



# Sol-Gel

Advanced Topical Therapy

NASDAQ: SLGL

September 2020



# FORWARD-LOOKING STATEMENTS

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “future,” “outlook,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential,” “continue,” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. The forward-looking statements in this presentation relate to, among other things, statements regarding the timing of the anticipated submission of an NDA for TWYNEO and the approval and commercial launch of EPSOLAY and TWYNEO, anticipated timing of results of the ongoing Phase 1 clinical trial of SGT-210, the expectation to launch a new generic drug starting in the second quarter of 2021, our expectations regarding our liquidity and ability to fund operational and capital expenditure requirements, and estimated sales of our product candidates. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties, and other important factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statement, including but not limited to the following: risks relating to the timing of the submission of an NDA for TWYNEO and risks relating to the PDFUA action date for EPSOLAY; the fact that we have and expect to continue to incur significant losses; our need for additional funding, which may not be available; our ability to complete the development of, and obtain marketing approval for, our product candidates; our ability to obtain and maintain regulatory approvals for our product candidates in our target markets and the possibility of adverse regulatory or legal actions relating to our product candidates even if regulatory approval is obtained; our ability to commercialize and launch our product candidates; our ability to obtain and maintain adequate protection of our intellectual property; our ability to manufacture our product candidates in commercial quantities, at an adequate quality or at an acceptable cost; our ability to establish adequate sales, marketing, and distribution channels; acceptance of our product candidates by healthcare professionals and patients; the possibility that we may face third-party claims of intellectual property infringement; the timing and results of clinical trials that we may conduct or that our competitors and others may conduct relating to our or their products; intense competition in our industry; potential product liability claims; potential adverse federal, state, and local government regulation in the United States, Europe, or Israel; the impact of pandemics, such as COVID-19 (coronavirus); and loss or retirement of key executives and research scientists. These and other important factors discussed in the Company’s Annual Report on Form 20-F filed with the Securities and Exchange Commission (“SEC”) on March 24, 2020, and our other reports filed with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this presentation. Any such forward-looking statements represent management’s estimates as of the date of this presentation. While we may elect to update such forward-looking statements at some point in the future, unless required by applicable law, we disclaim any obligation to do so, even if subsequent events cause our views to change. Thus, one should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements.

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## OVERVIEW

# OUR DERMATOLOGY COMPANY

### TECHNOLOGY

- Proprietary silica-based microencapsulation technology

### EPSOLAY<sup>®</sup>

- PDUFA goal date set for April 26, 2021
- Potential to be the first single-active BPO approved by the FDA as a prescription drug product

### TWYNEO<sup>®</sup>

- Positive Phase III results in acne vulgaris
- NDA submission expected in 2H/20
- Potential to be first FDA-approved acne treatment that contains fixed-dose combination of BPO and tretinoin

### SGT-210

- Ongoing Phase I proof-of-concept study for erlotinib gel in palmoplantar keratoderma
- Results expected next year

### EARLY STAGE

- Pending patent applications for tapinarof and roflumilast in various skin conditions

### GENERICS

- Ten 50/50 gross profit-sharing collaborations with Perrigo
- \$22.8 million in net revenues last year
- \$4.5 million in net revenues in 1H/20



# THE SCIENCE BEHIND OUR PROPRIETARY TECHNOLOGY

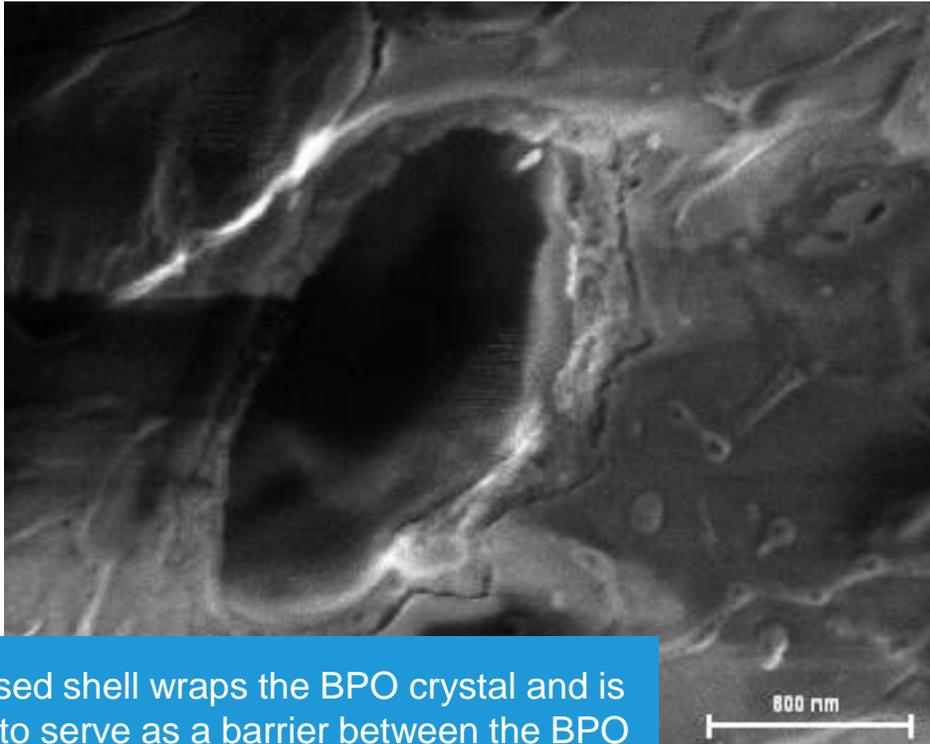
Aiming to provide effective and tolerable topical  
therapies to achieve local action



ENCAPSULATION IS DESIGNED TO ALLOW FOR CONTINUOUS FLOW

# ENCAPSULATED BENZOYL PEROXIDE (E-BPO)

CRYO-SEM PICTURE



Silica-based shell wraps the BPO crystal and is intended to serve as a barrier between the BPO crystals and the skin

ENERGY-DISPERSIVE X-RAY SPECTROSCOPY MAPPING



After application onto skin, BPO slowly migrates through the shell resulting in a continuous flow of BPO for up to 24 hours

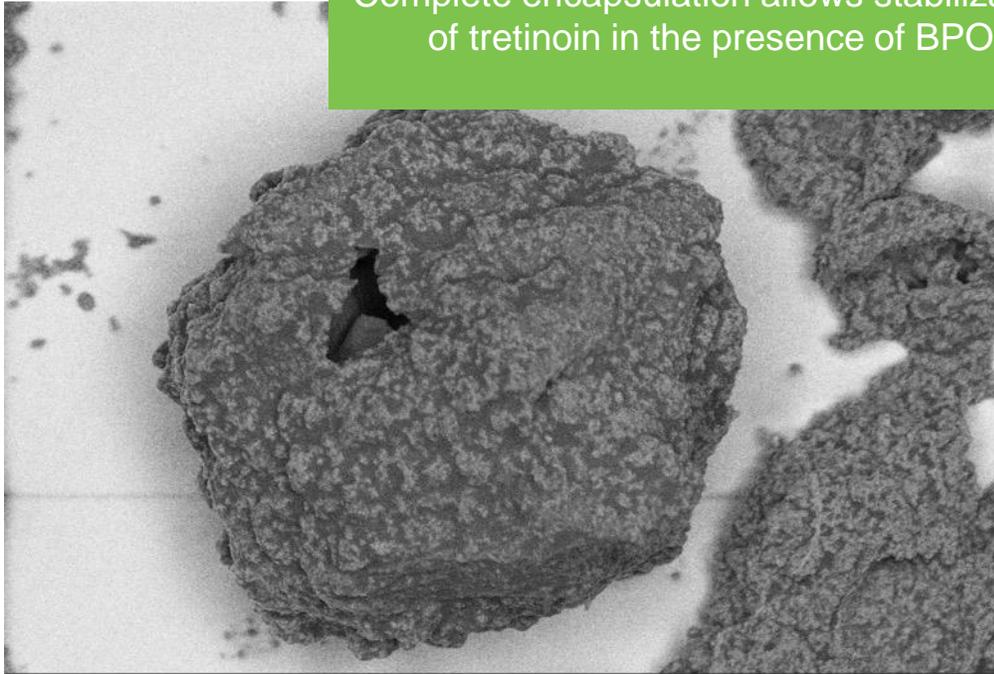


ENCAPSULATION IS DESIGNED TO ENHANCE STABILITY

# ENCAPSULATED TRETINOIN (E-TRETINOIN)

SEM PICTURE

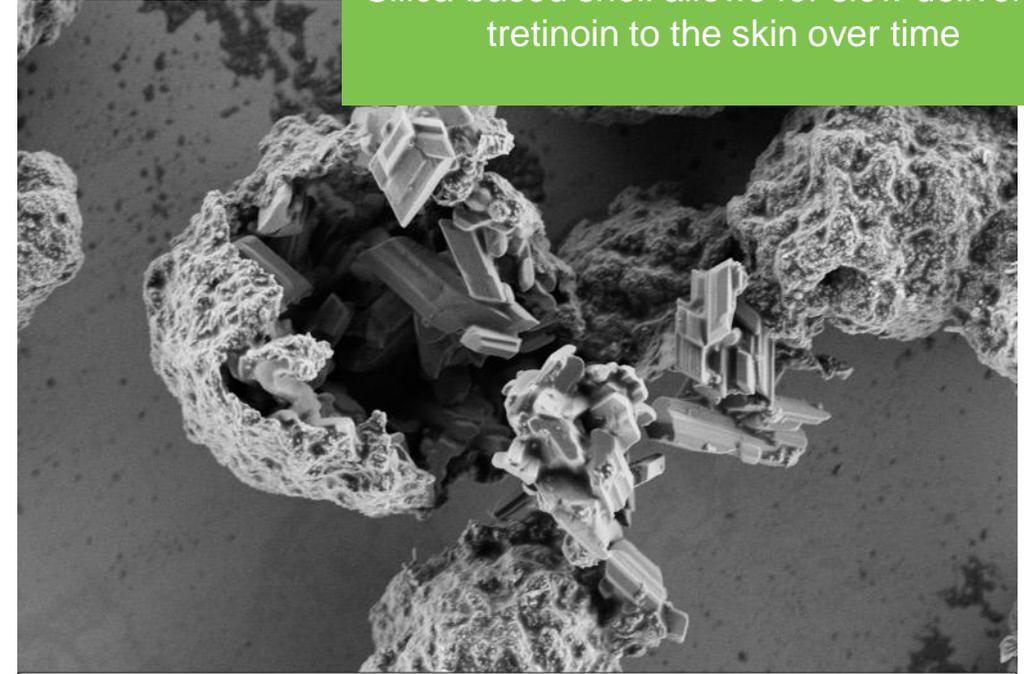
Complete encapsulation allows stabilization of tretinoin in the presence of BPO



2  $\mu$ m | Mag = 7.65 K X | EHT = 3.00 kV | Signal A = ESB | Date :18 Mar 2018 | ZEISS  
WD = 2.4 mm | Aperture Size = 30.00  $\mu$ m | File Name = 47613401-07.tif

