



# Sol-Gel

Advanced Topical Therapy

NASDAQ: SLGL

June 2021



# 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 PDUFA goal date for TWYNEO, approval and commercial launch of EPSOLAY and TWYNEO, the strategic partnership with Galderma, anticipated timing of the initiation of clinical trials for SGT-510, the intellectual property protection that would be provided by patents for SGT-210 and our tapinarof drug product, the timing of the launch of our tapinarof drug product, the future markets for various skin diseases, the timing of a test and a second POC study of erlotinib, projected profit margins, our expectations regarding our liquidity and ability to fund operational and capital expenditure requirements. 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 PDUFA action date for EPSOLAY, the timing of FDA approval, if any, of EPSOLAY and TWYNEO; the risk that we not receive any or all of the anticipated benefits of the strategic partnership with Galderma, the risk of a delay in the clinical trials for SGT-510; the risk that patents for SGT-210 and our tapinarof drug product will not provide the anticipated intellectual property protection; the risk of a delay in the launch of our tapinarof drug product; the risk that our estimate of the markets for psoriasis, atopic dermatitis and for hyperkeratotic skin diseases are inaccurate; the risk that our tapinarof drug product will not be the only other player besides the brand for a number of years; the risk of a delay in the timing of a test of erlotinib with a much higher concentrations in an animal model and the risk of a delay of a second POC study on PPK patients; 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 at all or on a timely basis; 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; 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; delays in the launch of product candidates and generic drugs; 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 4, 2021, and in 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.*

*These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this presentation. This presentation contains trademarks, trade names, and service marks of other companies, which are the property of their respective owners. We do not intend our use or display of other parties' trademarks, trade names, or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.*



## OVERVIEW

# OUR DERMATOLOGY COMPANY

### IPO

\$86.3M raised in February 2018

### GALDERMA PARTNERSHIP

5-year license, with option to regain brands. EPSOLAY PDUFA goal date was set for April 26, 2021 (awaiting FDA's pre-approval inspection). TWYNEO PDUFA goal date set for August 1, 2021

### PERRIGO PARTNERSHIP

Twelve 50/50 gross profit-sharing collaborations

## Our Pipeline

### ROFLUMILAST (SGT-510)

Our innovative investigational topical formulation of roflumilast (SGT-510) was found to be more effective than roflumilast cream, 0.3%, that was formulated by Sol-Gel according to conventional methods of cream formulation, in a human xenograft psoriasis animal model

### ERLOTINIB (SGT-210)

Our proof-of-concept study for erlotinib gel (SGT-210) in palmoplantar keratoderma patients was completed and indicated a possible modest improvement. We plan to investigate higher concentrations of erlotinib

### TAPINAROF (SGT-310)

We are currently developing an innovative investigational formulation of tapinarof (SGT-310) aiming to offer product formulation innovations and increased affordability for patients compared to the brand expected to be launched



## RECENT UPDATES

# STRATEGIC PARTNERSHIP WITH GALDERMA

- Exclusive commercialization agreements in the US for TWYNEO and EPSOLAY
- Up to \$15 million in upfront and product approval payments (assuming 2021 approvals of both products)
- Tiered double-digit royalties (mid- to high-teen percentage) of net sales
- Up to an additional \$9 million in sales milestone payments

- Option to regain commercialization rights 5 years following first sale
- We expect that by then markets will be well-established
- EPSOLAY and TWYNEO are patent protected until 2040 and 2038, respectively

- Deal is immediately cash flow positive, with capital to be redeployed towards our pipeline



