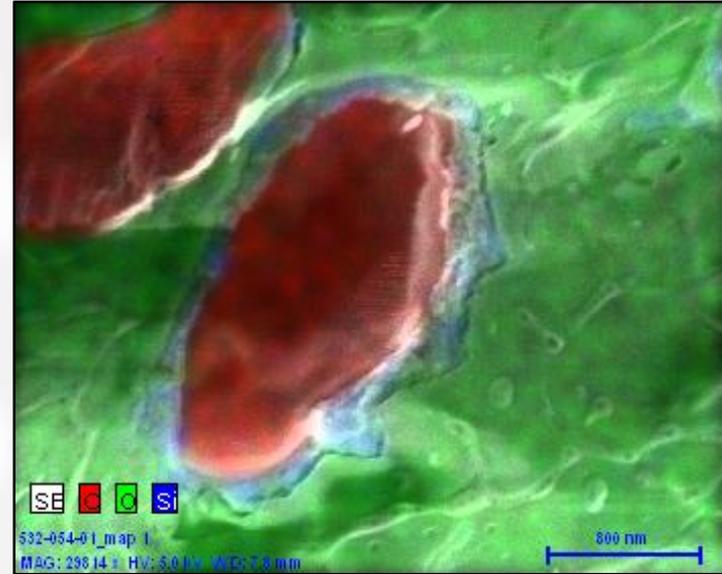


Stage 3: Polycation and silica are added in succession, in layers, to form the silica shell

# MICROENCAPSULATED BENZOYL PEROXIDE



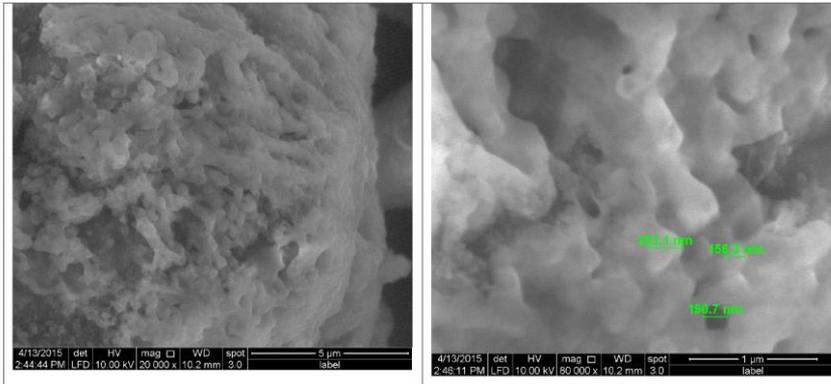
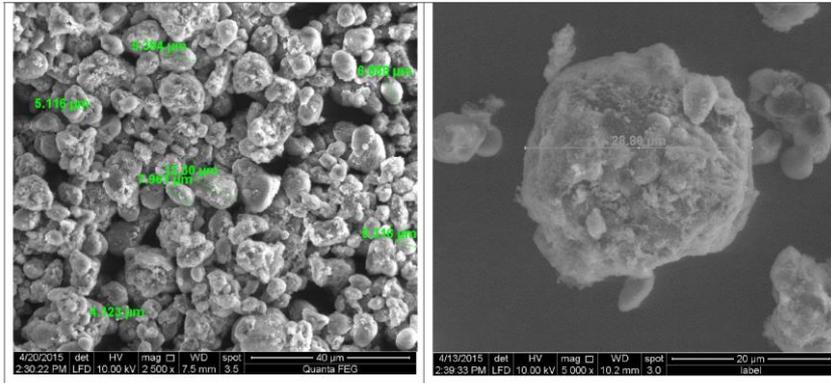
CRYO-SEM (Scanning Electron Microscopy) PICTURE



ENERGY-DISPERSIVE X-RAY SPECTROSCOPY MAPPING

Silica shell wraps BPO crystals and serves as a barrier between benzoyl peroxide crystals and skin, leading to less irritation

# MICROENCAPSULATED BENZOYL PEROXIDE



HIGH RESOLUTION SEM PICTURES

Skin lipids migrate through the silica shell to promote solubilization of BPO.  
Dissolved BPO then migrates to skin's sebaceous follicles

# MICROENCAPSULATION OF OIL DISPERSED APIS



Stage 1: Silica monomers and drug substance are emulsified together

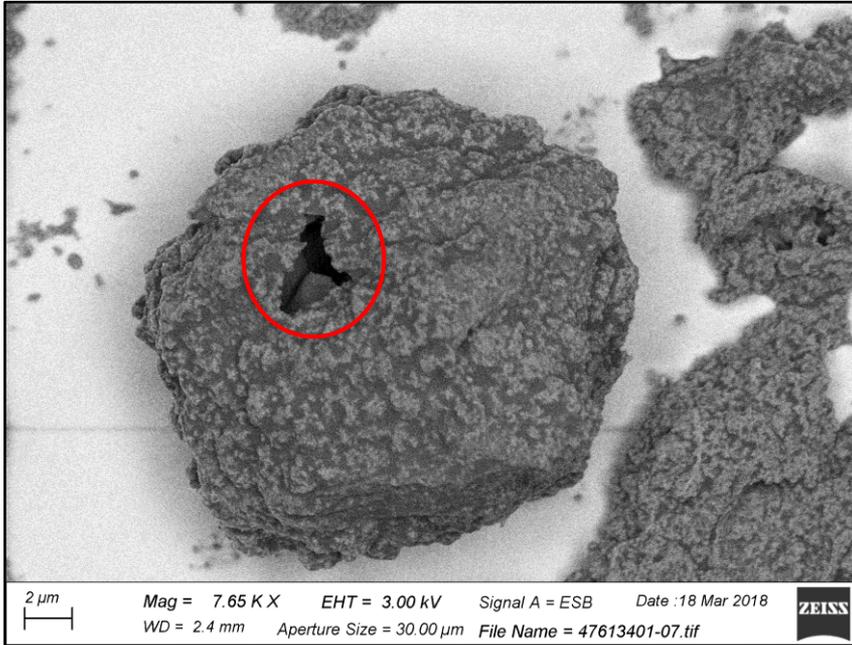


Stage 2: Silica monomers migrate to the oil/water interface in a well-controlled process