SEM PICTURE

Silica-based shell allows for slow delivery of tretinoin to the skin over time



10  $\mu$ m | Mag = 3.35 K X | EHT = 2.00 kV | Signal A = SE2 | Date :14 Mar 2019 | ZEISS  
WD = 4.8 mm | Aperture Size = 20.00  $\mu$ m | File Name = 519-112-01-\_12.tif



## THE CHALLENGE

# CHRONIC CONDITION WITH POOR ADHERENCE TO CURRENT TREATMENTS

## UNMET NEED IN PAPULOPUSTULAR ROSACEA



### Papulopustular Rosacea

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

### How is it Treated?

- Topical antimicrobials (metronidazole, clindamycin)
- Topical anti-mite (ivermectin)
- Systemic antibiotics (minocycline, doxycycline)

### Current Treatment Shortfalls

- Insufficient efficacy resulting in poor adherence
- Systemic side effects
- Contributing to antibiotic resistance

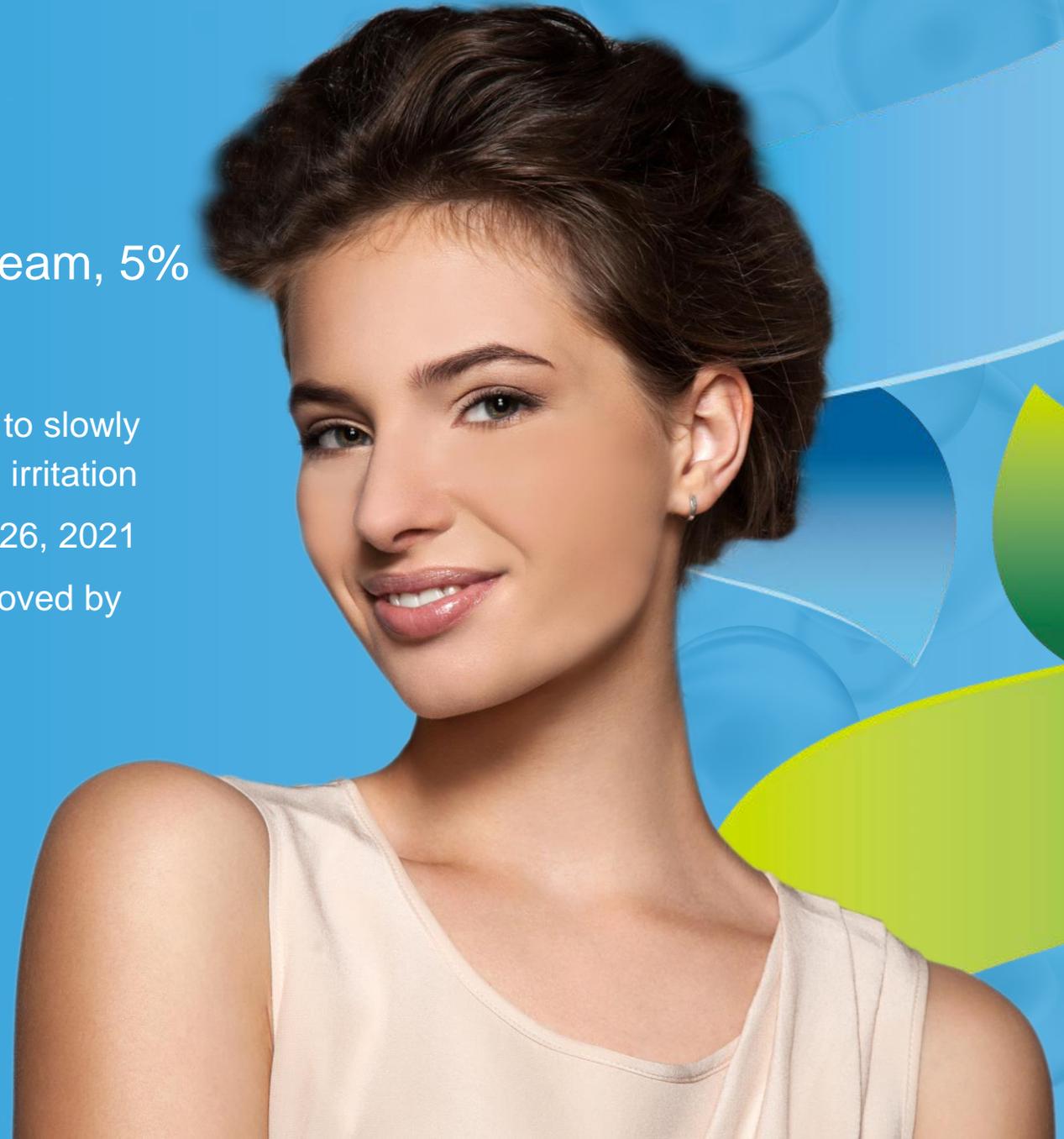
SOL-GEL SOLUTION\*

# EPSOLAY<sup>®</sup>

Encapsulated Benzoyl Peroxide Cream, 5%

- Encapsulation was designed to allow the BPO to slowly migrate from the microcapsules to help reduce irritation
- PDUFA goal date was set by the FDA for April 26, 2021
- Potential to be the first single-active BPO approved by the FDA as a prescription drug product

\* EPSOLAY is investigational. Safety and efficacy have not been established





EPSOLAY<sup>®</sup>

# PHASE III STUDIES

Two Parallel, Multicenter, Double-Blinded,  
Randomized, Vehicle-Controlled Studies, 2:1 Ratio, QD



## PHASE III DESIGN

# TWO CO-PRIMARY EFFICACY ENDPOINTS AT WEEK 12

### Inclusion Criteria

≥18 years old; “Moderate” or “Severe” acne; ≥15 to ≤70 inflammatory lesions; ≤2 nodules

### How is it Treated?

Weeks 2, 4, 8, 12 (end of study)

### Investigator Global Assessment (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

### Primary Endpoints

- **Proportion of patients with IGA “Clear” or “Almost Clear” relative to baseline at Week 12**
- **Absolute mean change in inflammatory lesion counts from baseline to Week 12**



## PHASE III CHARACTERISTICS

# WELL-BALANCED CLINICAL STUDIES

Baseline, Discontinuation & Completion		Study 54-01		Study 54-02	
		EPSOLAY	Vehicle	EPSOLAY	Vehicle
Baseline	IGA "Moderate" Subjects	210 (86.4%)	104 (88.1%)	227 (90.8%)	112 (91.8%)
	IGA "Severe" Subjects	33 (13.6%)	14 (11.9%)	23 (9.2%)	10 (8.2%)
	Mean Inflammatory Lesion Count (SD)	25.7 (11.07)	26.3 (12.45)	29.8 (14.00)	27.5 (13.04)
	Median Inflammatory Lesion Count (range)	22.0 (15-69)	21.0 (15-70)	25.0 (15-70)	22.5 (15-70)
Discontinued Subjects	Withdrawal by Subject	9	3	9	4
	Adverse Events	5	1	4	0
	Lost to Follow-Up	6	6	1	4
	Pregnancy/Protocol Violation/Other	1	1	1	1
<b>Intention-to-Treat (ITT)</b>		<b>243</b>	<b>118</b>	<b>250</b>	<b>122</b>

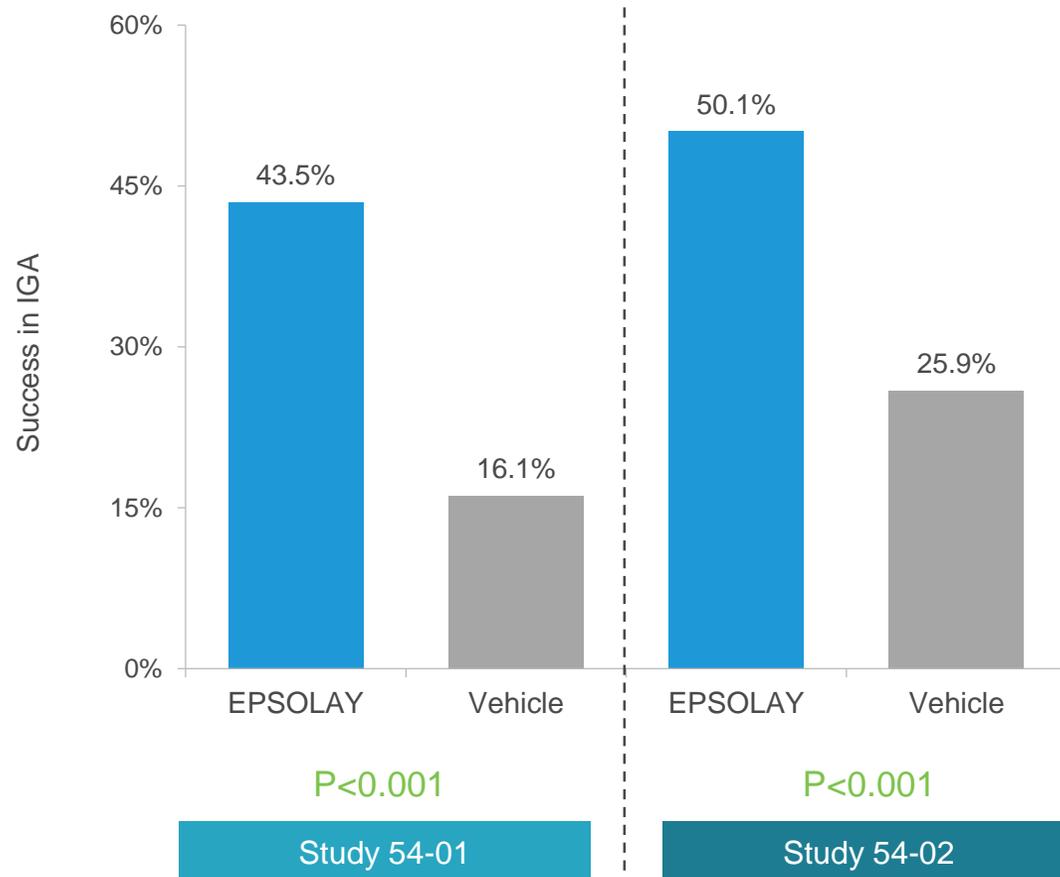
SD = Standard Deviation



## PHASE III RESULTS

# SUCCESS IN PRIMARY ENDPOINTS

Week 12  
Success in IGA (ITT)



Week 12  
Inflammatory Lesion Count  
Change from Baseline (ITT)





