



# Sol-Gel

Advanced Topical Therapy

NASDAQ: SLGL

June 22, 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, and the negotiations with a potential partner regarding the commercialization of EPSOLAY and TWYNEO, anticipated timing of results of the ongoing Phase 1 clinical trial of SGT-210, the expectation to launch a partnered 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 PDUFA action date for EPSOLAY; the timing of FDA approval, if any, of EPSOLAY and TWYNEO; the risk that we may not execute an agreement for the commercialization of EPSOLAY and TWYNEO and risks related to the terms thereof; 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; 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; 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.

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## OVERVIEW

# OUR DERMATOLOGY COMPANY

### TECHNOLOGY

- Proprietary silica-based microencapsulation technology

### EPSOLAY<sup>®</sup>

- 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

### TWYNEO<sup>®</sup>

- 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

### SGT-210

- Phase I proof-of-concept study for erlotinib gel in palmoplantar keratoderma was completed

### EARLY STAGE

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

### GENERICS

- Twelve 50/50 gross profit-sharing collaborations with Perrigo
- \$0.7 million in net revenues in 1Q/21



# THE SCIENCE BEHIND OUR PROPRIETARY TECHNOLOGY

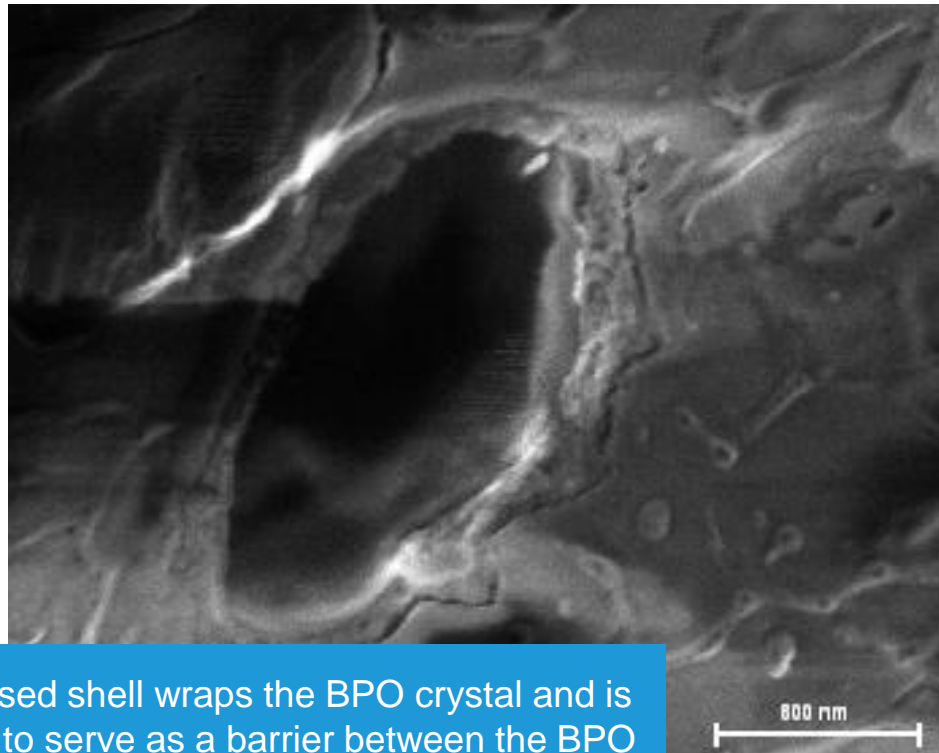
Aiming to provide effective and tolerable topical  
therapies to achieve local action