# THE SCIENCE BEHIND OUR PROPRIETARY TECHNOLOGY

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

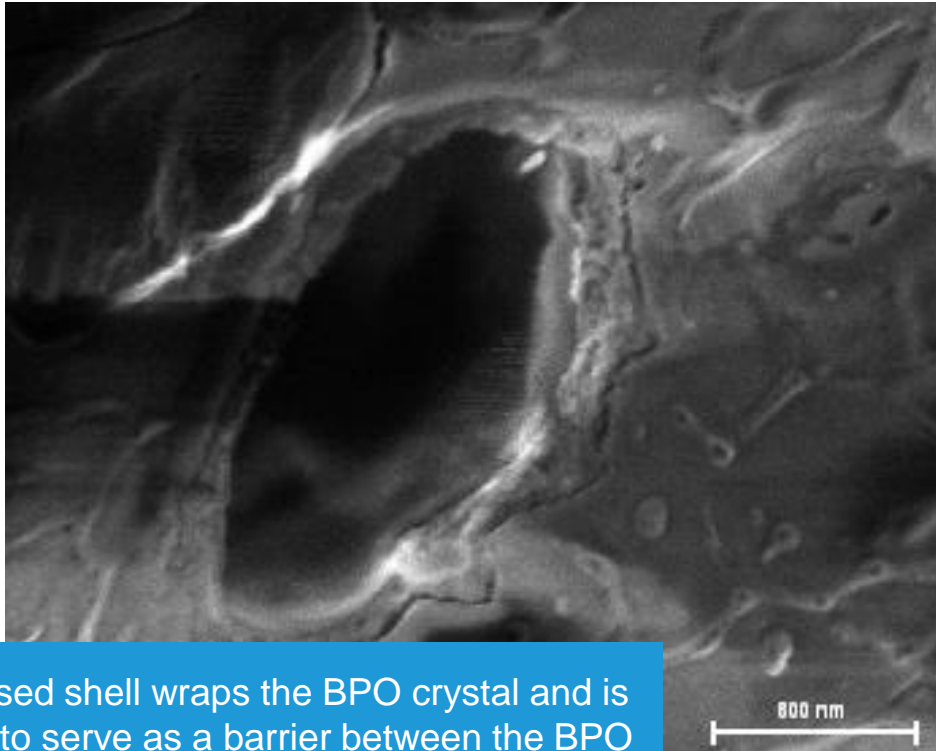




ENCAPSULATION IS DESIGNED TO ALLOW FOR CONTINUOUS FLOW

# 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

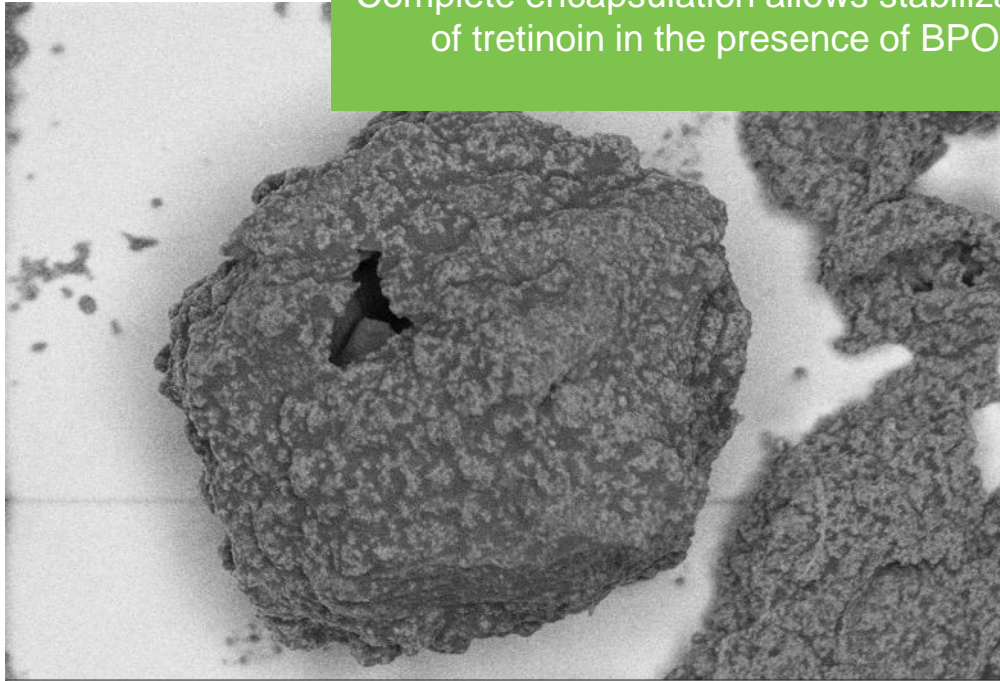


ENCAPSULATION IS DESIGNED TO ENHANCE STABILITY

# ENCAPSULATED TRETINOIN (E-TRETINOIN)

SEM PICTURE

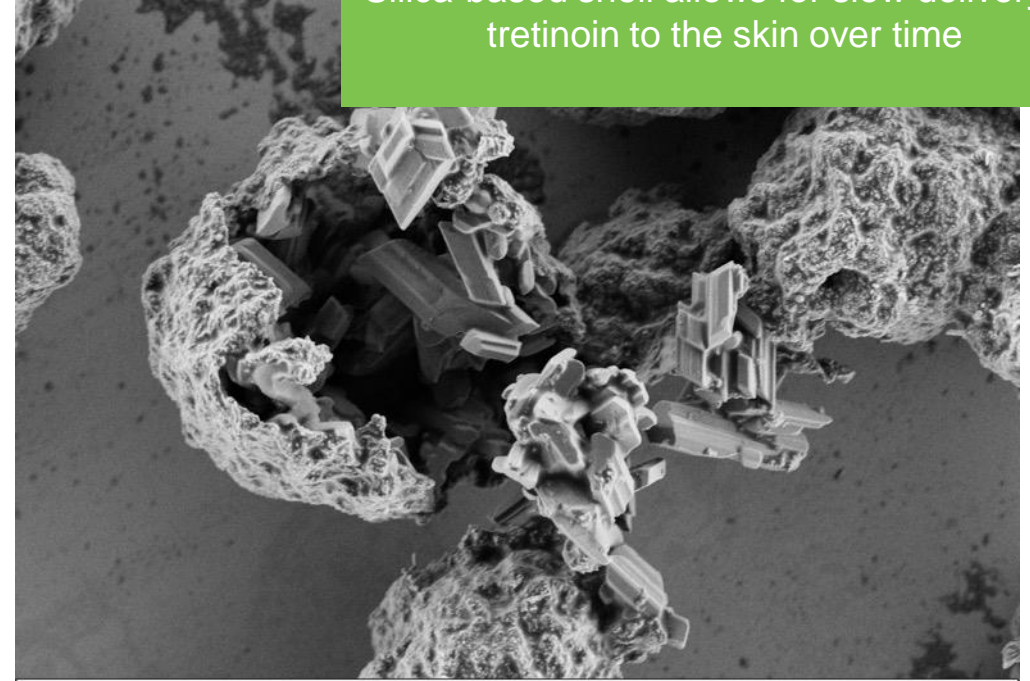
Complete encapsulation allows stabilization of tretinoin in the presence of BPO



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

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  
WD = 4.8 mm Aperture Size = 20.00  $\mu$ m File Name = 519-112-01\_12.tif ZEISS