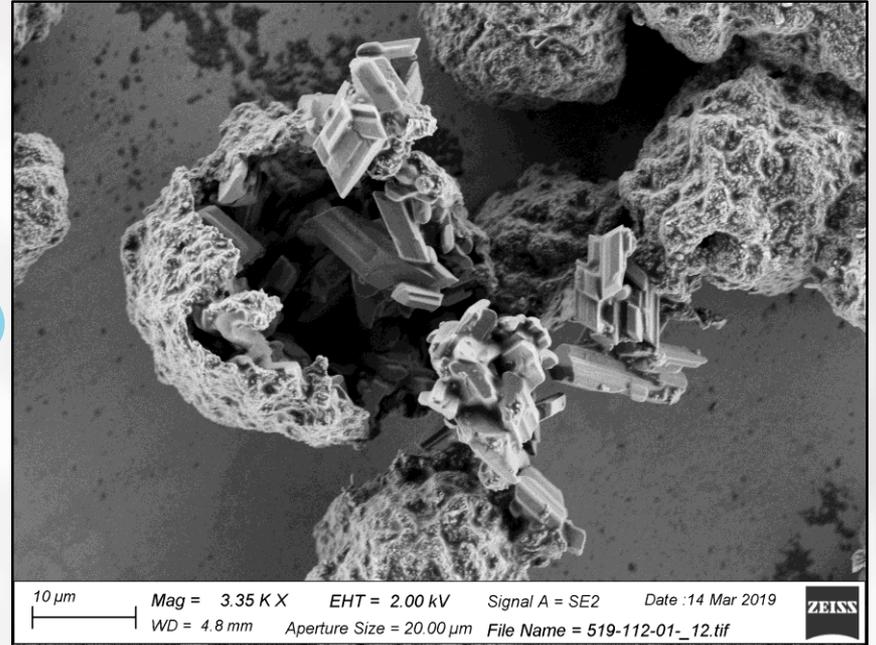
Stage 3: A silica shell, microcapsule is formed

# MICROENCAPSULATED TRETINOIN



SEM PICTURE

High microencapsulation efficiency protects tretinoin



SEM PICTURE

Microencapsulated tretinoin is stable in the presence of benzoyl peroxide

# ROSACEA IS A CHRONIC INFLAMMATORY SKIN DISEASE<sup>1</sup>

- Affects approximately 16 million Americans<sup>2</sup>
- Very high emotional and psychological impact<sup>3</sup>
- 5.46% of the adult general population is affected by rosacea<sup>4</sup>
- No latitude-dependent gradient in rosacea prevalence observed<sup>4</sup>
- Multiple subtypes/phenotypes often seen in a single patient<sup>4,5</sup>

Erythematous



1

Papulopustular



2



3



4

Phymatous

Ocular

1. Blount BW, Pelletier AL. Am Fam Physician. 2002;66:435-440.  
 2. National Rosacea Society. [http://www.rosacea.org/rr/2010/winter/article\\_1.php](http://www.rosacea.org/rr/2010/winter/article_1.php).  
 3. Moustafa F. J Am Acad Dermatol. 2014;71:973-980.  
 4. Gether L, et al. Br J Dermatol. 2018;179:282-289  
 5. Wilkin J, et al. J Am Acad Dermatol. 2004;50:907-912

# PAPULOPUSTULAR ROSACEA

## INFLAMMATORY CONDITION WITH POOR ADHERENCE TO CURRENT TREATMENTS

What is papulopustular rosacea?

Chronic, inflammatory condition that primarily affects the face, and is often characterized by flushing, redness, inflamed bumps, and pustules

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How is it treated?

Topical antimicrobials (metronidazole, clindamycin); topical anti-mite (ivermectin); systemic antibiotics (minocycline, doxycycline)

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What are the current treatment shortfalls?

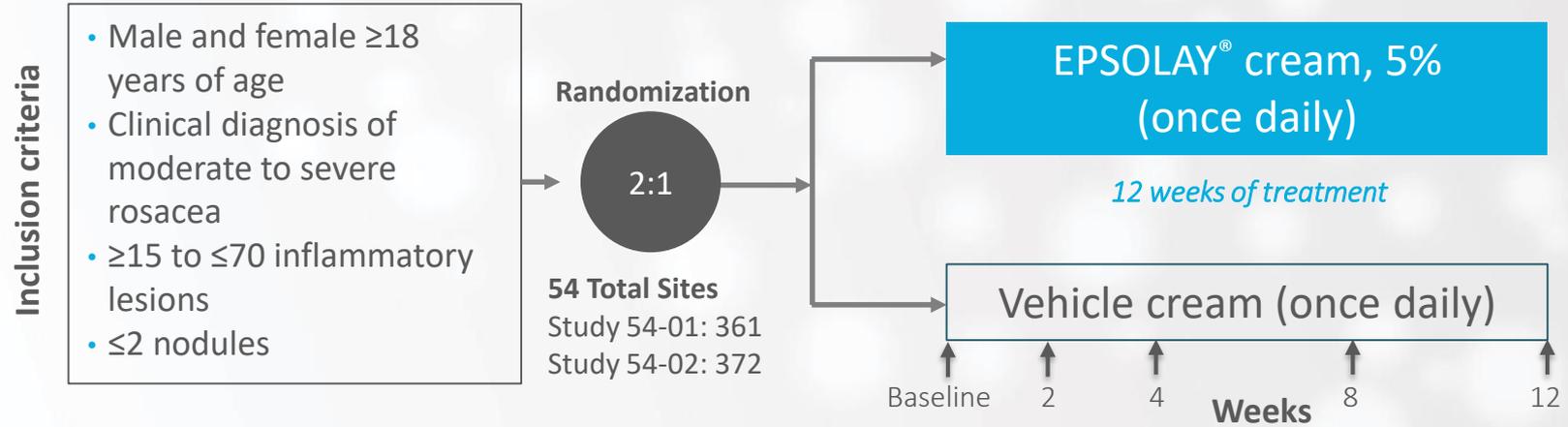
Insufficient efficacy resulting in poor adherence, contributing to antibiotic resistance; systemic side effects