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

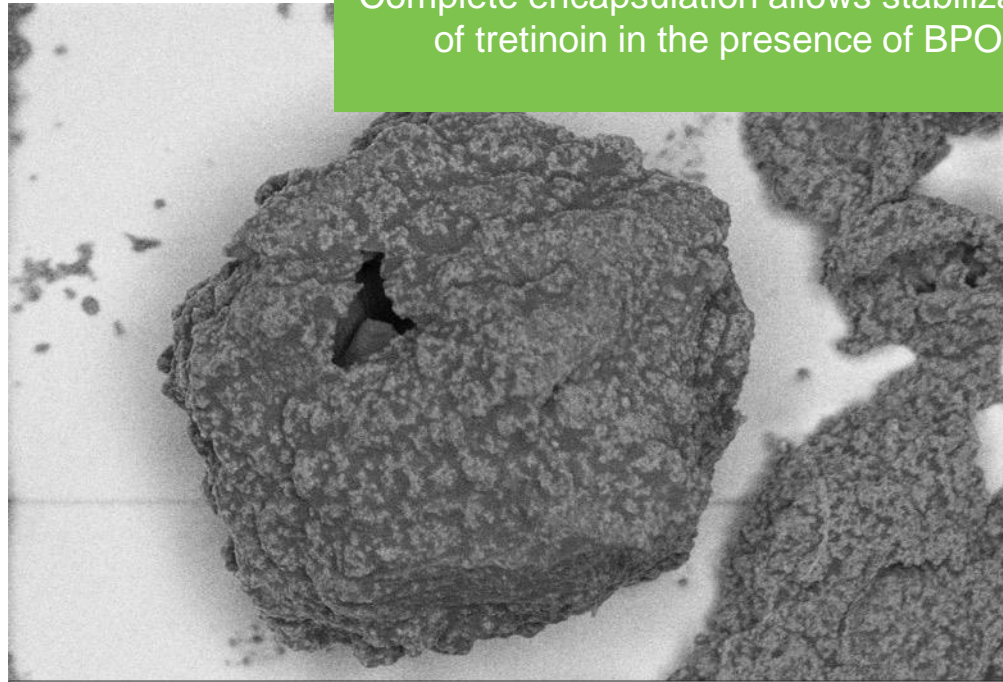


ENCAPSULATION IS DESIGNED TO ENHANCE STABILITY

# ENCAPSULATED TRETINOIN (E-TRETINOIN)

SEM PICTURE

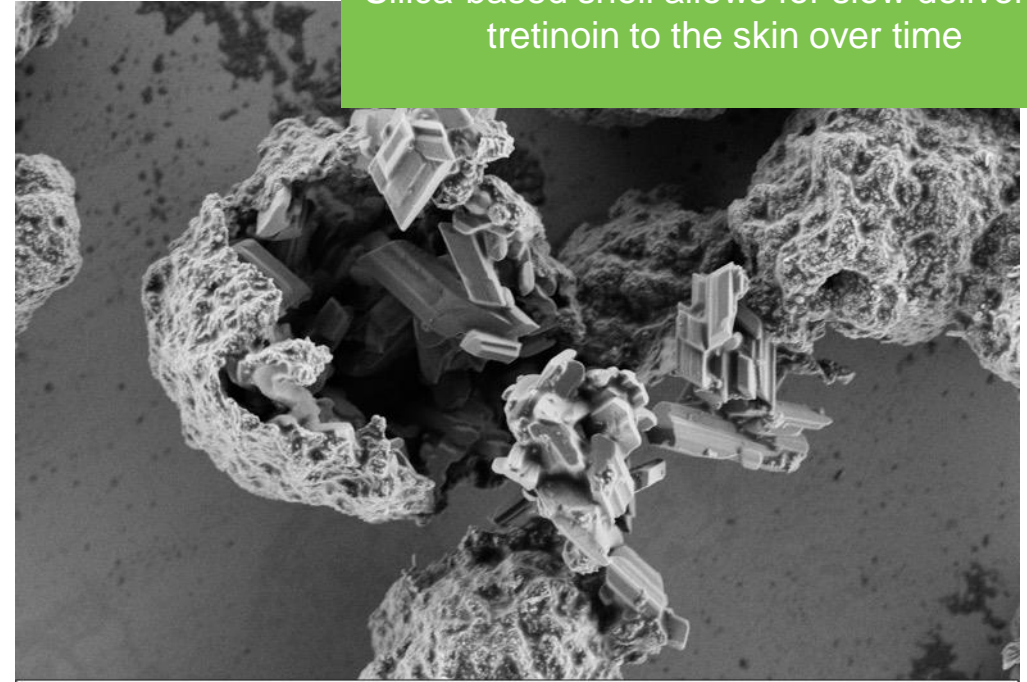
Complete encapsulation allows stabilization of tretinoin in the presence of BPO