## 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



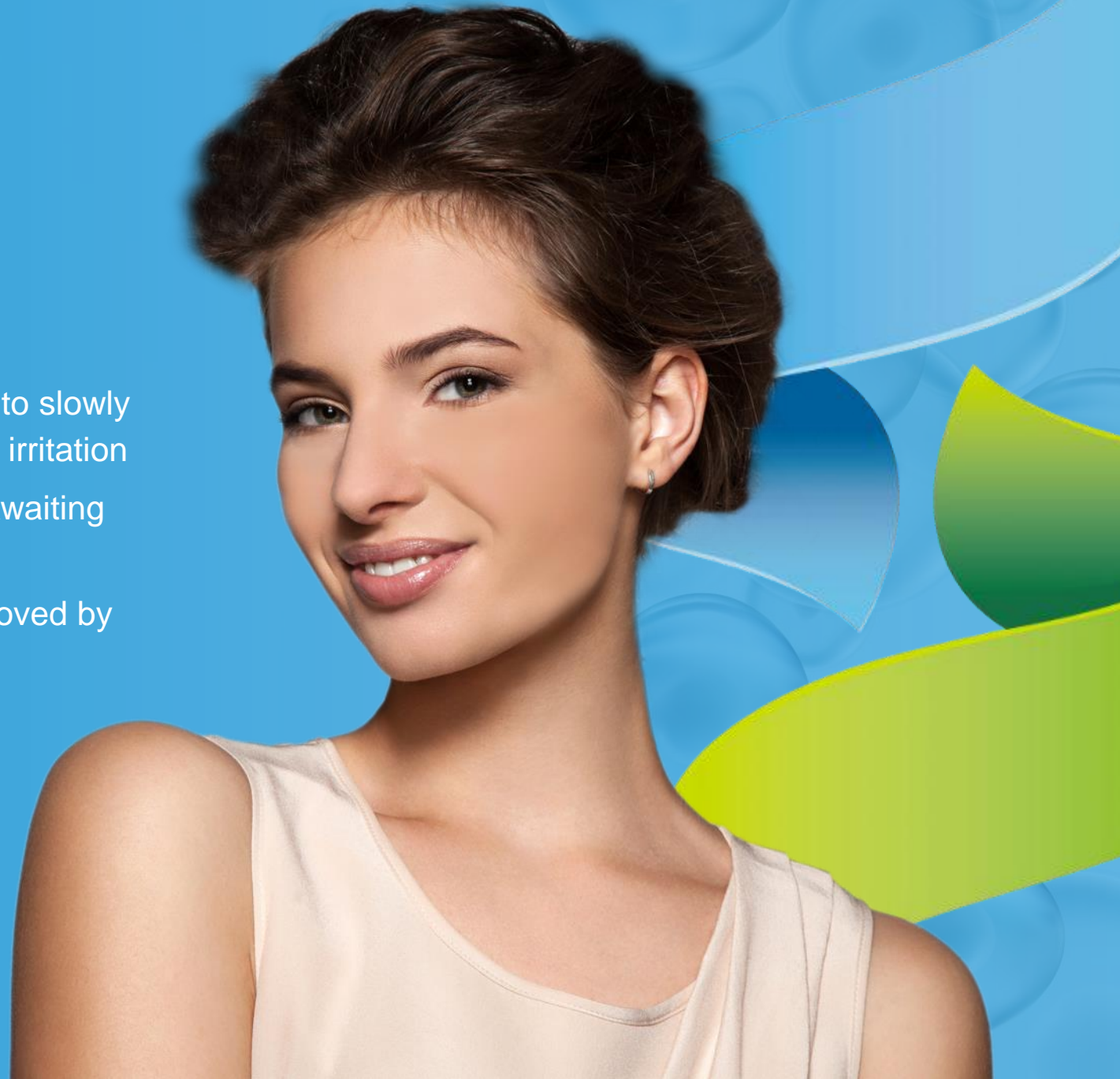
SOL-GEL SOLUTION\*

# EPSOLAY<sup>®</sup>

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 for April 26, 2021. Awaiting FDA's pre-approval inspection
- 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

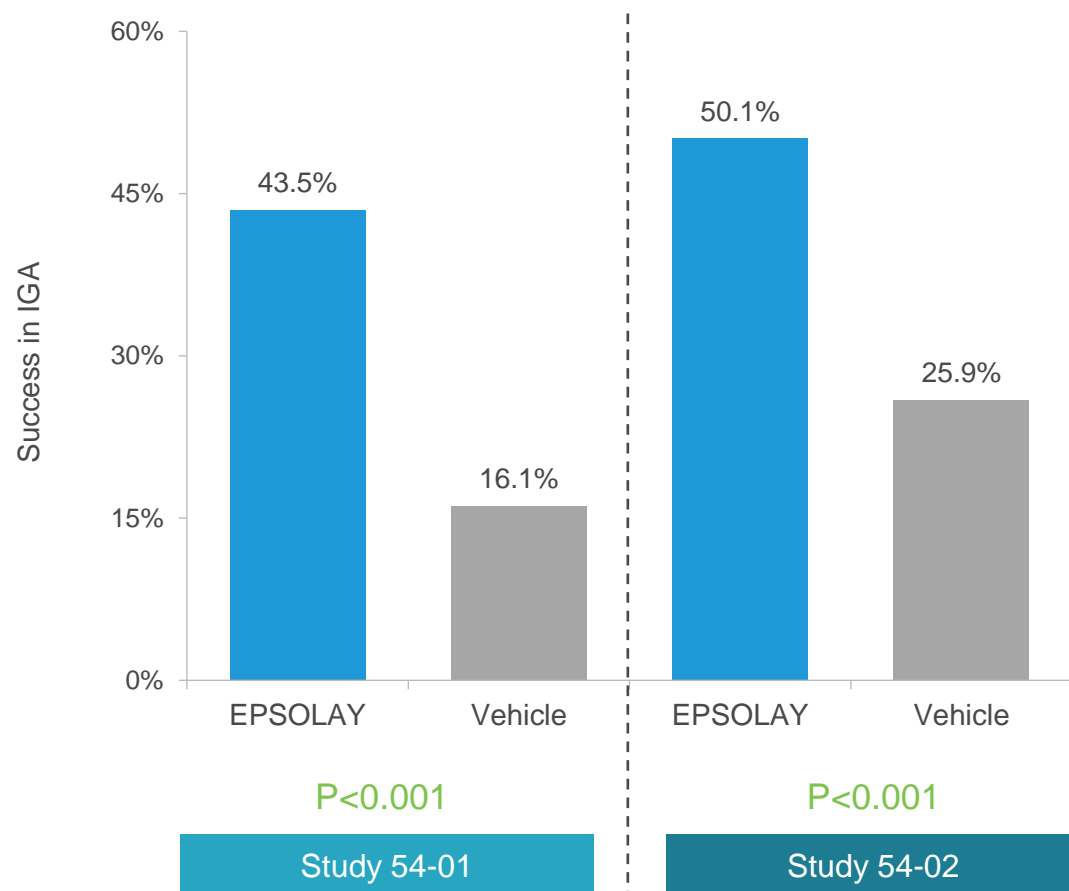
Two Parallel, Multicenter, Double-Blinded,  
Randomized, Vehicle-Controlled Studies, 2:1 Ratio, QD