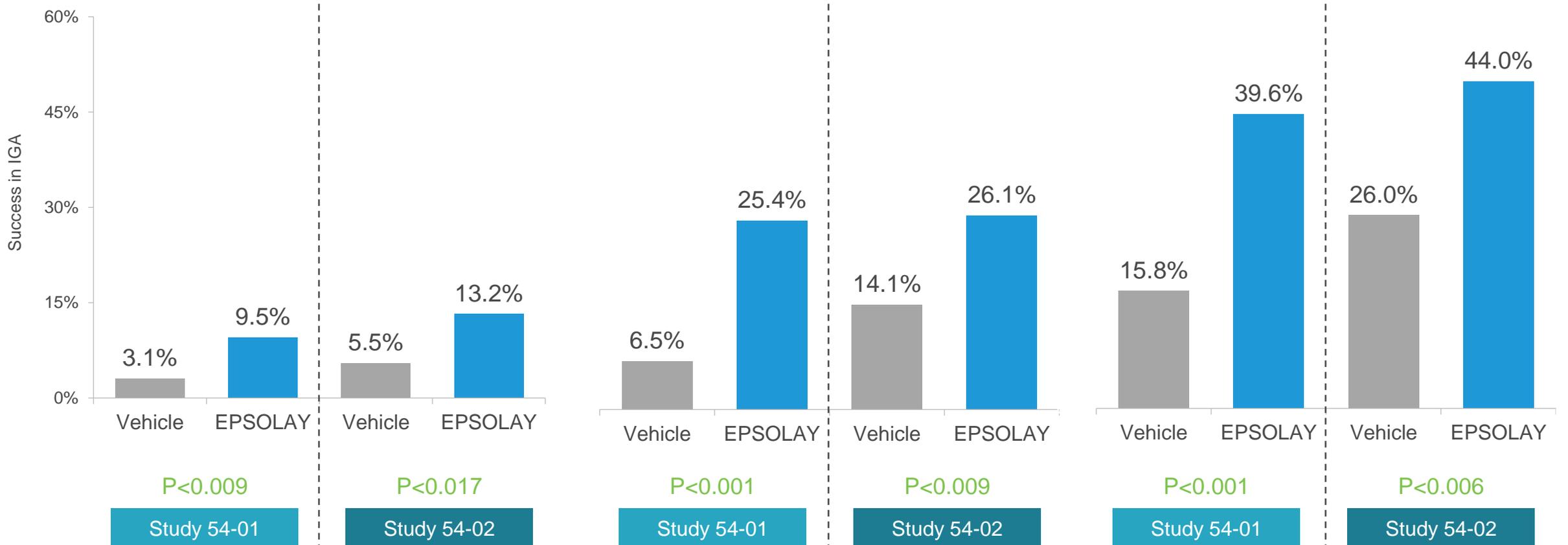
SUCCESS IN IGA

# IMPROVEMENT AS OF WEEK 2

Week 2  
Exploratory Endpoint (ITT)

Week 4  
Secondary Endpoint (ITT)

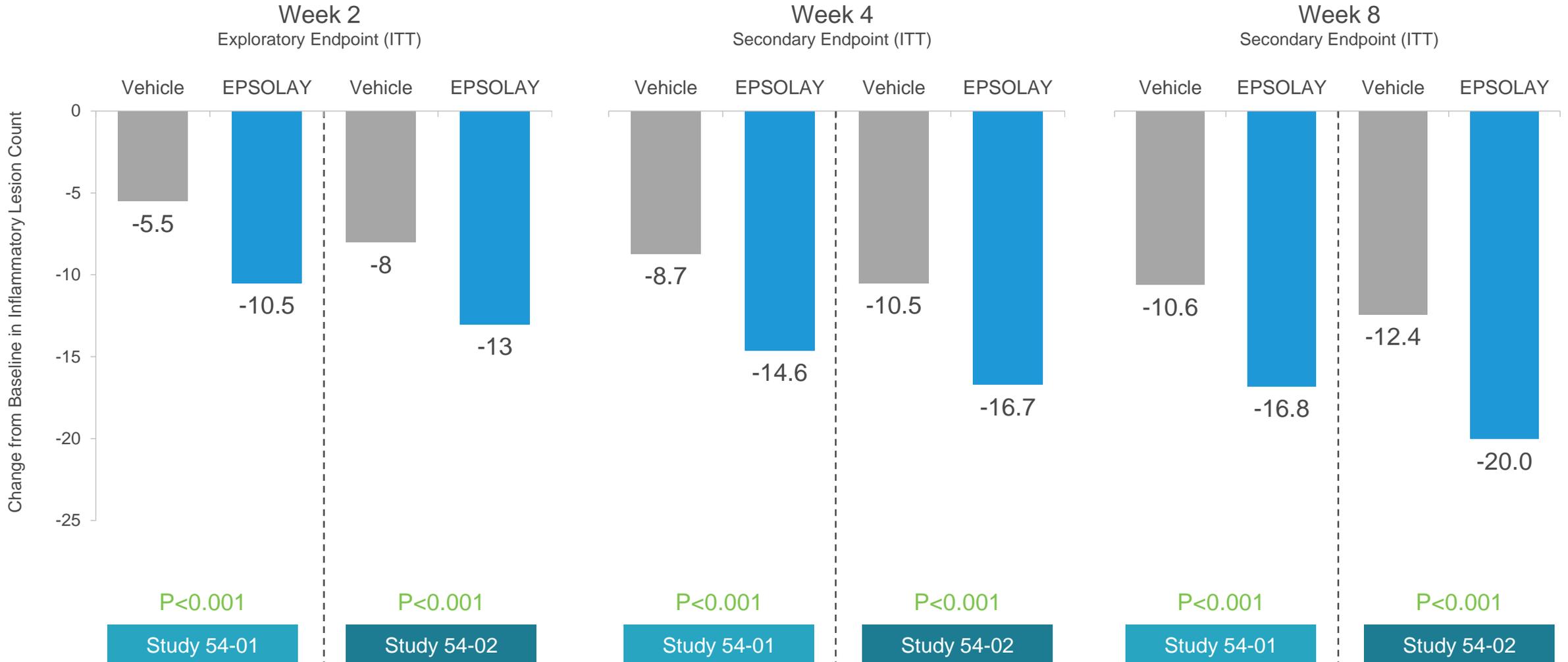
Week 8  
Secondary Endpoint (ITT)





## REDUCTION OF LESIONS

# IMPROVEMENT AS OF WEEK 2



Subject 116-009 || 41 years old | Female | White | Not Hispanic or Latino\*

# ONSET OF ACTION AS OF WEEK 2

BASELINE



"Severe"; 31 inflamed lesions

WEEK 2



"Clear"; No inflamed lesions

WEEK 4



"Clear"; No inflamed lesions

WEEK 8



"Clear"; No inflamed lesions

WEEK 12



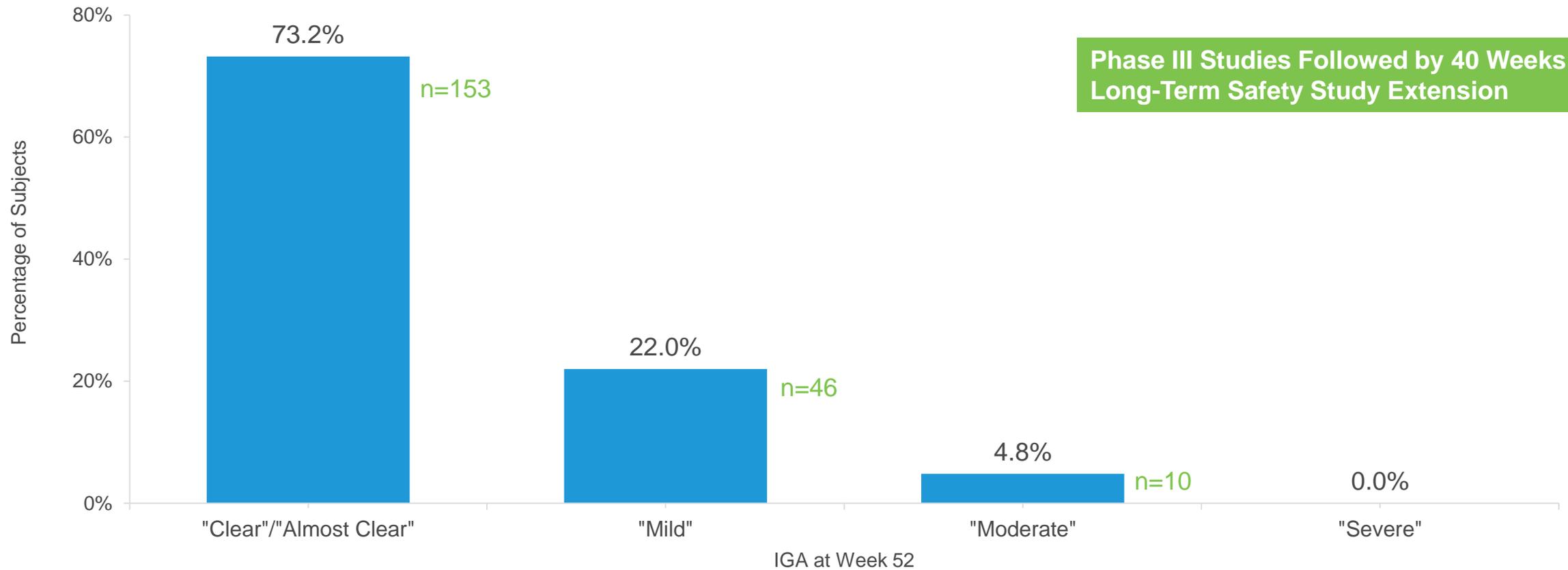
"Almost Clear"; 1 inflamed lesion

\* Individual results vary



## LONG-TERM SAFETY STUDY

# IMPROVEMENT IN IGA\*

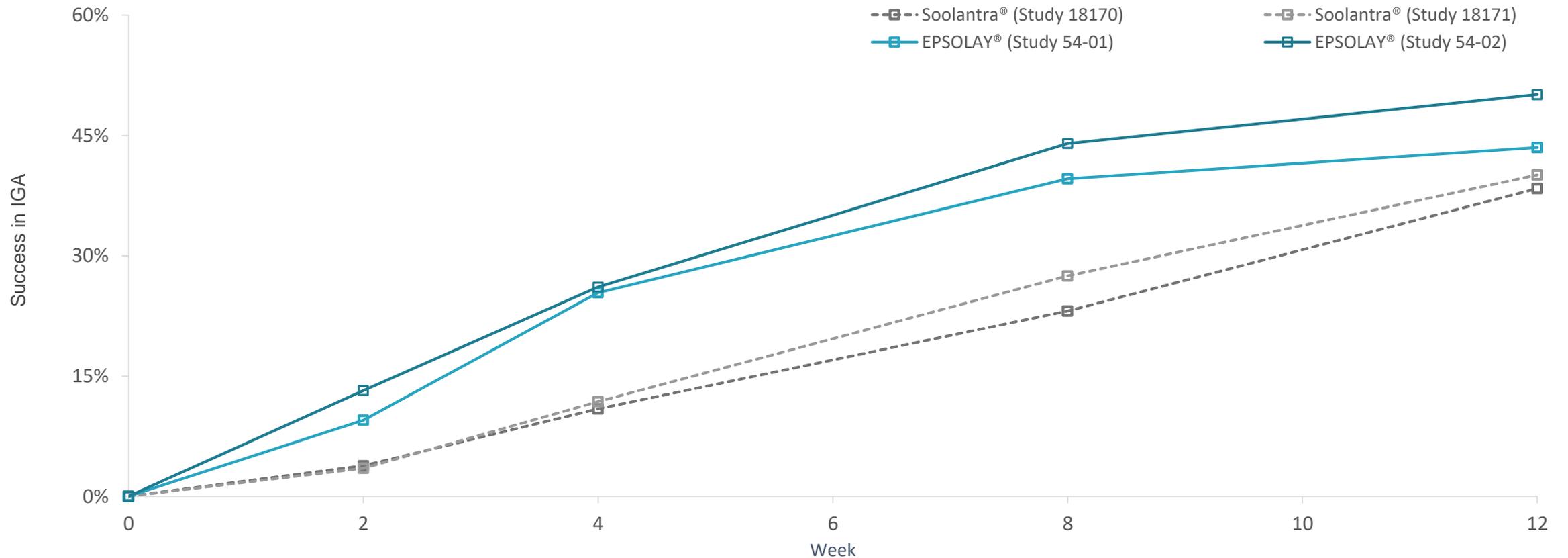


\* This study was not designed for efficacy; however, efficacy was evaluated. Interpret results with caution