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# EPSOLAY® STUDY DESIGN

*Two phase III, double-blind, randomized, vehicle-controlled studies*



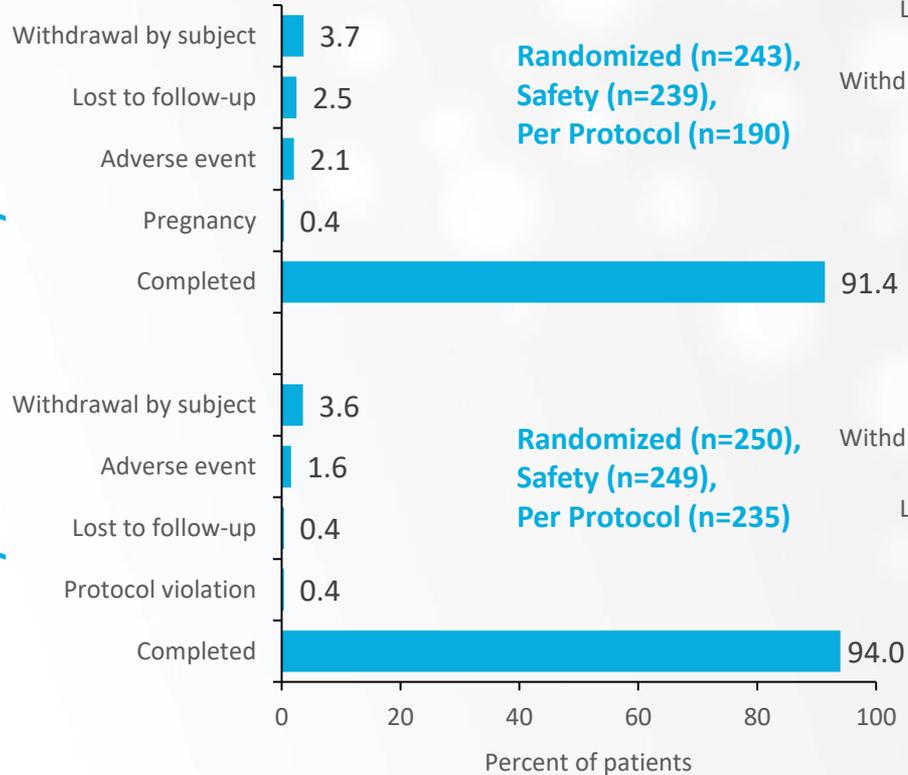
## PRIMARY ENDPOINTS:

- Proportion of patients with the primary measure of success, "Clear" (0) or "Almost clear" (1), in the Investigator Global Assessment (IGA) relative to baseline at Week 12
- Absolute mean change in inflammatory lesion counts from baseline to Week 12

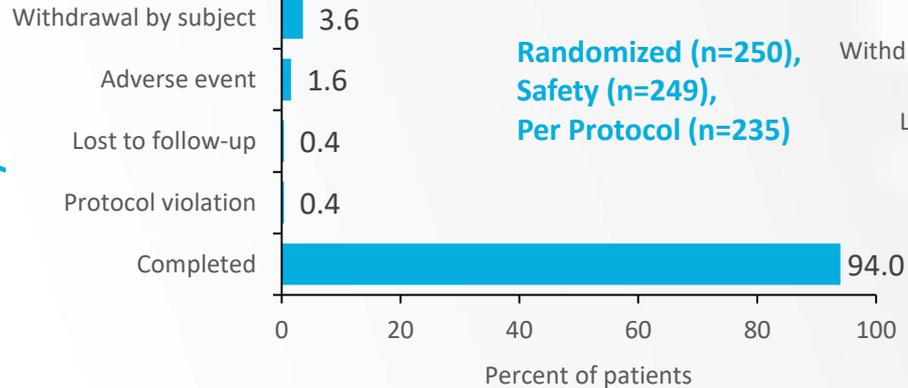
# STUDY POPULATIONS & DISCONTINUATION \*