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

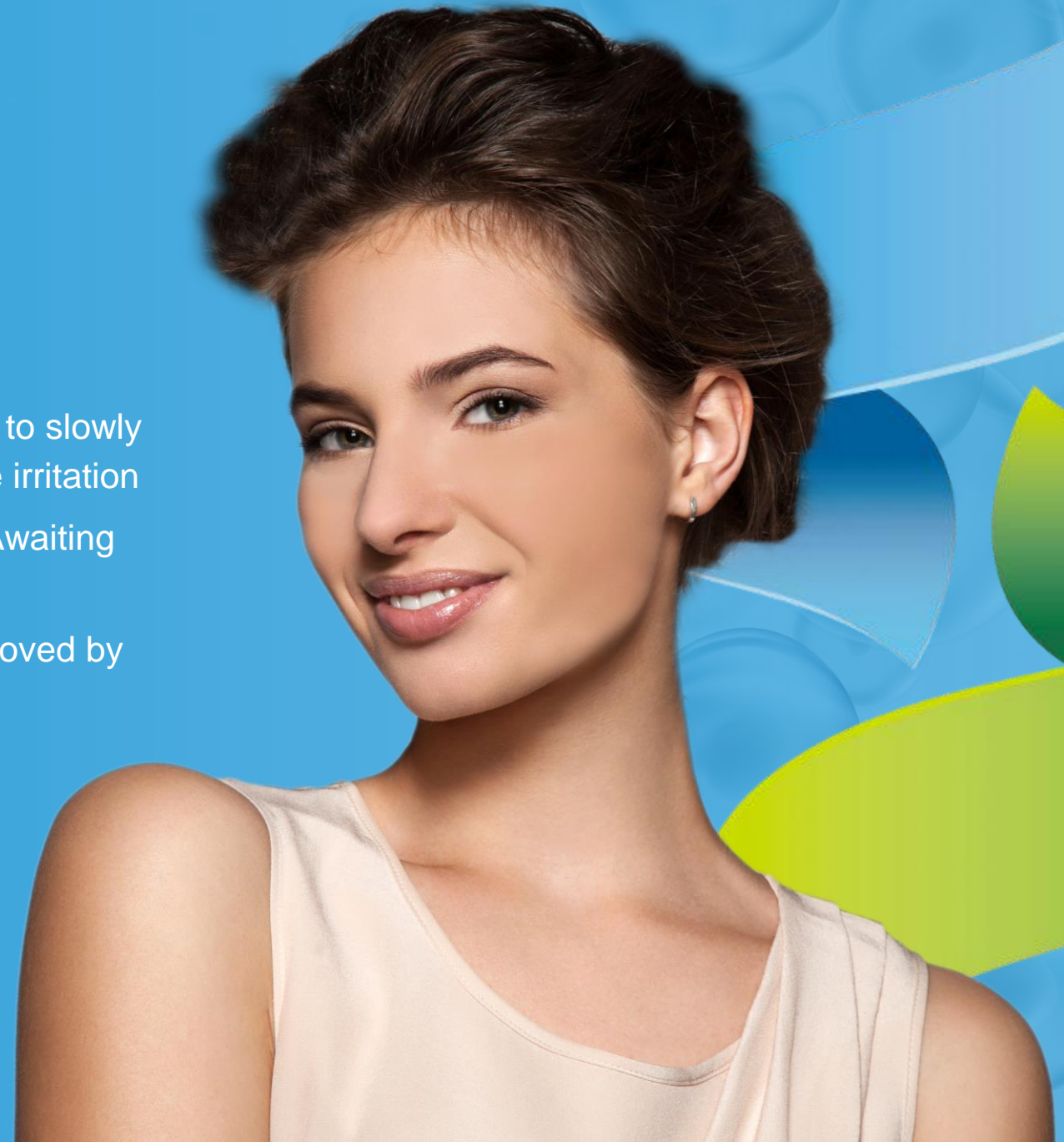
SOL-GEL SOLUTION\*

# EPSOLAY<sup>®</sup>

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