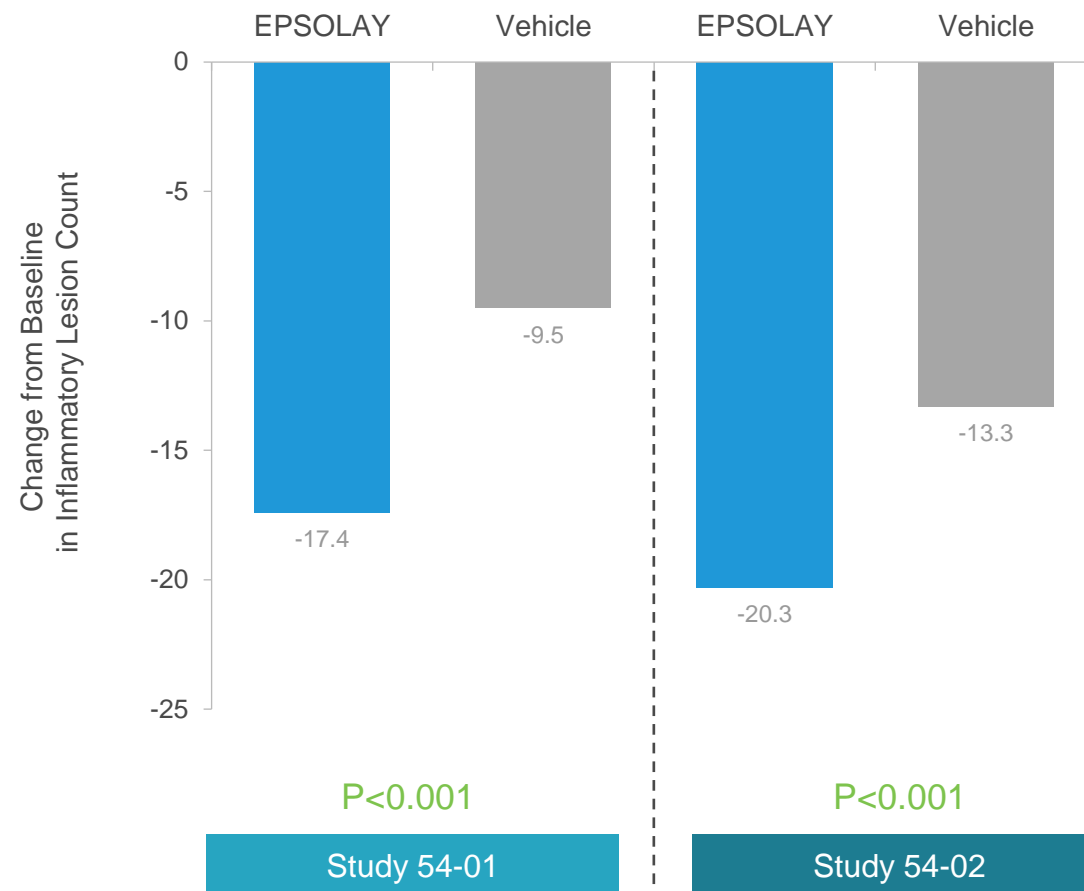
# PHASE III RESULTS

## SUCCESS IN PRIMARY ENDPOINTS

Week 12  
Success in IGA (ITT)



Week 12  
Inflammatory Lesion Count  
Change from Baseline (ITT)