## EPSOLAY®

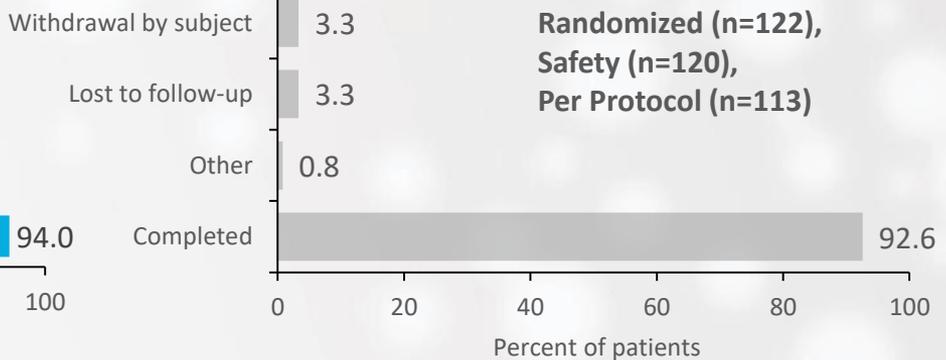
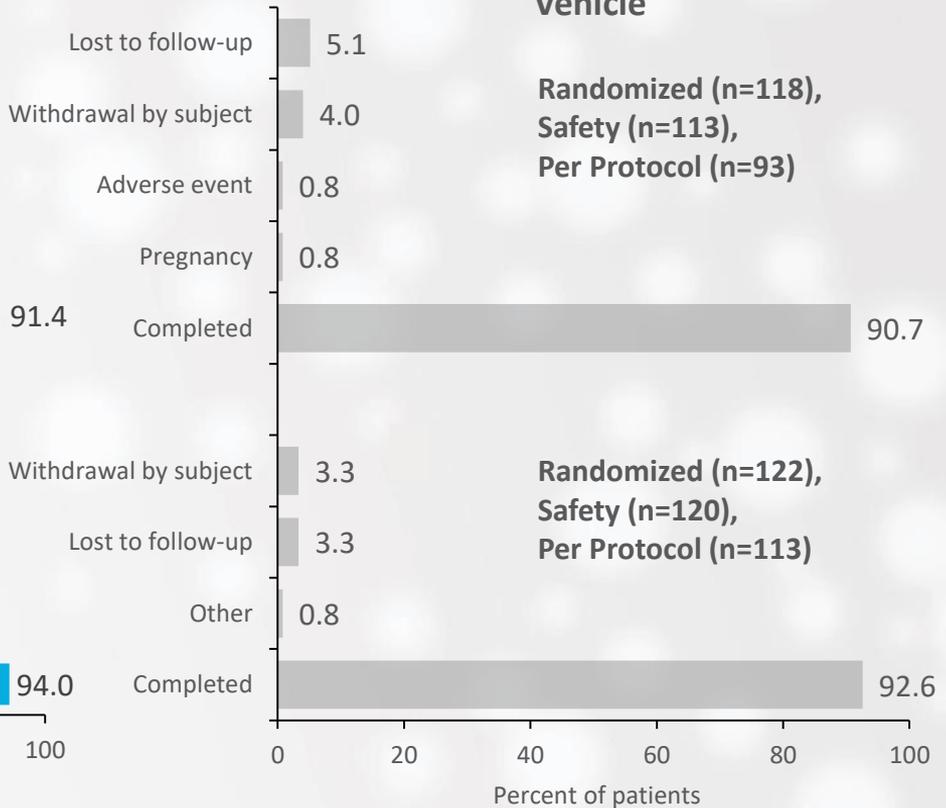
Study 54-01