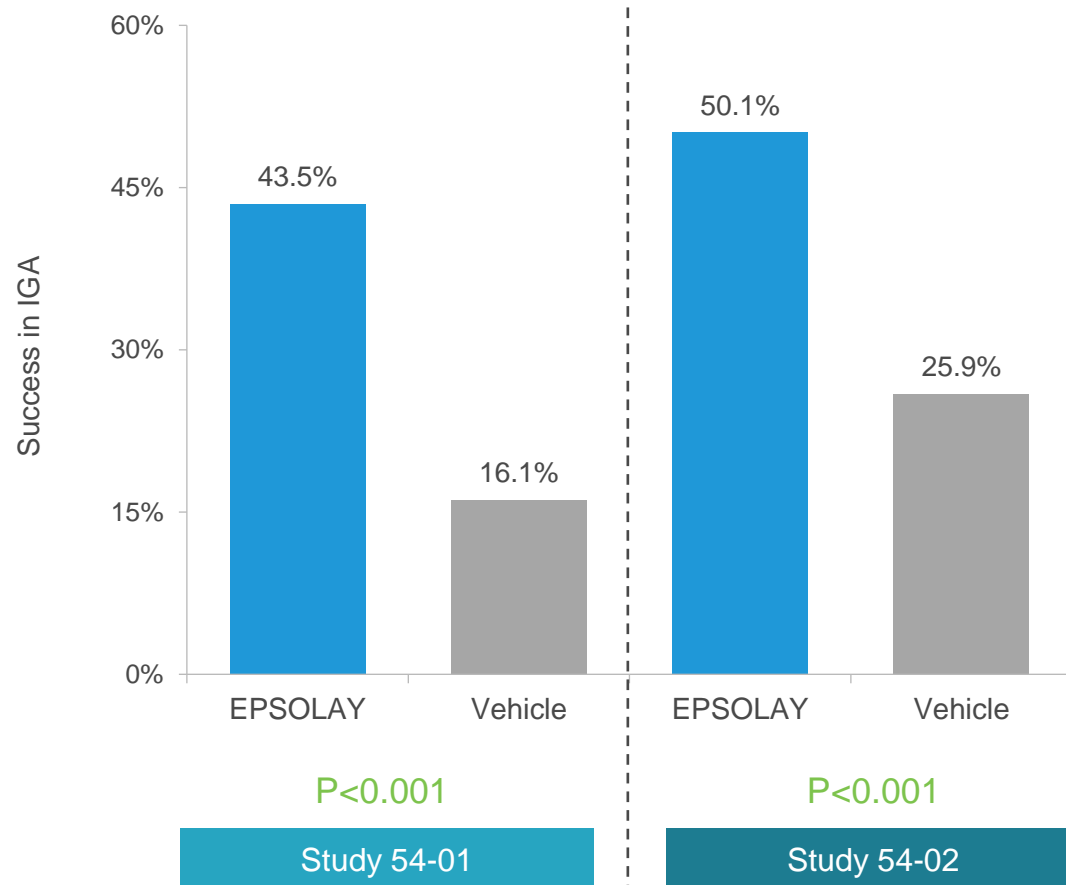
Two Parallel, Multicenter, Double-Blinded,  
Randomized, Vehicle-Controlled Studies, 2:1 Ratio, QD