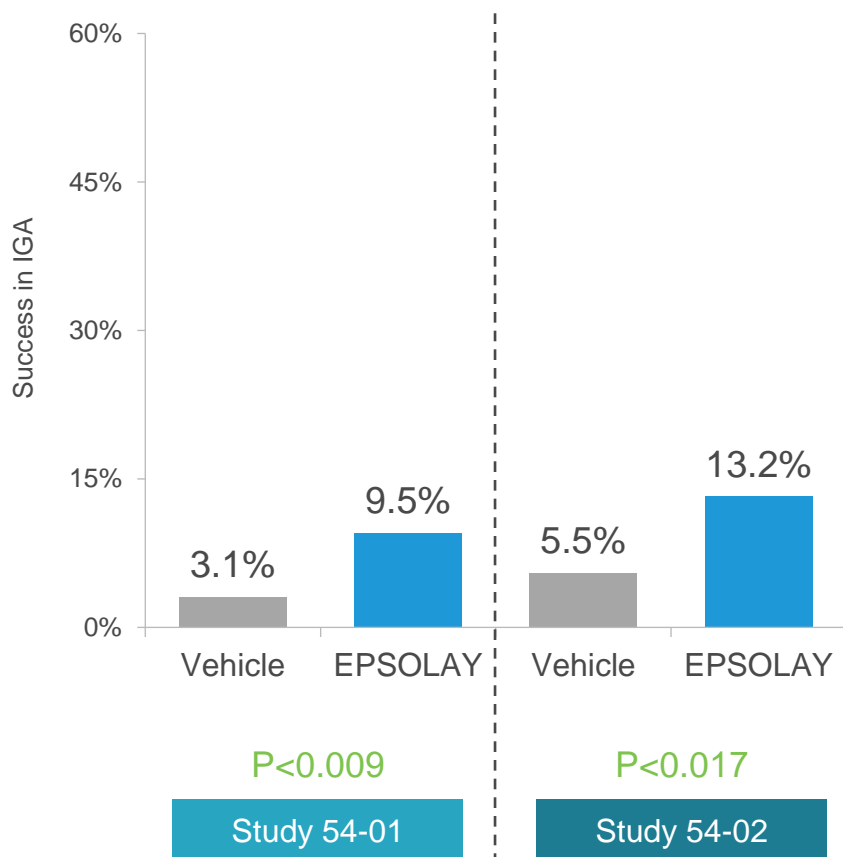




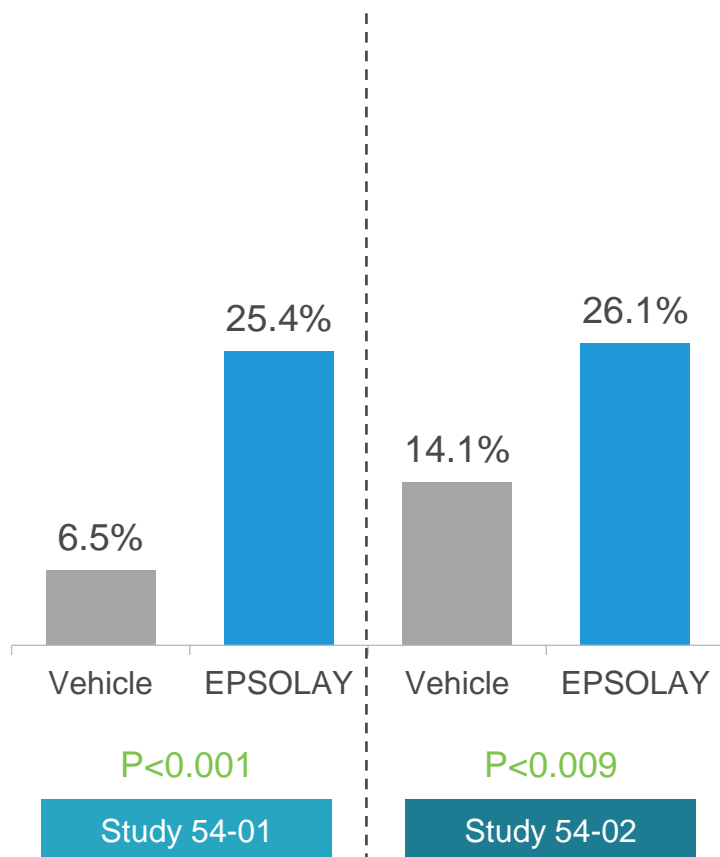
# SUCCESS IN IGA

## IMPROVEMENT AS OF WEEK 2

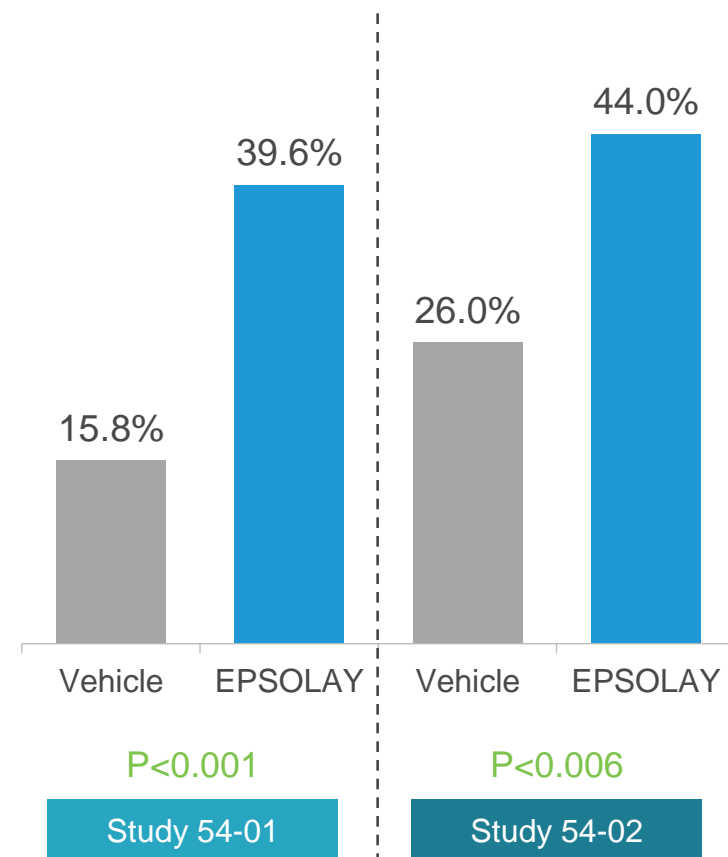
Week 2  
Exploratory Endpoint (ITT)



Week 4  
Secondary Endpoint (ITT)



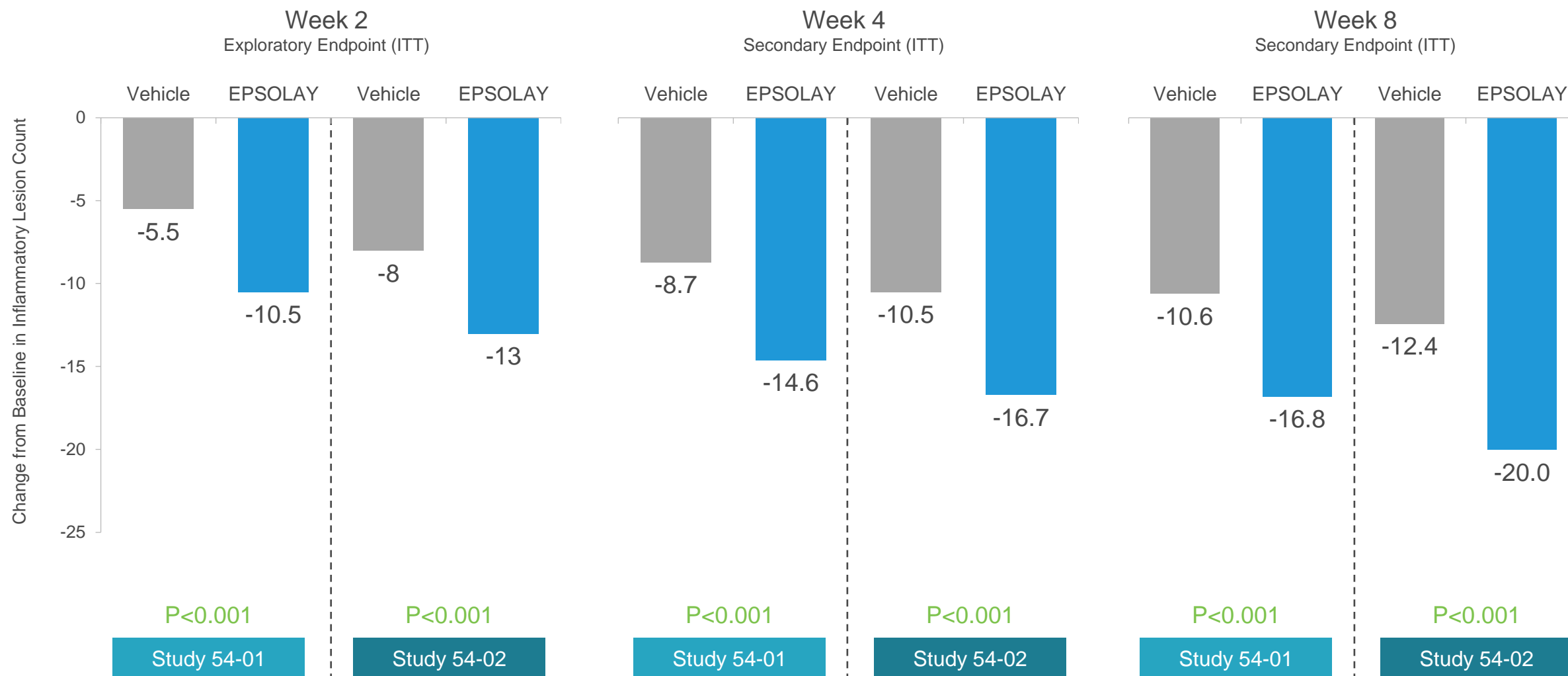
Week 8  
Secondary Endpoint (ITT)