SIDE-BY-SIDE WITH HISTORICAL RESULTS\*

# IMPROVEMENT OVER TIME



\* 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 HISTORICAL RESULTS\*

# PRIMARY ENDPOINTS

Difference from Vehicle

Success in IGA

Inflammatory Lesion Percent Change from Baseline

**EPSOLAY<sup>®</sup>**  
12-week study

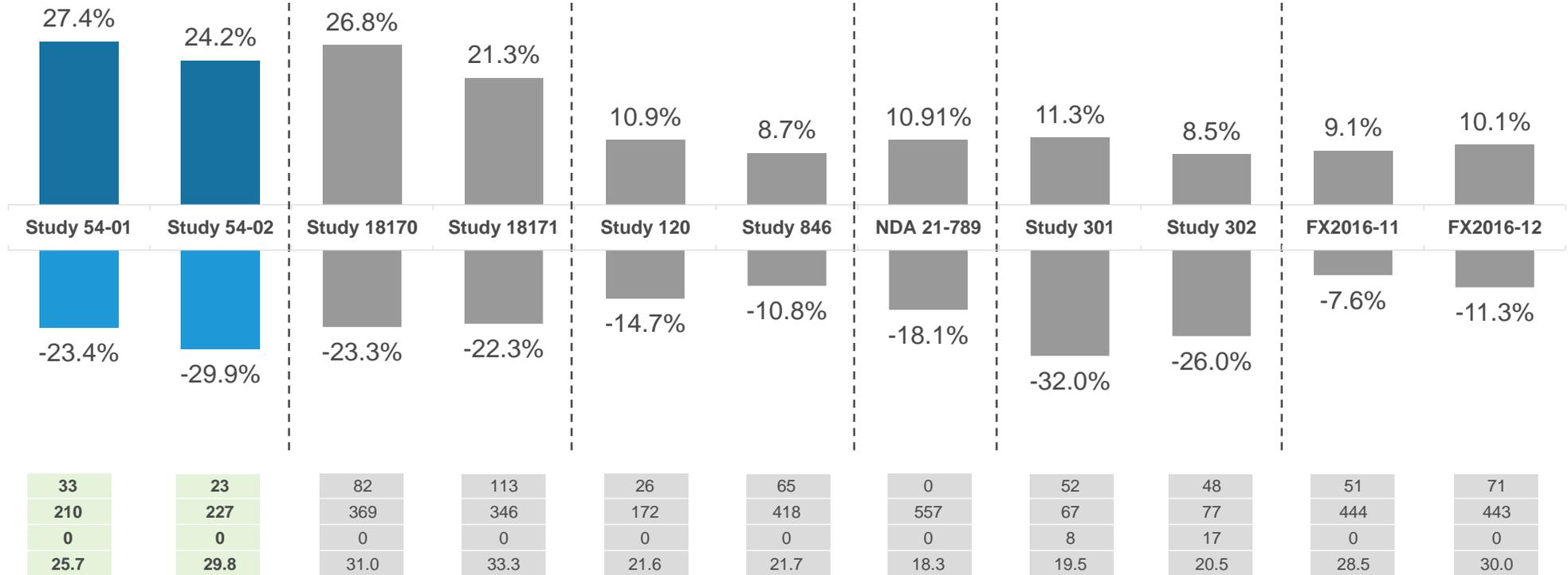
ONCE-DAILY  
**soolantra<sup>®</sup>**  
(IVERMECTIN) CREAM, 1%

**Finacea.**  
(azelaic acid) Foam, 15%

**metrogel 1%**  
10-week study

Once-daily 40 mg<sup>†</sup> Capsules  
**ORacea<sup>®</sup>**  
(doxycycline, USP)  
120 mg immediate release & 10 mg delayed release tablets  
16-week study  
Per os

**zilxi<sup>™</sup>**  
(minocycline)  
topical foam, 1.5%  
12-week study



Baseline Characteristics of Active Arm	IGA	Severe	33	23	82	113	26	65	0	52	48	51	71
		Moderate	210	227	369	346	172	418	557	67	77	444	443
		Mild	0	0	0	0	0	0	0	8	17	0	0
	Inflammatory Lesions	25.7	29.8	31.0	33.3	21.6	21.7	18.3	19.5	20.5	28.5	30.0	

\* 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



PRIMARYLY MILD-TO-MODERATE

# TREATMENT-EMERGENT ADVERSE EVENTS

Subjects with Treatment-Emergent Adverse Events (TEAEs)	Study 54-01		Study 54-02	
	EPSOLAY (n=239)	Vehicle (n=113)	EPSOLAY (n=249)	Vehicle (n=120)
Treatment-Related Mild & Moderate TEAEs	12 (5%) <sup>^</sup>	3 (2.7%) <sup>^</sup>	8 (3.2%) <sup>^</sup>	0
Treatment-Related Severe TEAEs	2 (0.8%) <sup>¥</sup>	0	1 (0.4%) <sup>*</sup>	0
Not-Related TEAEs	35 (14.6%)	14 (12.4%)	41 (16.5%)	22 (18.2%)
Not-Related Serious TEAEs	0	1 (0.9%) <sup>†</sup>	1 (0.4%) <sup>‡</sup>	0

<sup>^</sup> Most frequently reported adverse events being application site erythema, pain and pruritus

<sup>¥</sup> One subject with application site erythema and another with application site pruritus and pain

<sup>\*</sup> One subject with application site erythema

<sup>†</sup> One subject with femur fracture

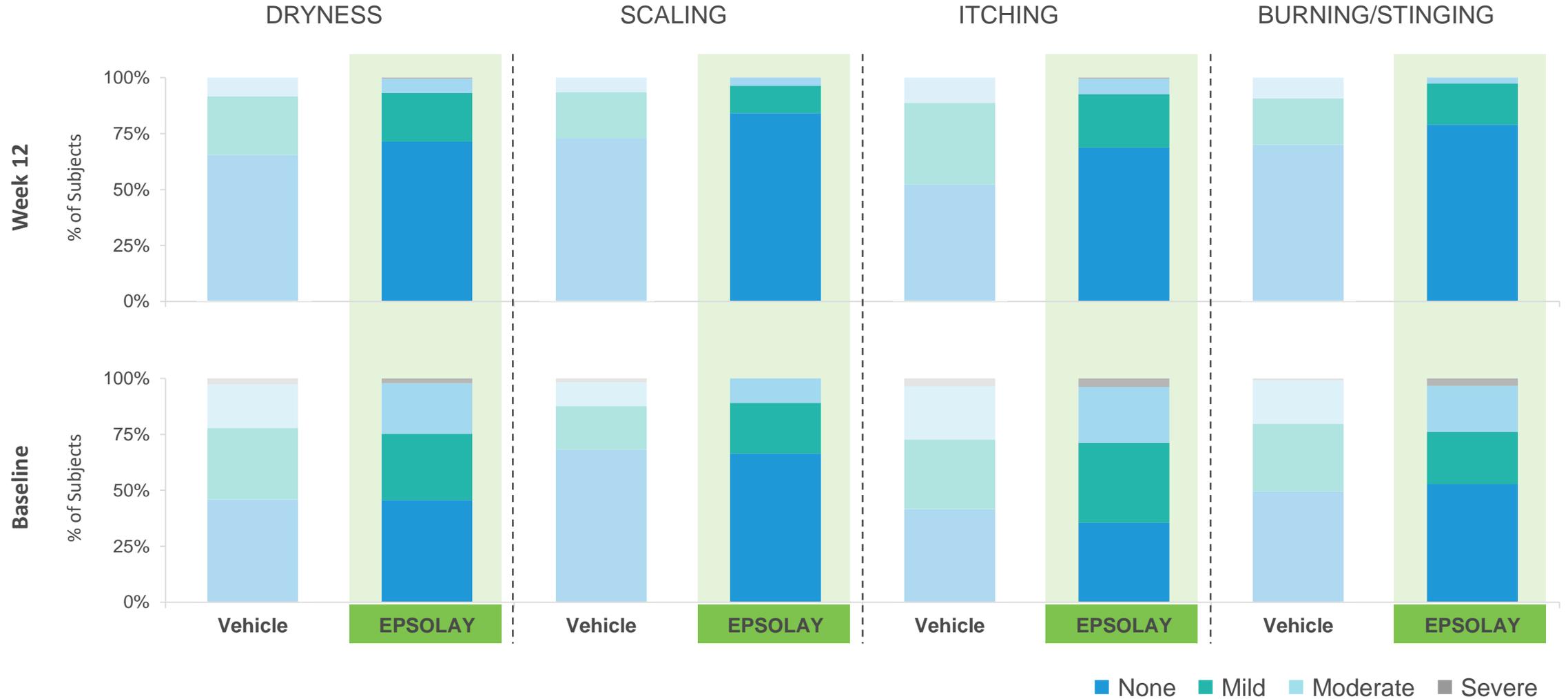
<sup>‡</sup> One subject with spinal compression fracture