Study 54-02



## Vehicle



\*ITT (Intent-to-treat) population

# PATIENT SEVERITY AT BASELINE

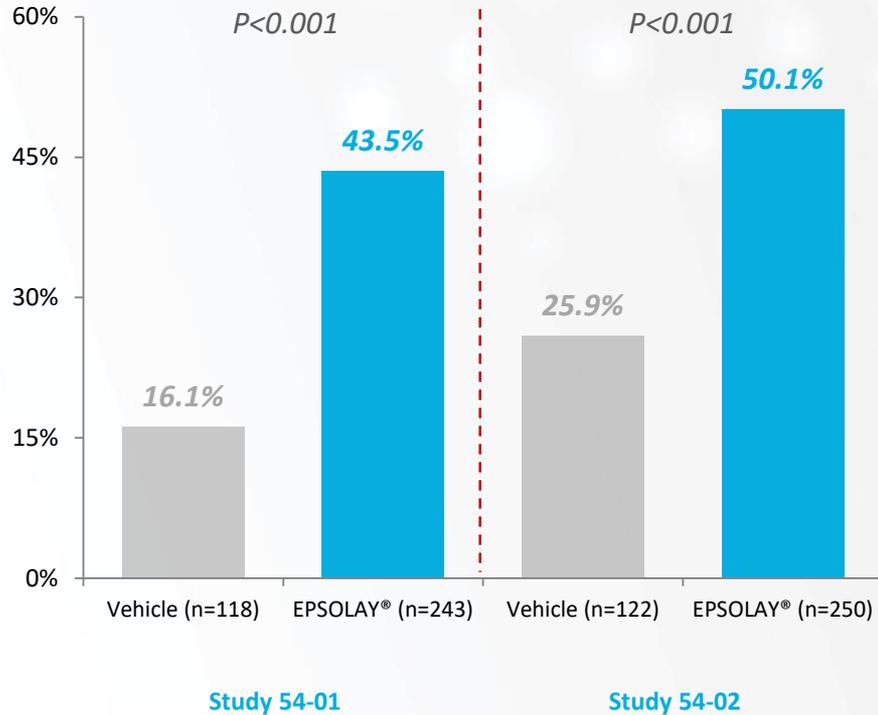
## Study 54-01

## Study 54-02

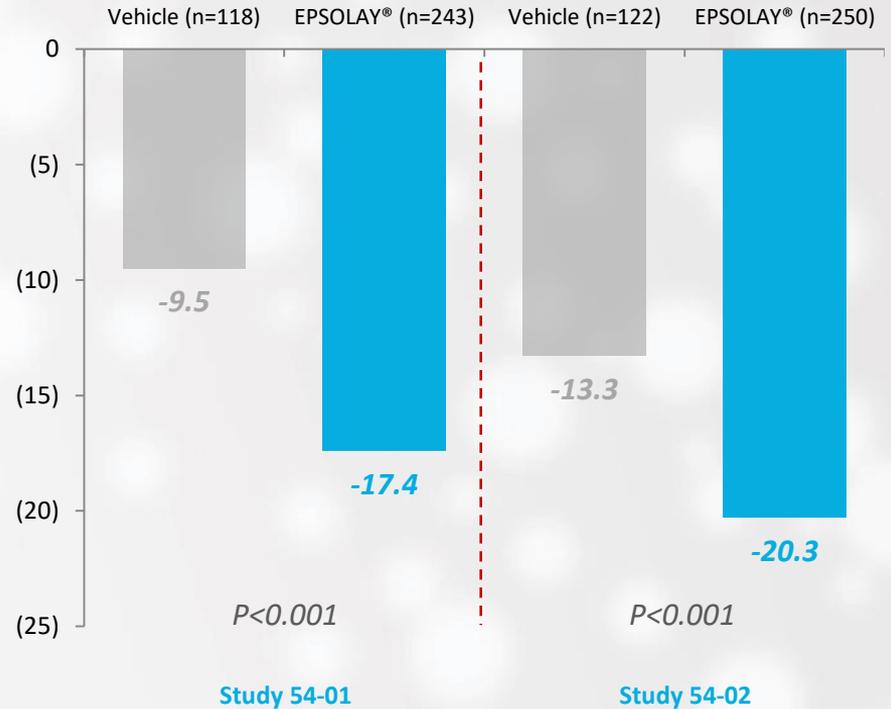
Characteristic	Study 54-01		Study 54-02	
	EPSOLAY®	Vehicle	EPSOLAY®	Vehicle
IGA “Moderate”	210 (86.4%)	104 (88.1%)	227 (90.8%)	112 (91.8%)
IGA “Severe”	33 (13.6%)	14 (11.9%)	23 (9.2%)	10 (8.2%)
Mean lesion count (SD)	25.7 (11.07)	26.3 (12.45)	29.8 (14.00)	27.5 (13.04)
Median lesion count (range)	22.0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

# PRIMARY ENDPOINTS\*

## Success in IGA at Week 12



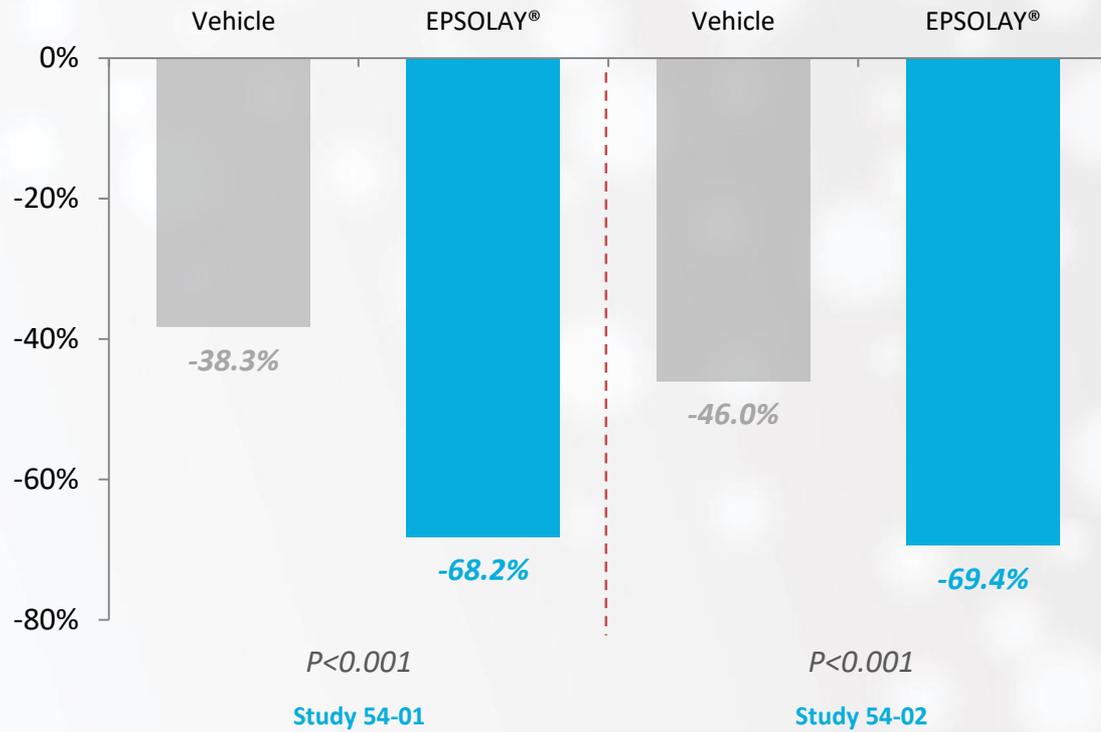
## Inflammatory Lesion Count Change From Baseline at Week 12