# 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



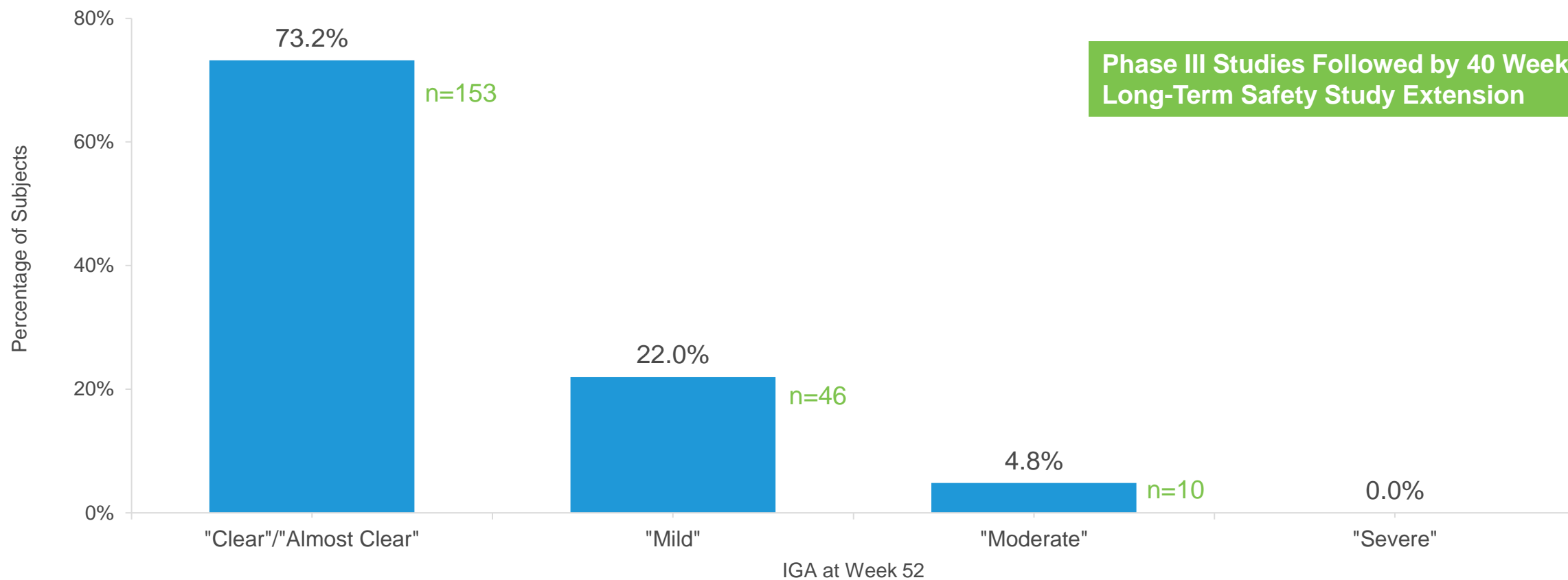
"Almost Clear"; 1 inflamed lesion

\* 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



LONG-TERM SAFETY STUDY

# 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>

Benzoyl Peroxide 3% & 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
- PDUFA goal date set for August 1, 2021
- 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 RESULTS