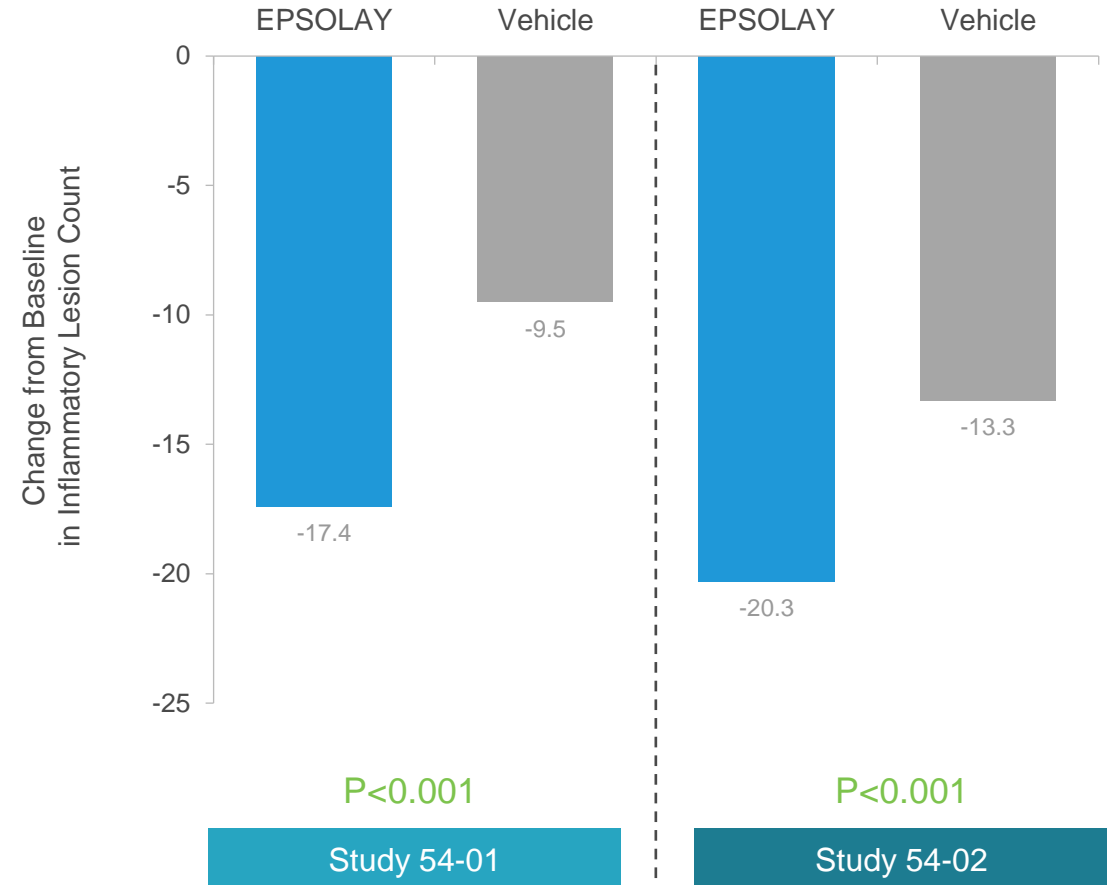
## PHASE III RESULTS

# SUCCESS IN PRIMARY ENDPOINTS

Week 12  
Success in IGA (ITT)



Week 12  
Inflammatory Lesion Count  
Change from Baseline (ITT)