FEWER AT WEEK 12 THAN AT BASELINE

# LOCAL SKIN IRRITATIONS

Study 54-01

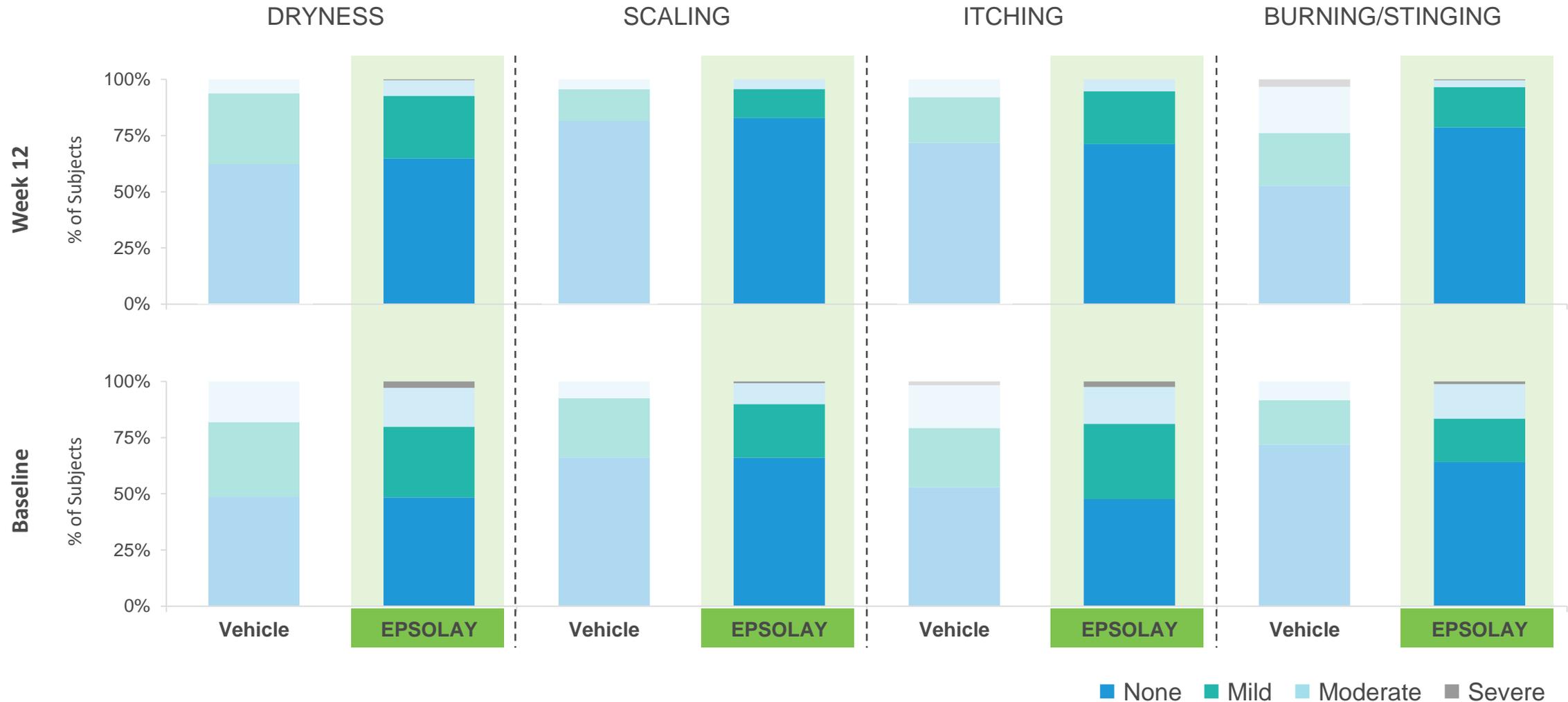




COMPARABLE TO VEHICLE

# LOCAL SKIN IRRITATIONS

Study 54-02





## THE CHALLENGE

MULTIFACTORIAL  
DISEASE  
REQUIRING  
POWERFUL  
COMBINATION  
TREATMENTS

UNMET NEED IN  
ACNE VULGARIS



### Acne Vulgaris

A multifactorial disease of the pilosebaceous unit, involving abnormalities in sebum production, follicular epithelial desquamation, bacterial proliferation, and inflammation

### How is it Treated?

- Topical BPO, retinoids (such as tretinoin, adapalene), antibiotics, and their combinations
- Oral Isotretinoin and antibiotics

### Current Treatment Shortfalls

- Insufficient efficacy negatively affects self-esteem
- Systemic side effects
- Contributes to antibiotic resistance

SOL-GEL SOLUTION\*

# TWYNEO<sup>®</sup>

Encapsulated Benzoyl Peroxide 3% &  
Encapsulated Tretinoin 0.1%, Cream

- Encapsulation was designed to stabilize tretinoin and to enable both tretinoin and BPO to slowly migrate from their microcapsules to help reduce irritation
- NDA submission expected in 2H/20
- Potential to be first FDA-approved acne treatment that contains fixed-dose combination of BPO and tretinoin



\* TWYNEO is investigational. Safety and efficacy have not been established



# TWYNEO<sup>®</sup>

## PHASE III STUDIES

Two Parallel, Multicenter, Double-Blinded,  
Randomized, Vehicle-Controlled Studies, 2:1 Ratio, QD



## PHASE III DESIGN

# THREE CO-PRIMARY EFFICACY ENDPOINTS AT WEEK 12

### Inclusion Criteria

≥9 years old; “Moderate” or “Severe” acne; ≥20 to ≤100 inflammatory lesions; ≥30 to ≤150 non-inflammatory lesions; ≤2 cysts/nodules

### Visits

Weeks 2, 4, 8, 12 (end of study)

### Investigator Global Assessment (IGA) Definition

- **“Clear”**: Normal, clear skin with no evidence of acne vulgaris
- **“Almost Clear”**: Rare non-inflammatory lesions present, with rare non-inflamed papules (papules must be resolving and may be hyperpigmented, though not pink-red)
- **“Mild”**: Some non-inflammatory lesions are present, with few inflammatory lesions (papules/pustules only; no nodulo-cystic lesions)
- **“Moderate”**: Multiple Non-inflammatory lesions and, inflammatory lesions are evident (several to many comedones and papules/pustules, and there may or may not be one small nodulo-cystic lesion)
- **“Severe”**: Inflammatory lesions are more apparent, many comedones and papules/pustules, there may or may not be a few nodulo-cystic lesions

### Primary Endpoints

- **Proportion of subjects with an assessment of "Clear" or "Almost Clear" and with at least a 2-grade improvement in IGA from baseline at Week 12**
- **Absolute change in inflammatory lesion counts from baseline at Week 12**
- **Absolute change in non-inflammatory lesion counts from baseline at Week 12**



## PHASE III CHARACTERISTICS

# WELL-BALANCED CLINICAL STUDIES

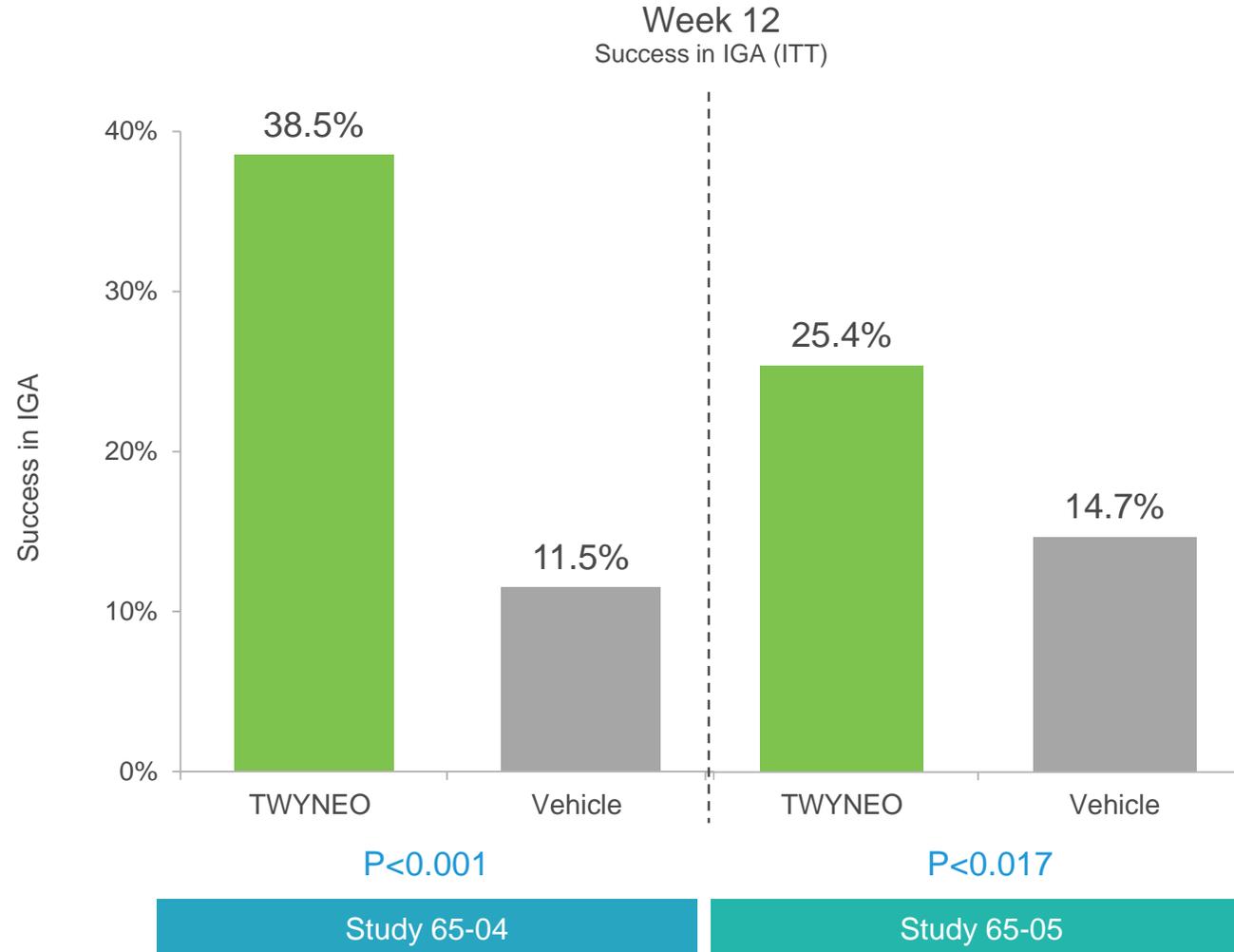
Baseline, Discontinuation & Completion		Study 65-04		Study 65-05	
		TWYNEO	Vehicle	TWYNEO	Vehicle
Baseline	IGA "Moderate" Subjects	251 (89.3%)	132 (92.3%)	262 (90.3%)	133 (93.0%)
	IGA "Severe" Subjects	30 (10.7%)	11 (7.7%)	28 (9.7%)	10 (7.0%)
	Mean Inflammatory Lesion Count (SD)	33.5 (14.62)	33.5 (14.69)	28.2 (8.70)	27.5 (8.52)
	Median Inflammatory Lesion Count (range)	28.0 (20-92)	28.0 (20-90)	25.0 (20-62)	25 (20-75)
	Mean Non-Inflammatory Lesion Count (SD)	48.6 (20.24)	47.1 (19.97)	44.6 (18.03)	44.9 (18.82)
	Median Non-Inflammatory Lesion Count (range)	42.0 (30-148)	41.0 (30-140)	39.0 (23-149)	38.0 (30-123)
Discontinued Subjects	Withdrawal by Subject/Parent/Guardien	13	5	18	5
	Adverse Events	4	0	12	0
	Lost to Follow-Up	10	7	15	7
	Pregnancy/Protocol Violation/Physician Decision/Other	5	0	3	0
<b>Intention-to-Treat (ITT)</b>		<b>281</b>	<b>143</b>	<b>290</b>	<b>144</b>