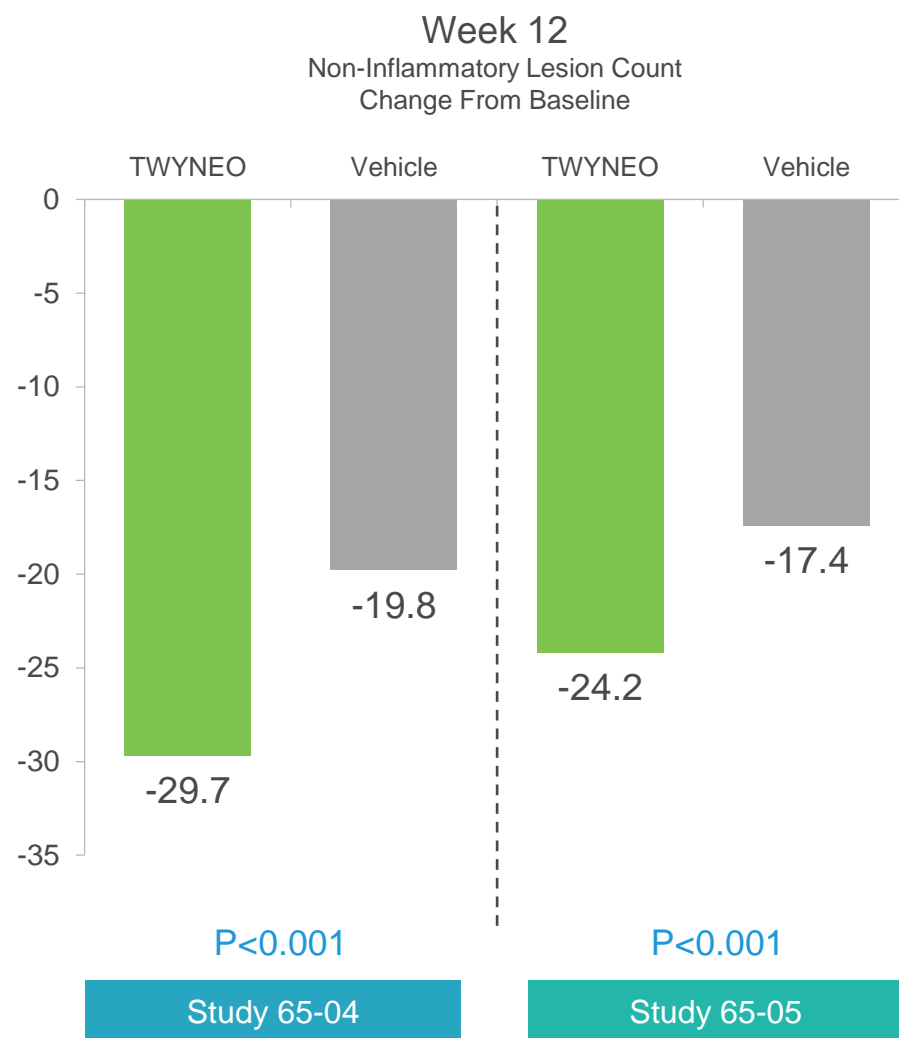
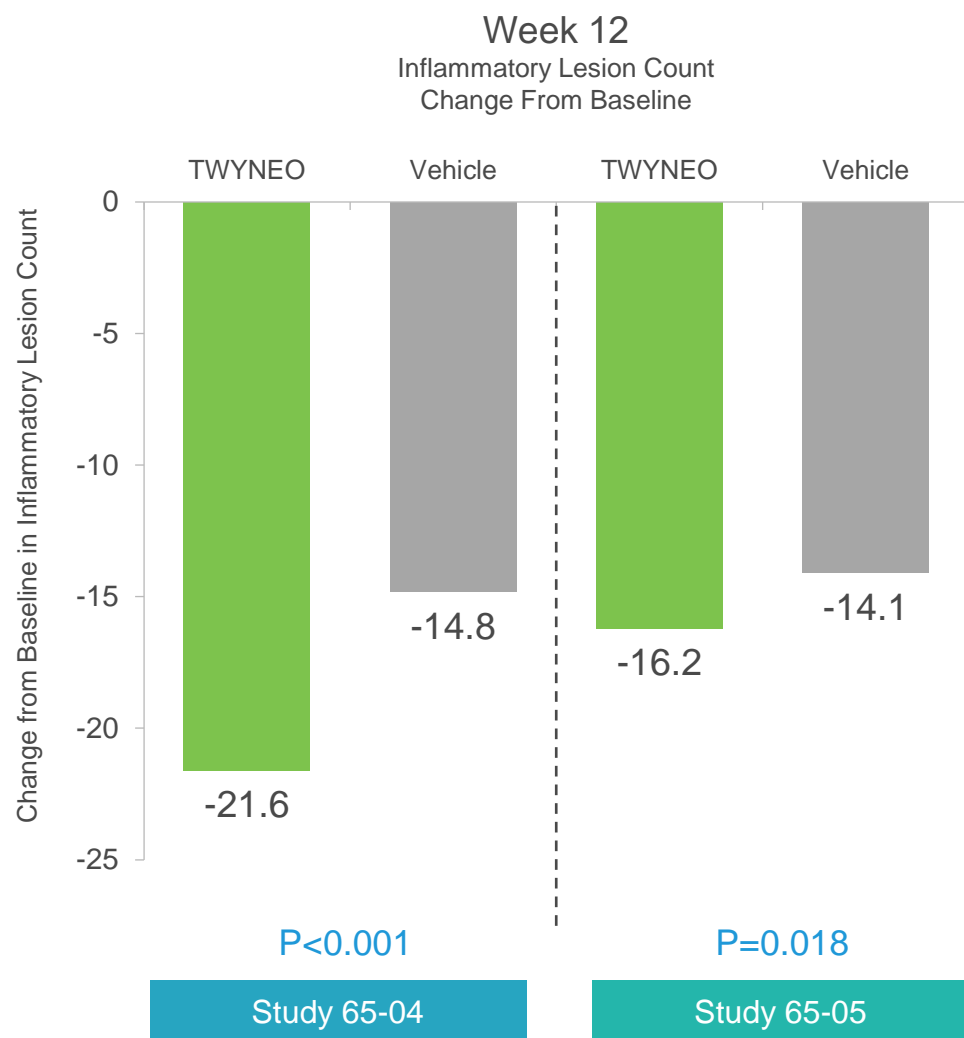
## SUCCESS IN IGA





## 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



# BROAD LONG-TERM INTELLECUAL PROPERTY ESTATE



25 patent applications for erlotinib, tapinarof and roflumilast in various skin conditions  
(as of February 26, 2021)



EPSOLAY is protected until 2040 by granted patents and until 2041 by a pending patent application