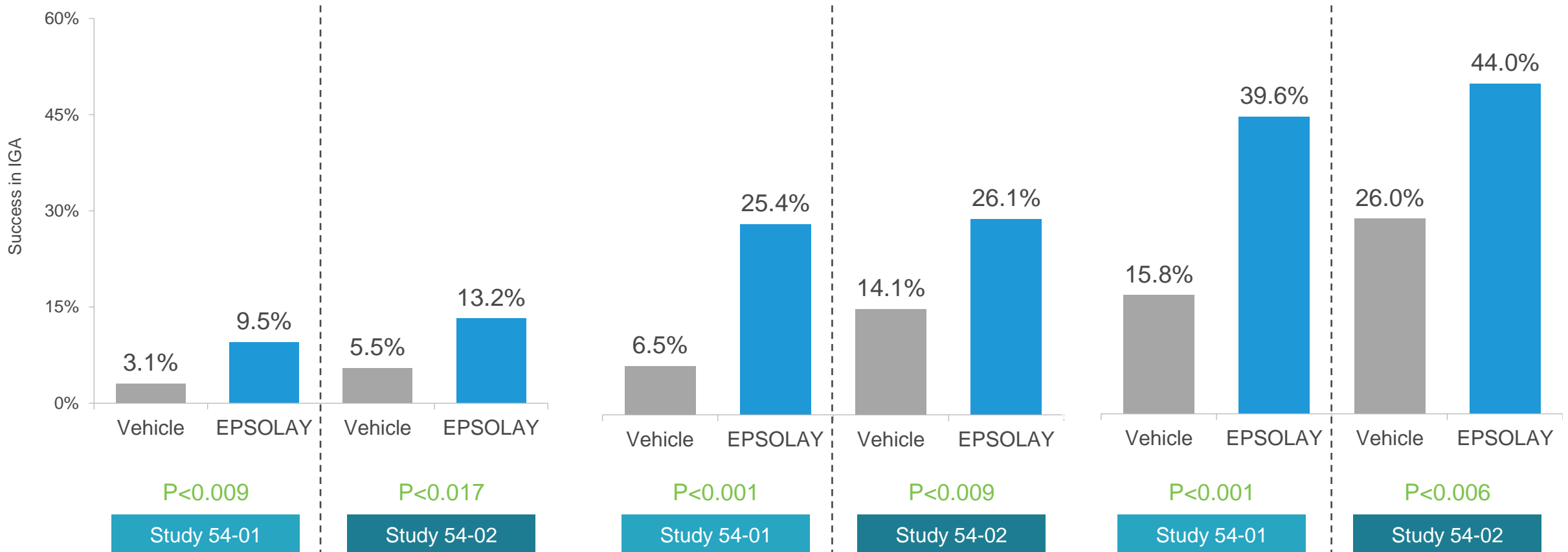
SUCCESS IN IGA

# IMPROVEMENT AS OF WEEK 2

Week 2  
Exploratory Endpoint (ITT)

Week 4  
Secondary Endpoint (ITT)

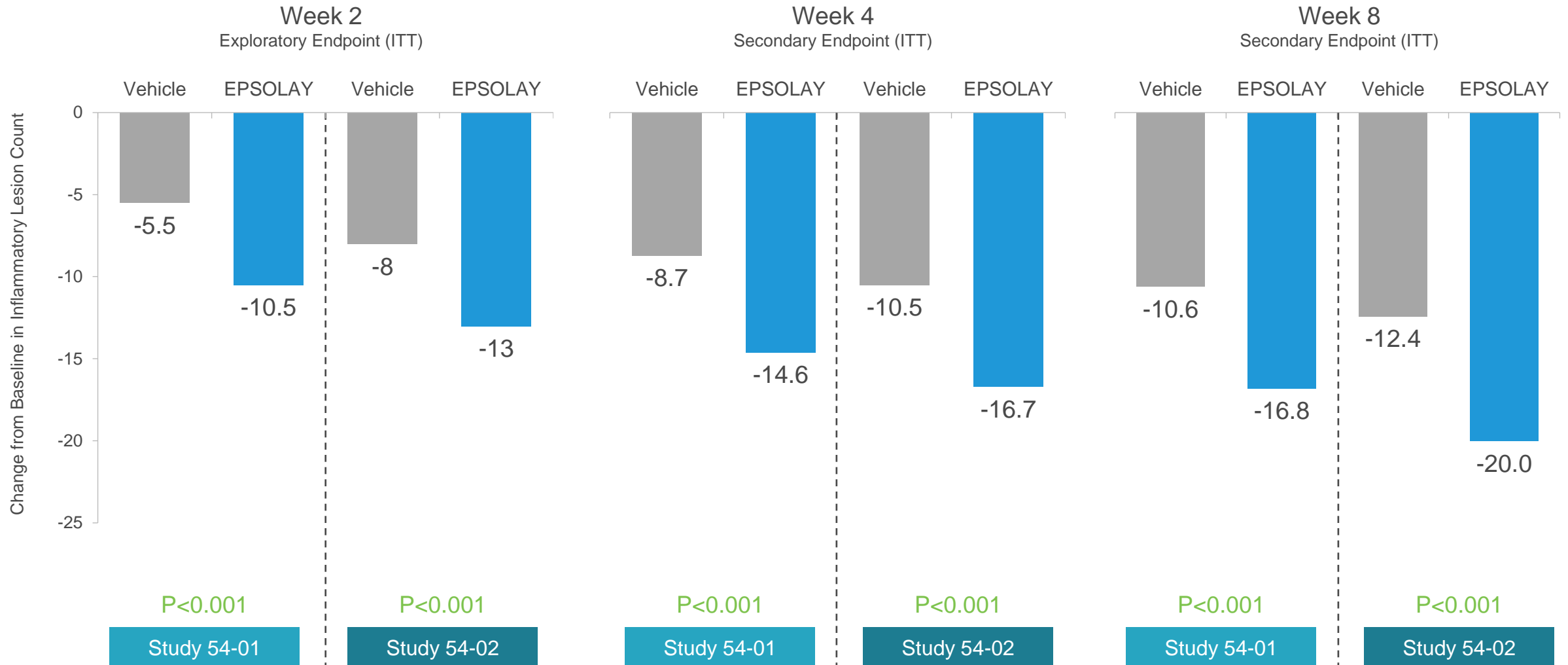
Week 8  
Secondary Endpoint (ITT)