SD = Standard Deviation



## PHASE III RESULTS

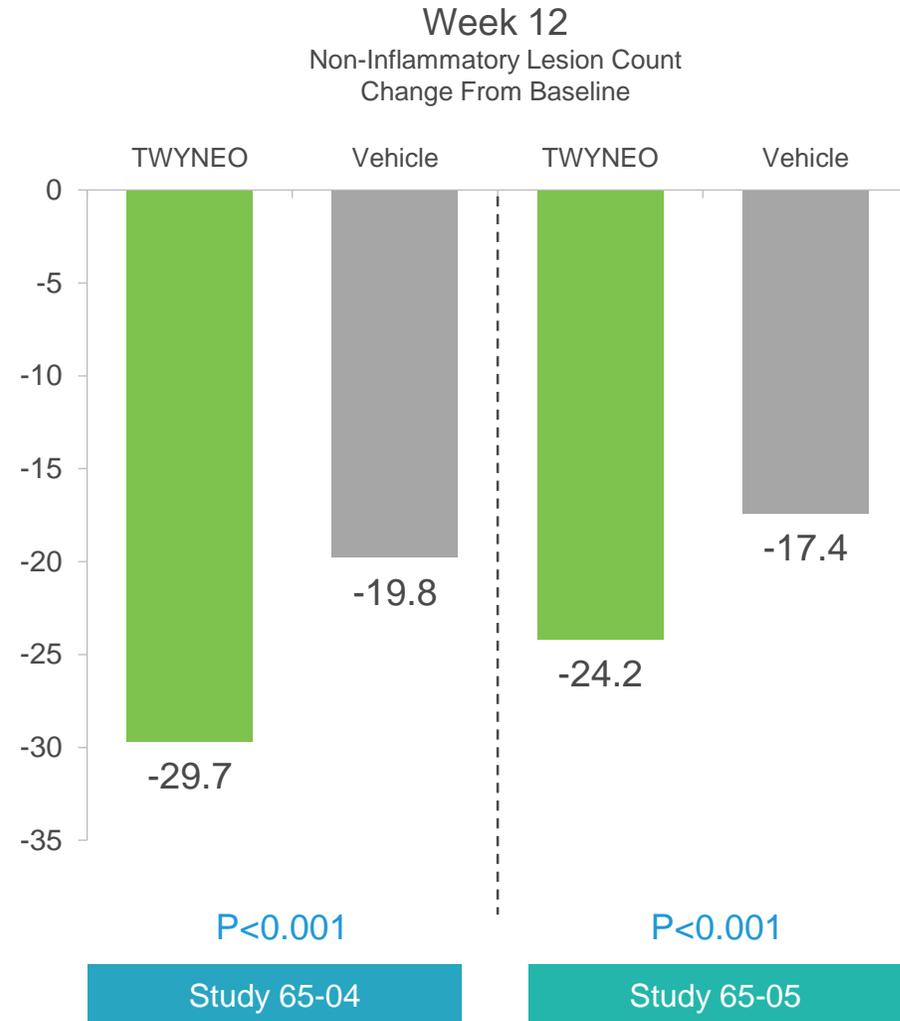
# SUCCESS IN IGA





## PHASE III RESULTS

# SUCCESS IN REDUCING LESIONS



Subject 507-003 || 18 years old | Female | White | Not Hispanic or Latino\*

# IMPROVEMENT IN SEVERE PATIENT

BASELINE



"Severe"; 29 inflamed lesions  
31 non-inflamed lesions; 1 nodule

WEEK 12



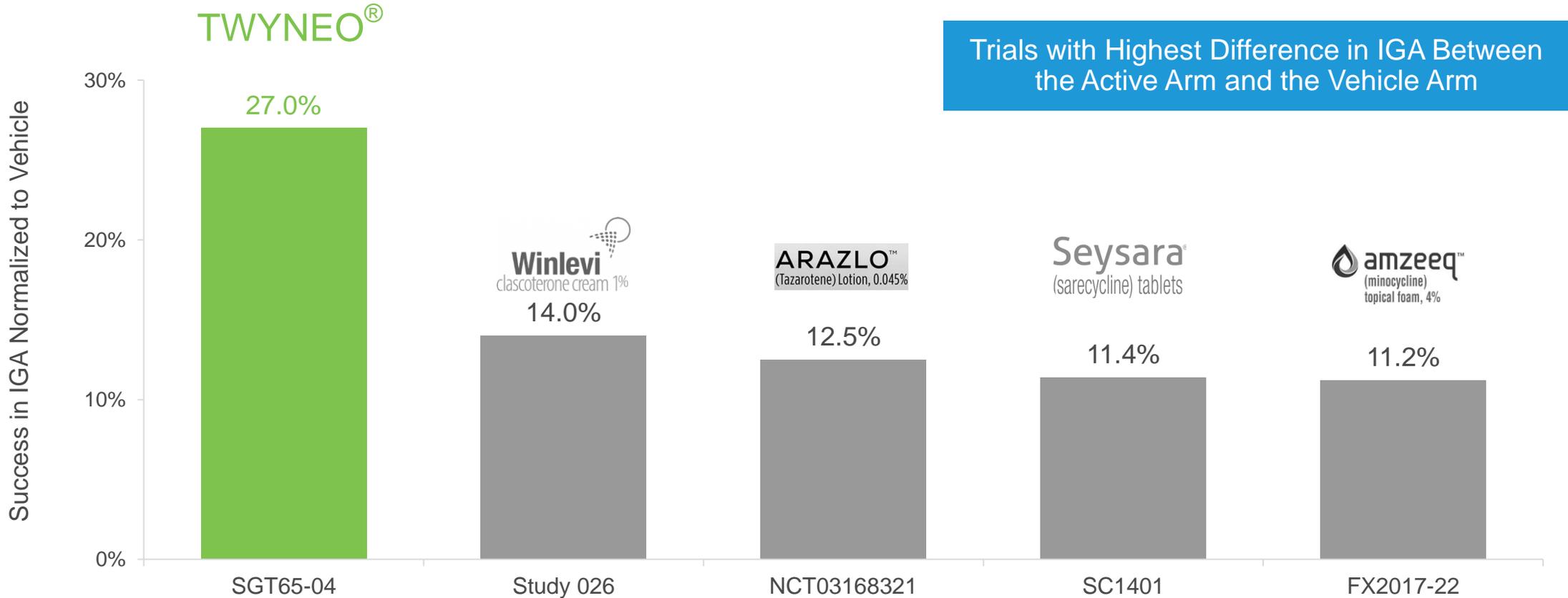
"Moderate"; 9 inflamed lesions  
5 non-inflamed lesions; No nodules

\* Individual results vary



SIDE-BY-SIDE WITH HISTORICAL RESULTS\*

# SUCCESS IN IGA

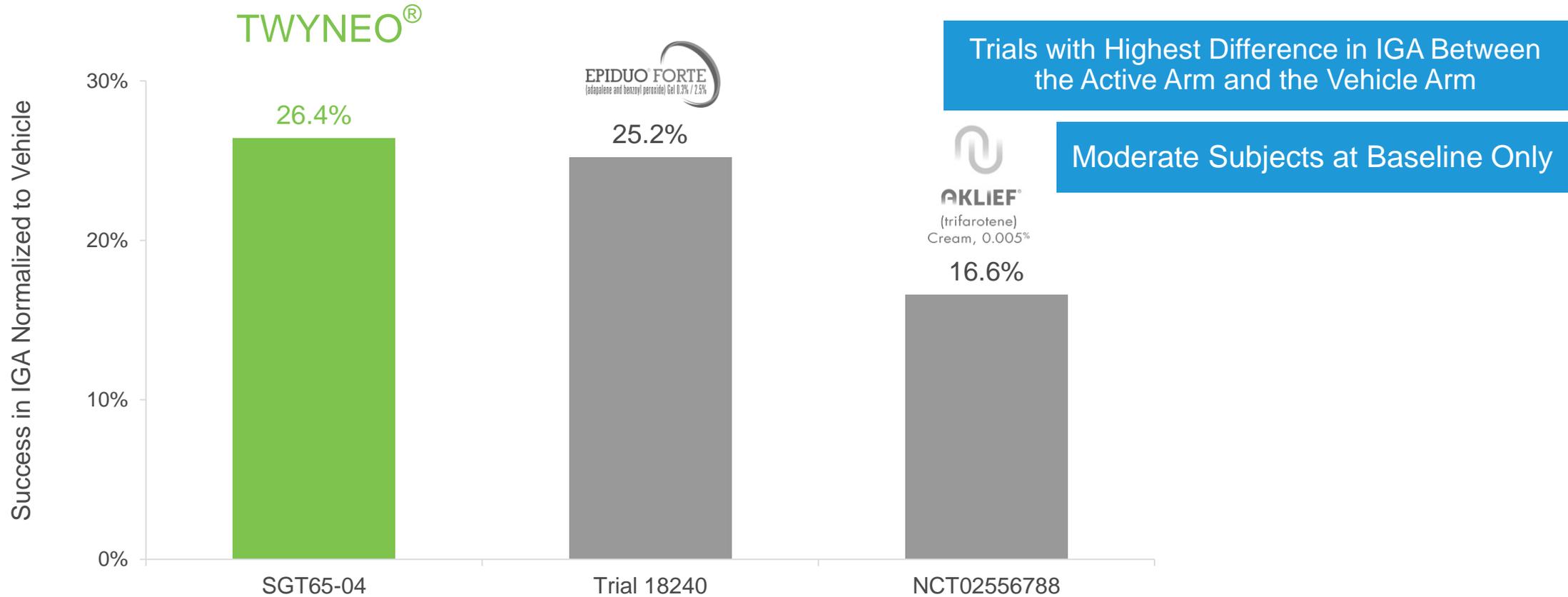


\* Sol-Gel did not conduct a head-to-head comparison trial or study. The results described above are for illustrative purposes only and should not be construed as conclusions to be drawn as if we conducted a head-to-head comparison trial or study



SIDE-BY-SIDE WITH HISTORICAL RESULTS\*

# SUCCESS IN IGA



\* 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



PRIMARILY MILD-TO-MODERATE

# TREATMENT-EMERGENT ADVERSE EVENTS

Subjects with Treatment-Emergent Adverse Events (TEAEs)	Study 65-04		Study 65-05	
	TWYNEO (n=274)	Vehicle (n=139)	TWYNEO (n=281)	Vehicle (n=138)
Treatment-Related Mild & Moderate TEAEs	46 (16.8%) <sup>^</sup>	2 (1.4%) <sup>^</sup>	39 (13.8%) <sup>^</sup>	3 (2.2%)
Treatment-Related Severe TEAEs	4 (1.5%) <sup>¥</sup>	0	1 (0.4%) <sup>*</sup>	0
Not-Related TEAEs	19 (6.9%)	13 (9.4%)	27 (9.6%)	15 (10.9%)
Missing Subjects	0	0	1 (0.4%)	0
Not-Related Serious TEAEs	0	0	1 (0.4%) <sup>†</sup>	1 (0.7%) <sup>‡</sup>

<sup>^</sup>Most frequently reported adverse events being application site pain, dryness, erythema and exfoliation

<sup>¥</sup>Two subjects with application site pain, a third subject with application site pain and exfoliation, and fourth subject with application site pruritus