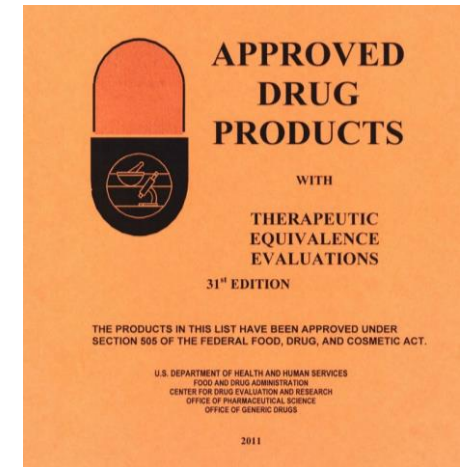
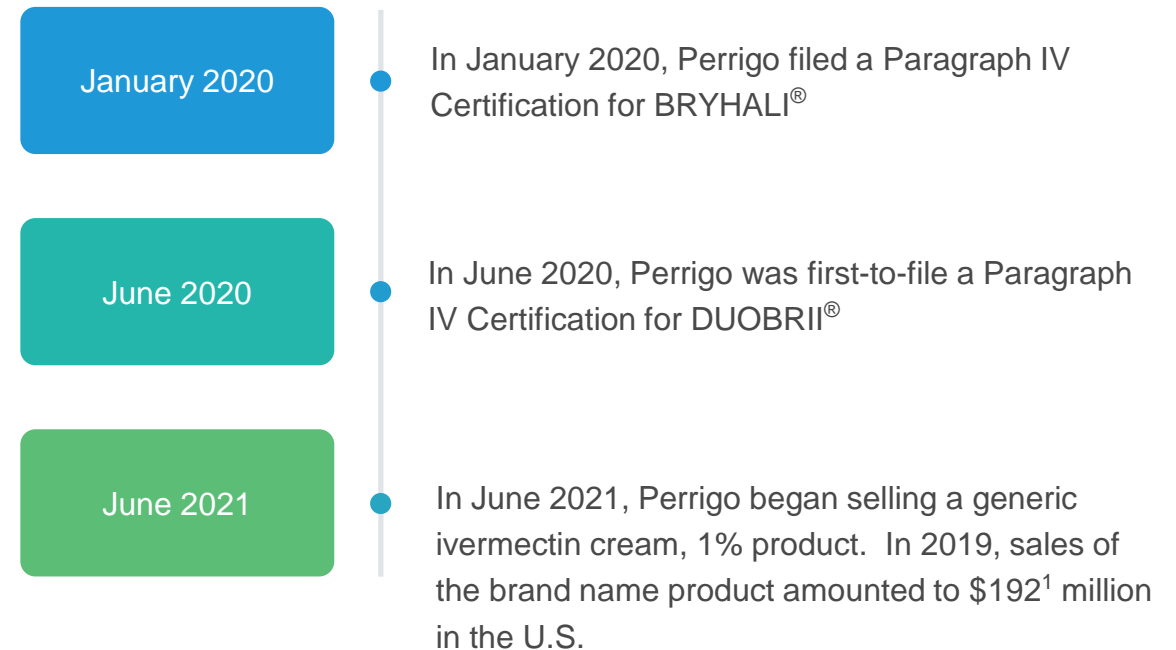
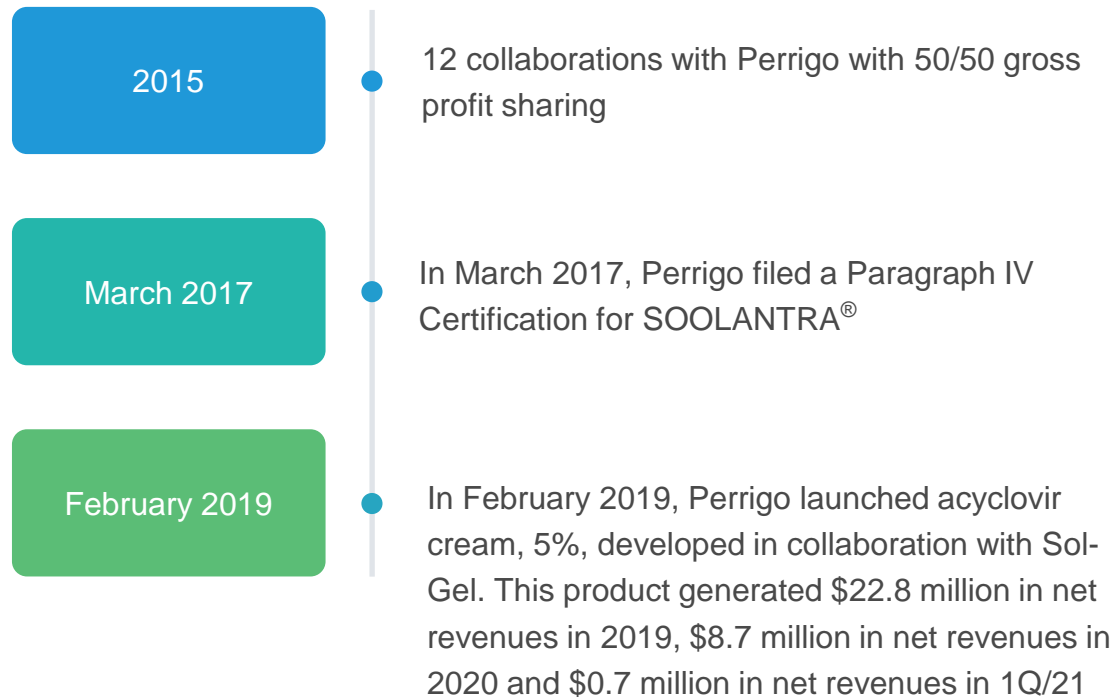


TWYNEO is protected until 2038 by granted patents and until 2041 by a pending patent application





# LUCRATIVE GENERIC PRODUCTS AND PIPELINE





## RECENT UPDATES

# PIPELINE PROGRESS



Our innovative investigational topical formulation of roflumilast (SGT-510) was found to be more effective than roflumilast cream, 0.3%, that was formulated by Sol-Gel according to conventional methods of cream formulation, in a human xenograft psoriasis animal model



We are currently developing an innovative investigational formulation of tapinarof (SGT-310) aiming to offer product formulation innovations and increased affordability for patients compared to the brand expected to be launched



Our proof-of-concept study for erlotinib gel (SGT-210) in palmoplantar keratoderma patients was completed and indicated a possible modest improvement. We plan to investigate higher concentrations of erlotinib





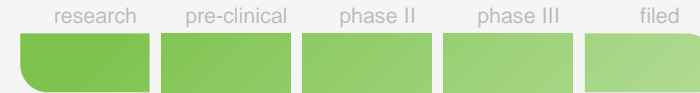
# A DIVERSE PIPELINE OF TOPICAL SKIN MEDICATIONS

## EPSOLAY

- PDUFA GOAL date was set for April 26. Awaiting FDA's pre-approval inspection.

### EPSOLAY®

(benzoyl peroxide) Cream, 5%  
*Papulopustular Rosacea*



Galderma  
Partnership – U.S.

## TWYNEO

- PDUFA goal date set for August 1, 2021

### TWYNEO®

(benzoyl peroxide and tretinoin) Cream, 3%/0.1%  
*Acne Vulgaris*



Galderma  
Partnership – U.S.

### SGT-210 (erlotinib)

*Palmoplantar Keratoderma*



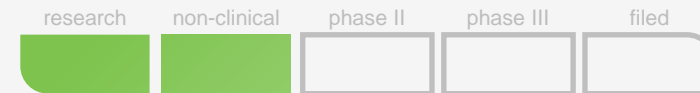
### SGT-310 (tapinarof)

*Psoriasis & Other Dermatologic Indications*



### SGT-510 (roflumilast)

*Psoriasis & Other Dermatologic Indications*



REVENUE STREAM FROM PARTNERSHIPS WILL SUPPORT DEVELOPMENT OF OUR INNOVATIVE PIPELINE

# FINANCIAL PROFILE

- 01 Gross proceeds of \$86.3 million raised in IPO on February 5, 2018
- 02 Gross proceeds of \$11.5 and \$23 million raised in public follow-on offerings on August 12, 2019 and February 13, 2020, respectively
- 03 Additional \$5 million investment by controlling shareholder in April 2020
- 04 23,028,264 Ordinary Shares as of March 31, 2021
- 05 \$8.7 million net revenues from generic products in 2020 and \$0.7 million net revenues from generic products in 1Q/21
- 06 \$42.1 million in cash and investments as of May 31, 2021
- 07 Based on Galderma's upfront and milestone payments, we expect that our cash resources will enable funding of operational and capital expenditure requirements into the first quarter of 2023 (assuming timely approval of both products in 2021)



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Advanced Topical Therapy

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