\*ITT population

# SECONDARY ENDPOINT\*

## Inflammatory Lesion Percent Change From Baseline to Week 12

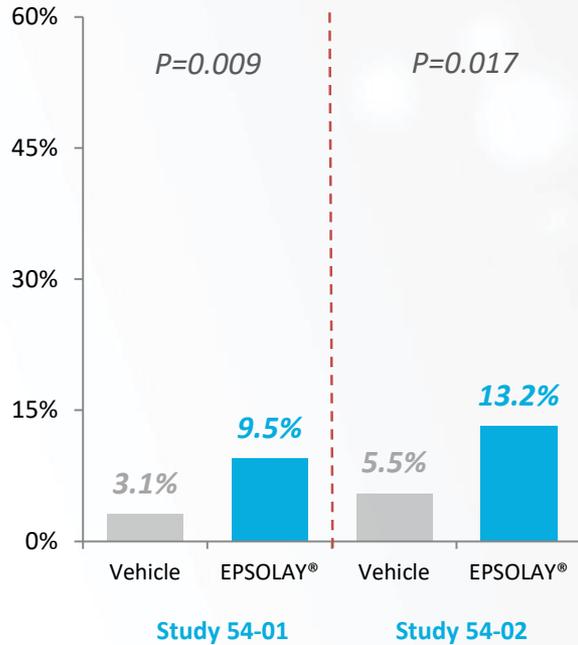


\*ITT population

# SUCCESS IN IGA\*

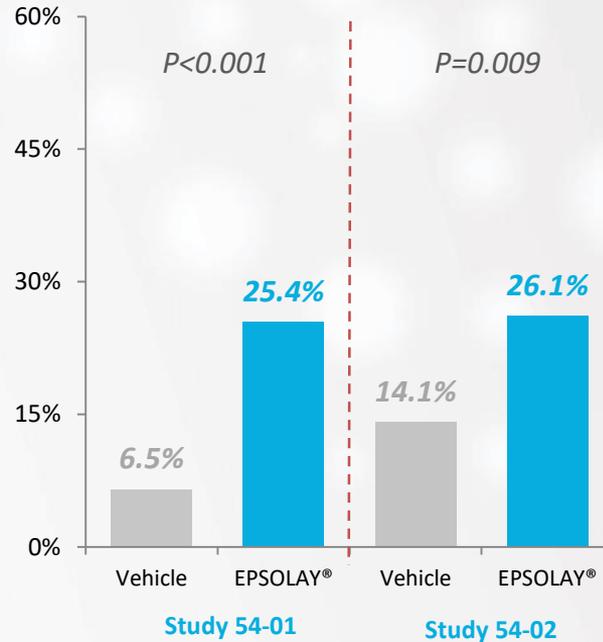
## Week 2

Exploratory Endpoint



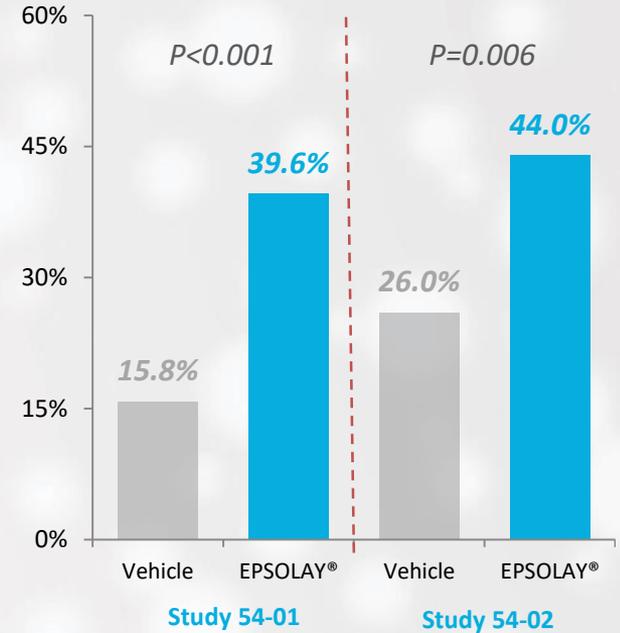
## Week 4

Secondary Endpoint



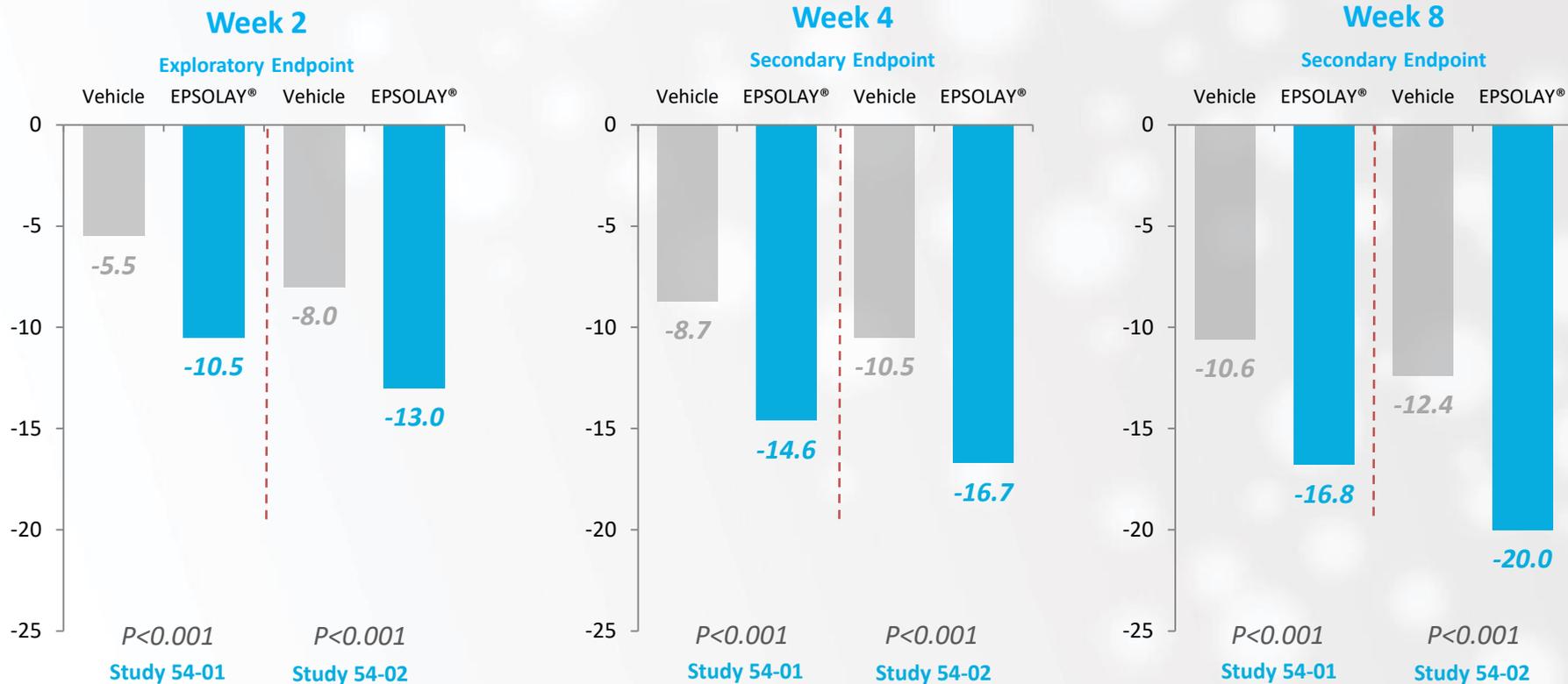
## Week 8

Secondary Endpoint