<sup>\*</sup>One subject with application site pain, dryness and pruritus

<sup>†</sup>One subject with depression

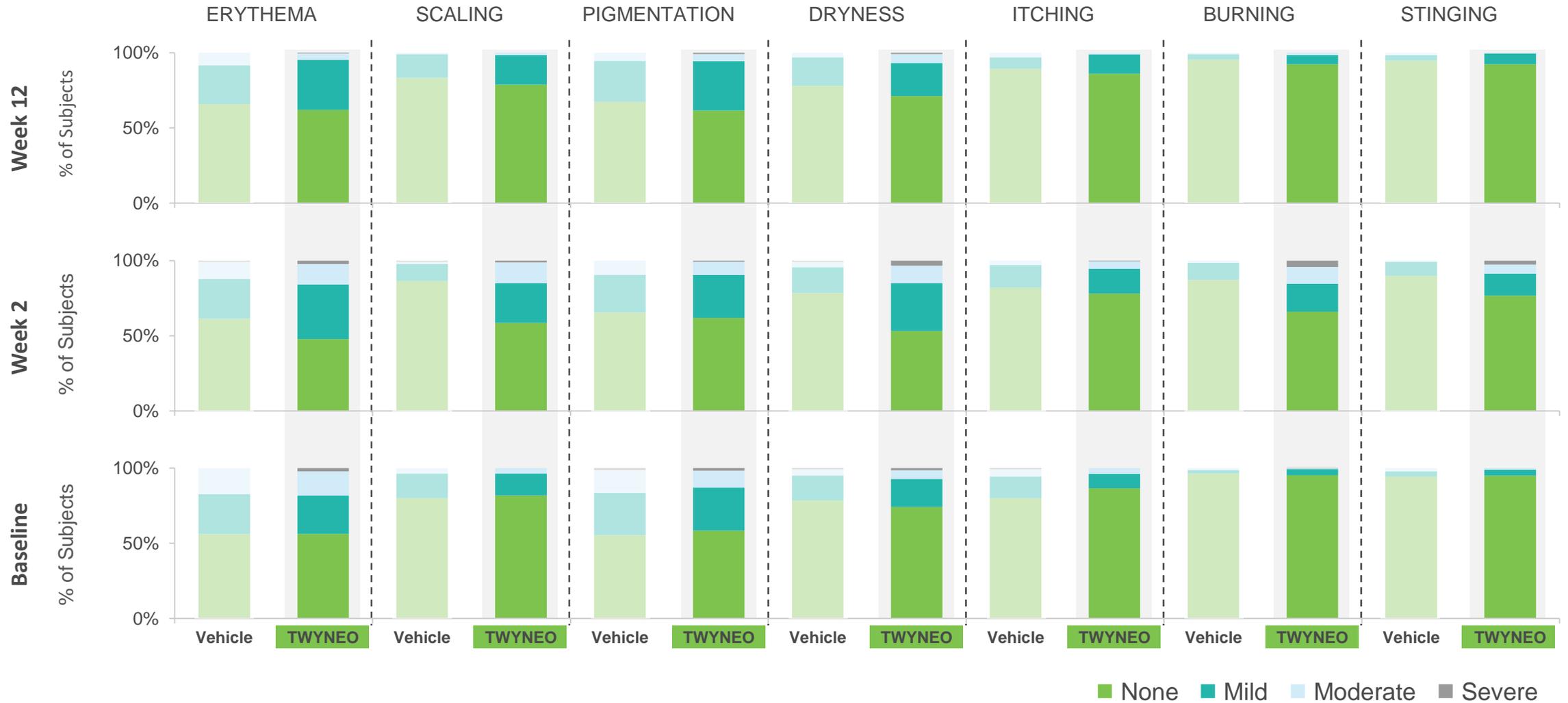
<sup>‡</sup>One subject with depression, bipolar II disorder and conduct disorder



MILD AND IMPROVED OVER TIME

# LOCAL SKIN REACTIONS

Study 65-04





MILD AND IMPROVED OVER TIME

# LOCAL SKIN REACTIONS

Study 65-05





# BROAD LONG-TERM INTELLECTUAL PROPERTY ESTATE



- EPSOLAY is protected until 2032 by granted patents and until 2040 by pending patent
- TWYNEO is protected until 2038 by granted patents and until 2040 by pending patent
- 22 pending patent applications for erlotinib, tapinarof and roflumilast in various skin conditions (as of July 30, 2020)



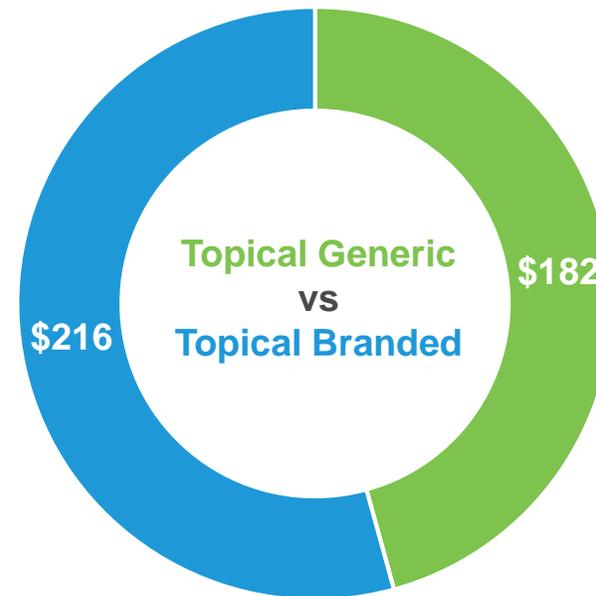
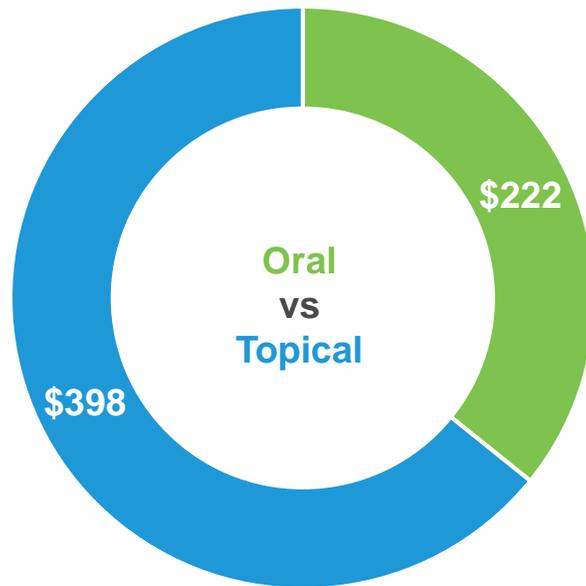
COMMERCIALIZATION  
&  
FINANCIALS



2019 (IN \$US)

# PAPULOPUSTULAR ROSACEA US MARKET

Branded Topicals are Important Segment

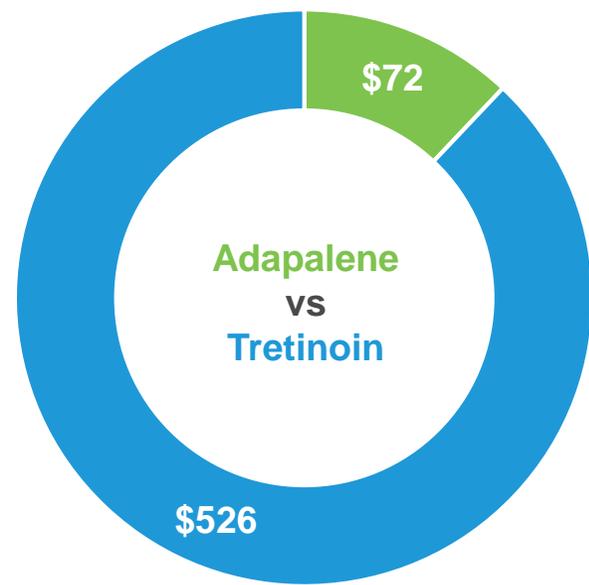
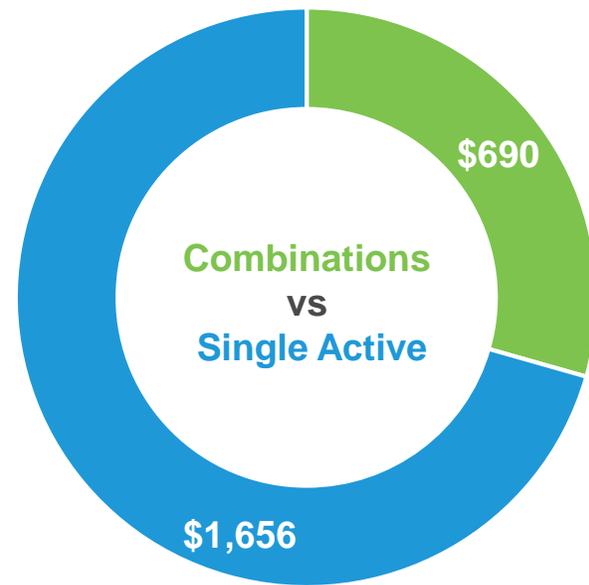
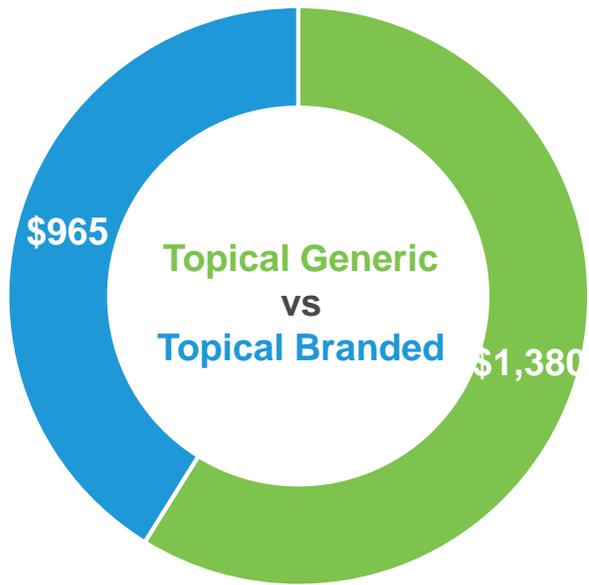
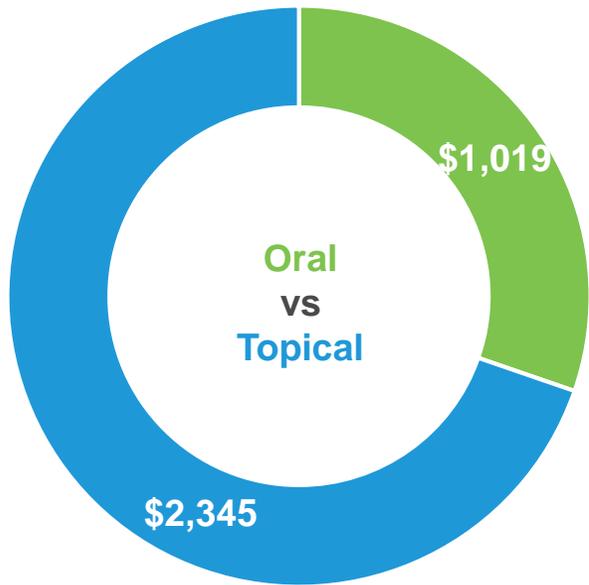


Source: IQVIA; Year 2019



2019 (IN \$US)  
**ACNE VULGARIS US MARKET**

**Branded Topical Combinations are Important Segment  
 Tretinoin is the Most Prescribed Topical Retinoid**



Source: IQVIA; Year 2019



# EPSOLAY & TWYNEO ARE COMPELLING ENOUGH TO DRIVE PAYOR COVERAGE

EPSOLAY<sup>®</sup>



TWYNEO<sup>®</sup>

- “All respondents recognized the product as a unique molecule for rosacea”
- “Near unanimous recognition as additional option for rosacea”
- “If priced and rebated similarly to the covered products, coverage seems likely”

- “Unique MOA will qualify it for formulary addition, price will determine its position”
- “If you price it like Epiduo, it will be managed like Epiduo”
- “If similarly priced with better tolerability, it would become preferred brand”

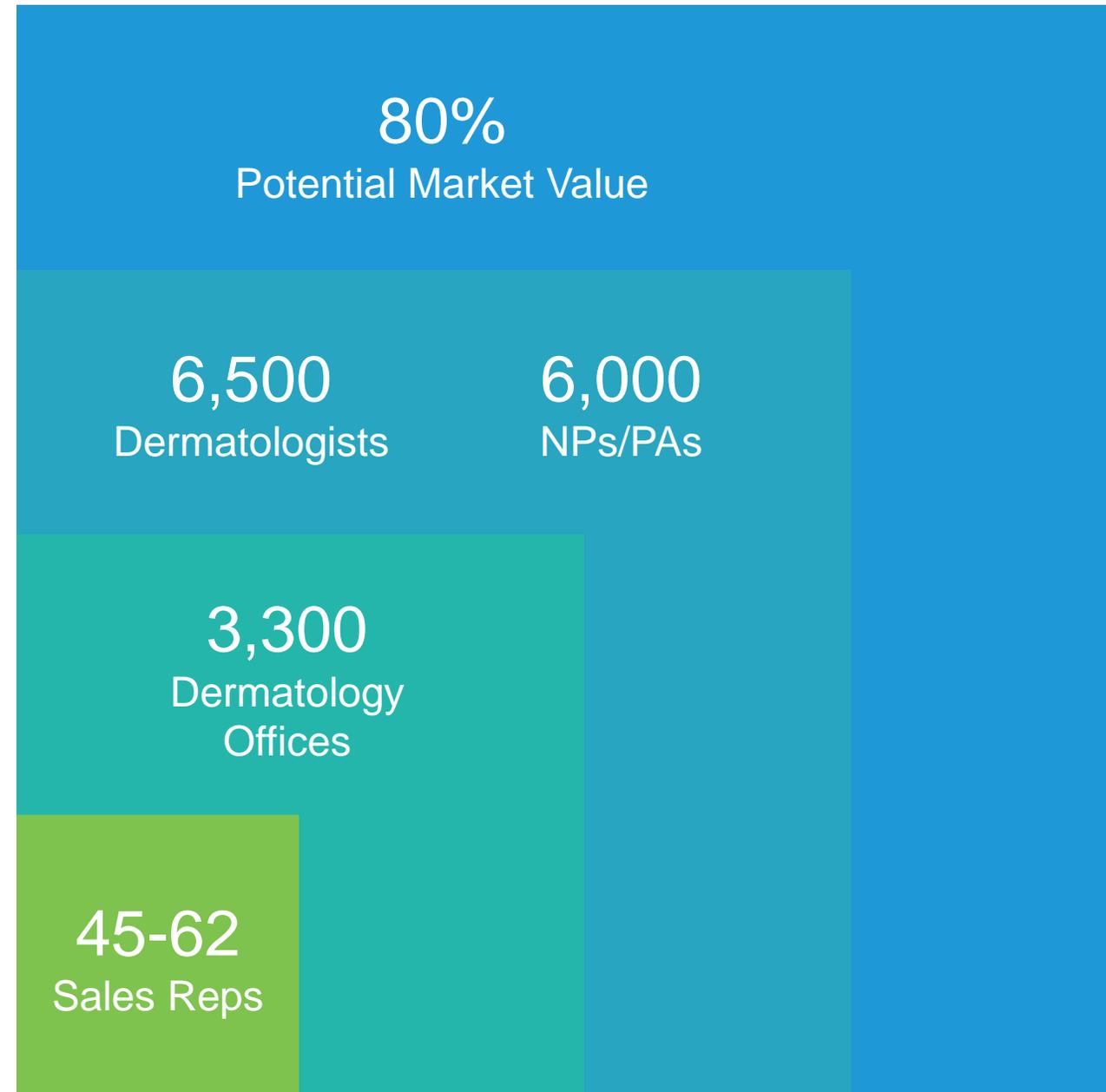
Sources: NaviSync LLC (Morristown, NJ), Sol-Gel Managed Market Access for Acne and Rosacea, July 2019  
NaviSync LLC (Morristown, NJ), Twyneo Payer Market Research Topline Summary, February 2020



# LEAN COMMERCIALIZATION APPROACH

Efficiently Reaching 80%  
Dermatology TRx in Acne  
and Papulopustular Rosacea

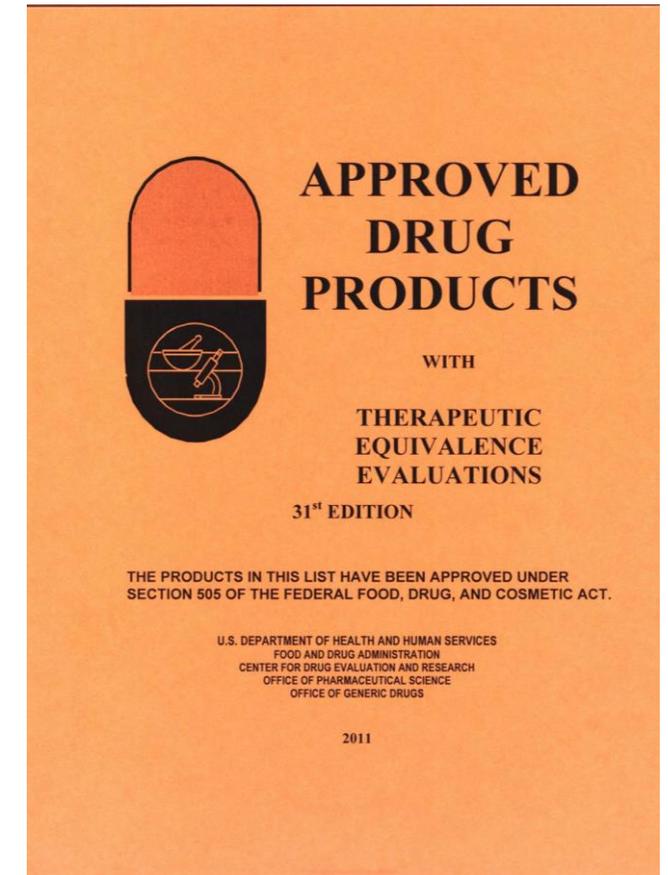
Source: Syneos Health (Morrisville, NC), Sol-Gel Market Analysis, June 2019





# LUCRATIVE GENERIC PIPELINE

- Ten collaborations with Perrigo with 50/50 gross profit sharing
- In March 2017, Perrigo filed a Paragraph IV Certification for Soolantra<sup>®</sup>
- In February 2019, Perrigo launched acyclovir cream, 5%, developed in collaboration with Sol-Gel. As of today this is the only generic product on the market other than an authorized generic. This product generated \$22.8 million in net revenues in 2019 and \$4.5 million in net revenues in 1H/20
- In January 2020, Perrigo filed a Paragraph IV Certification for Bryhali<sup>®</sup>
- In June 2020, Perrigo was first-to-file a Paragraph IV Certification for Duobrii<sup>®</sup>
- The launch of a partnered generic drug is expected in 2Q/21. In 2019, sales of the brand name product exceeded \$180 million in the US





# STRONG FINANCIAL PROFILE

- Gross proceeds of \$86.3 million raised in IPO on February 5, 2018
- Gross proceeds of \$11.5 and \$23 million raised in public follow-on offerings on August 12, 2019 and February 13, 2020, respectively
- Additional \$5 million investment by controlling shareholder in April 2020
- 22,996,948 Ordinary Shares as of June 30, 2020
- \$4.5 million net revenues from generic products in 1H/2020
- \$66.0 million in cash and investments as of June 30, 2020
- Cash resources will enable funding of operational and capital expenditure requirements into the third quarter of 2021

LOOKING FORWARD





WHAT'S AHEAD

SGT-210

# PALMOPLANTAR KERATODERMA

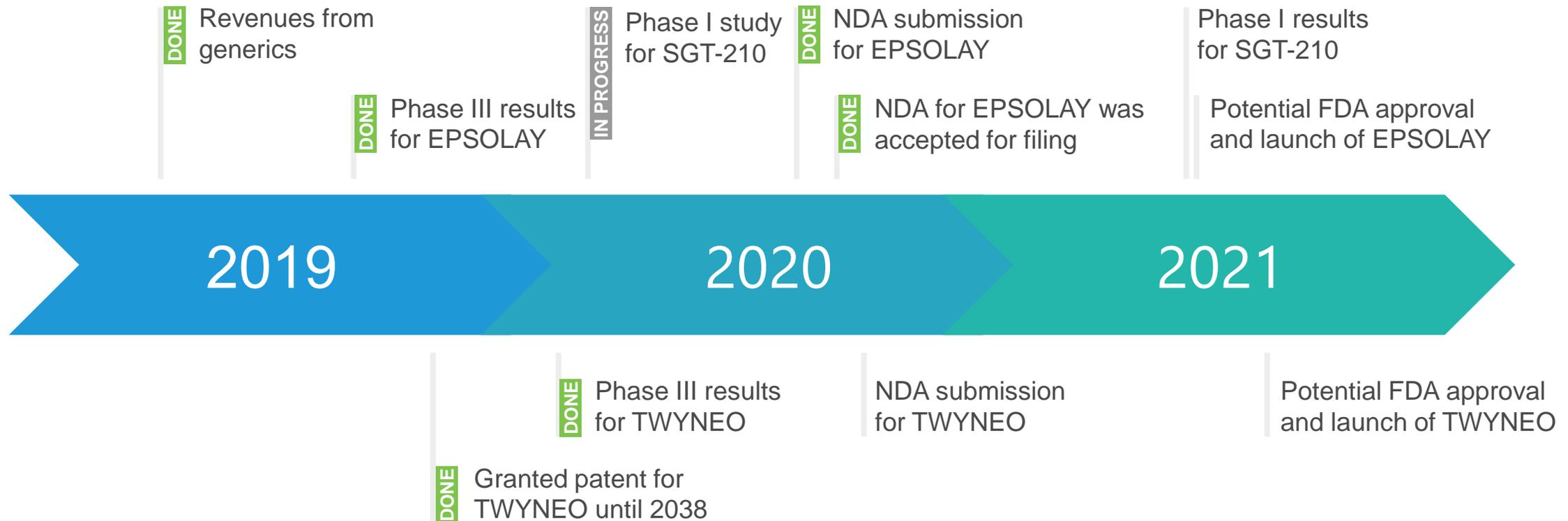


**Palmoplantar keratoderma (PPK)** is a group of skin conditions characterized by thickening of the skin on the palms of the hands and soles of the feet

**Phase I proof-of-concept study for erlotinib gel in PPK is ongoing**



# RECENT MILESTONES & NEXT STEPS





# Sol-Gel

Advanced Topical Therapy

NASDAQ: SLGL