\*ITT population

# INFLAMMATORY LESION COUNT- CHANGE FROM BASELINE\*



\*ITT population

# IMPROVEMENT OVER TIME

Baseline

Week 2

Week 4

Week 8

Week 12



IGA

4

0

0

0

1



IGA

3

2

1

0

0

# IMPROVEMENT OVER TIME

Baseline

Week 2

Week 4

Week 8

Week 12



IGA

3

0

0

0

0



IGA

4

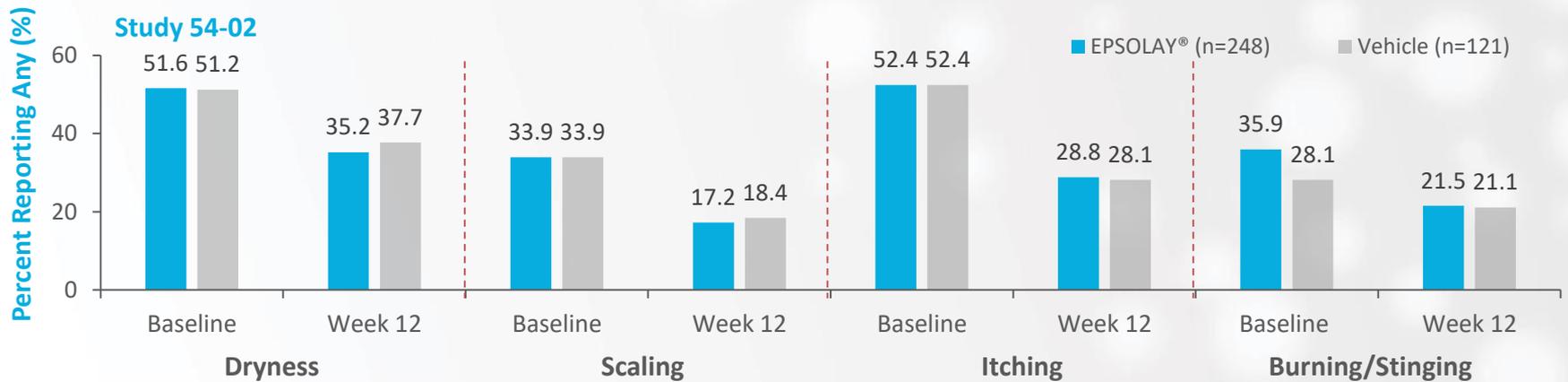
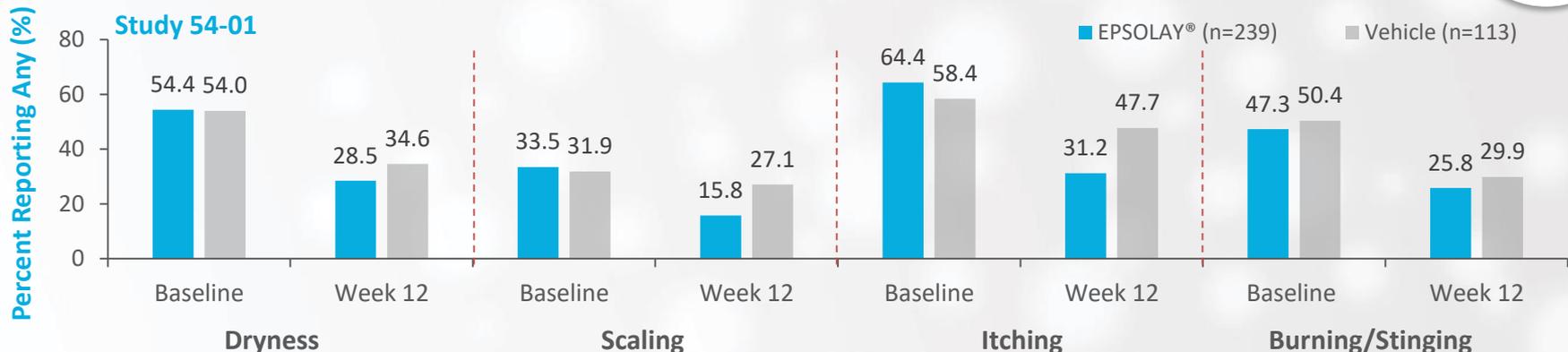
3

3

3

2

# SKIN TOLERABILITY\*

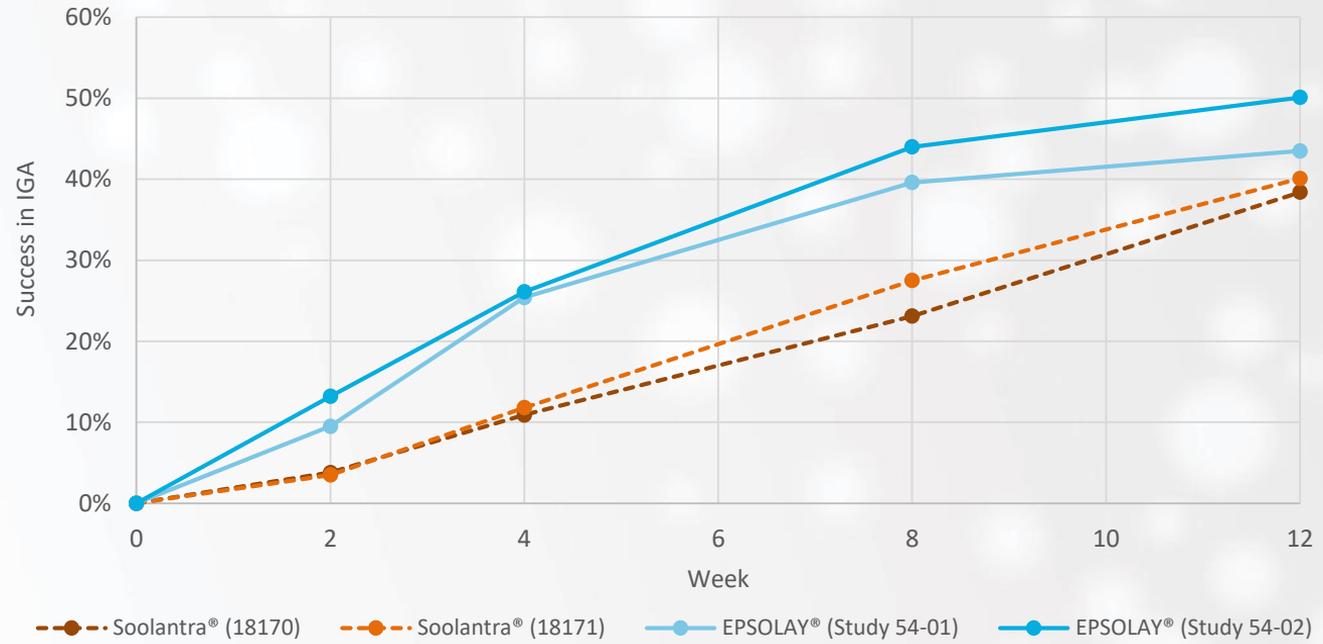


\*Safety population.



# CHANGE IN IGA OVER THE COURSE OF 12 WEEKS TREATMENT IN COMPARISON TO HISTORICAL DATA OF SOOLANTRA® \*

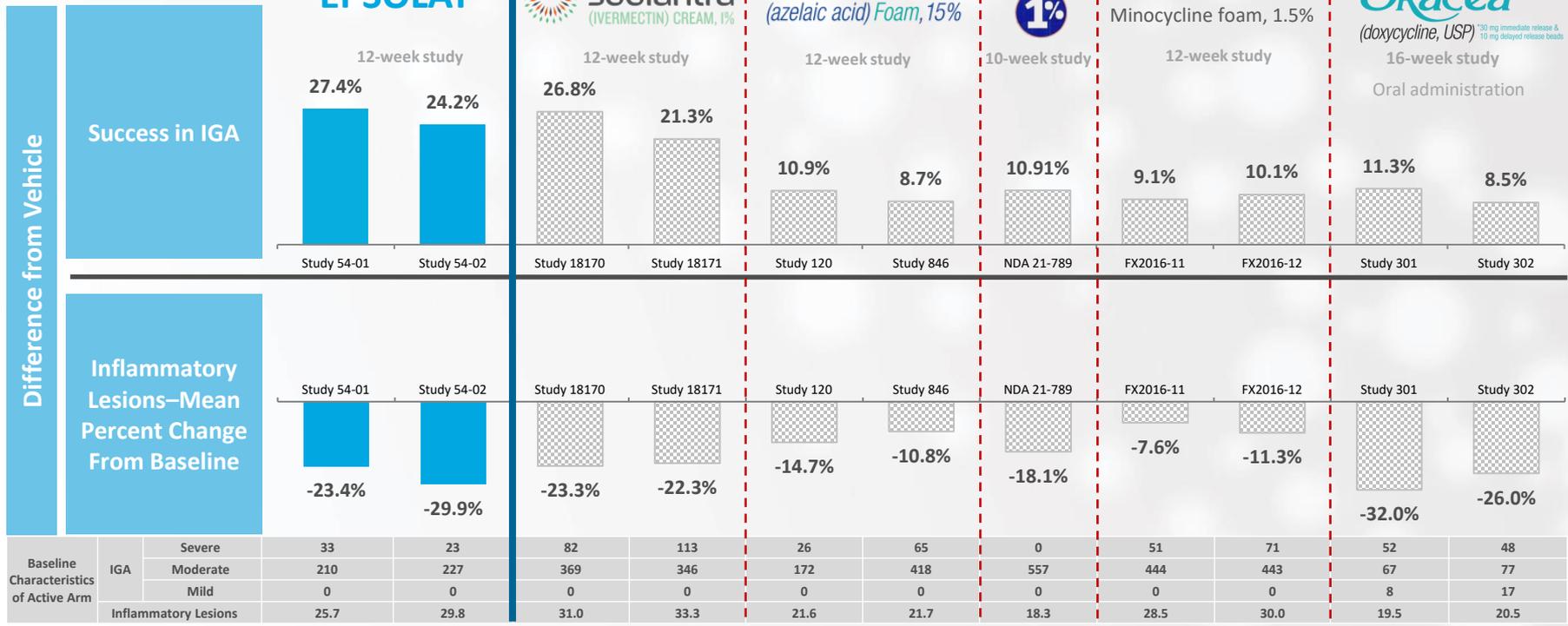
## Two weeks to rosacea symptoms relief



\*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\*



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## SUMMARY



- Epsolay®: A once-daily cream containing microencapsulated benzoyl peroxide, 5%, for the treatment of inflammatory lesions of rosacea (PPR)
- Benzoyl peroxide is an oxidizing agent that successfully treats acne but cannot be well-tolerated by rosacea patients
- Sol-Gel's microencapsulation technology was designed to improve efficacy, reduce irritation and hence contribute to patient compliance
- Phase 3 studies results in rosacea demonstrated:
  - Statistical significant improvement VS. vehicle was achieved for co-primary endpoints and all secondary endpoints
  - Efficacy with statistically significant improvement was demonstrated as early as Week 2, and maintained through Week 4, 8 and 12
  - Well-tolerated, similar to vehicle
- Improvement of topical drug performance using Sol-Gel's microencapsulation holds promise in other treatments including acne vulgaris, currently completing phase 3 studies



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