## 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



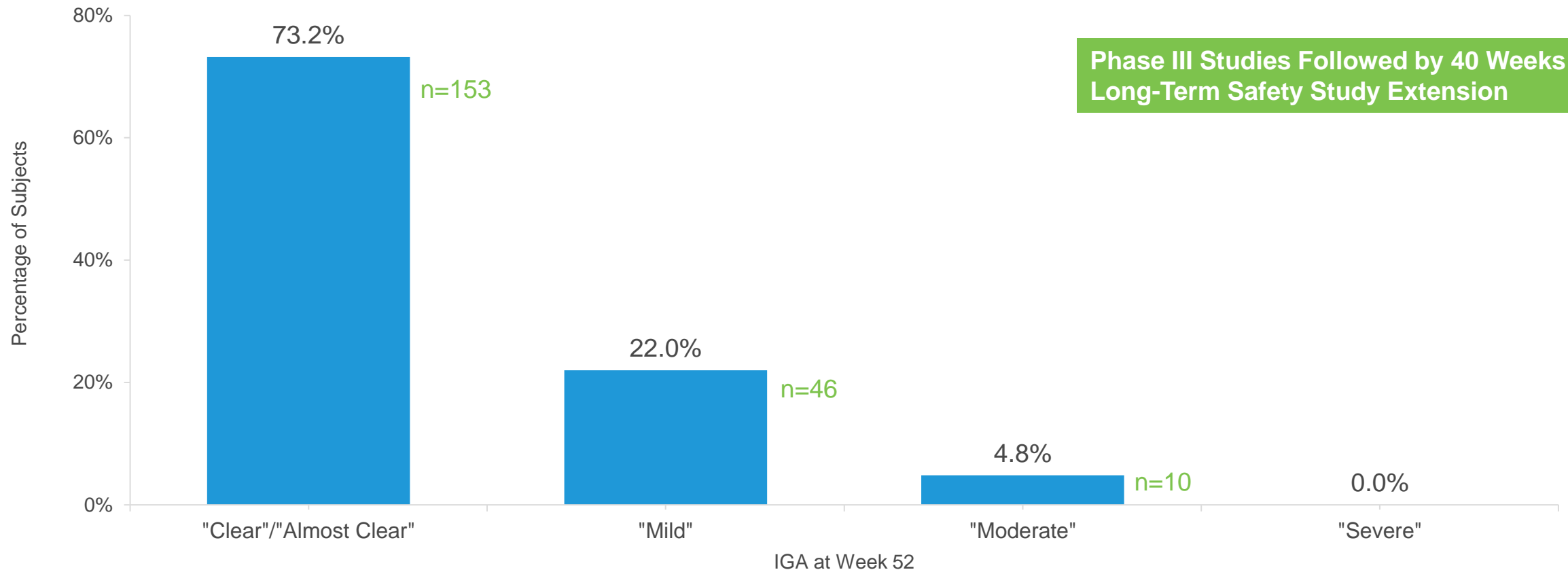
"Almost Clear"; 1 inflamed lesion

\* 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



## 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>

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>

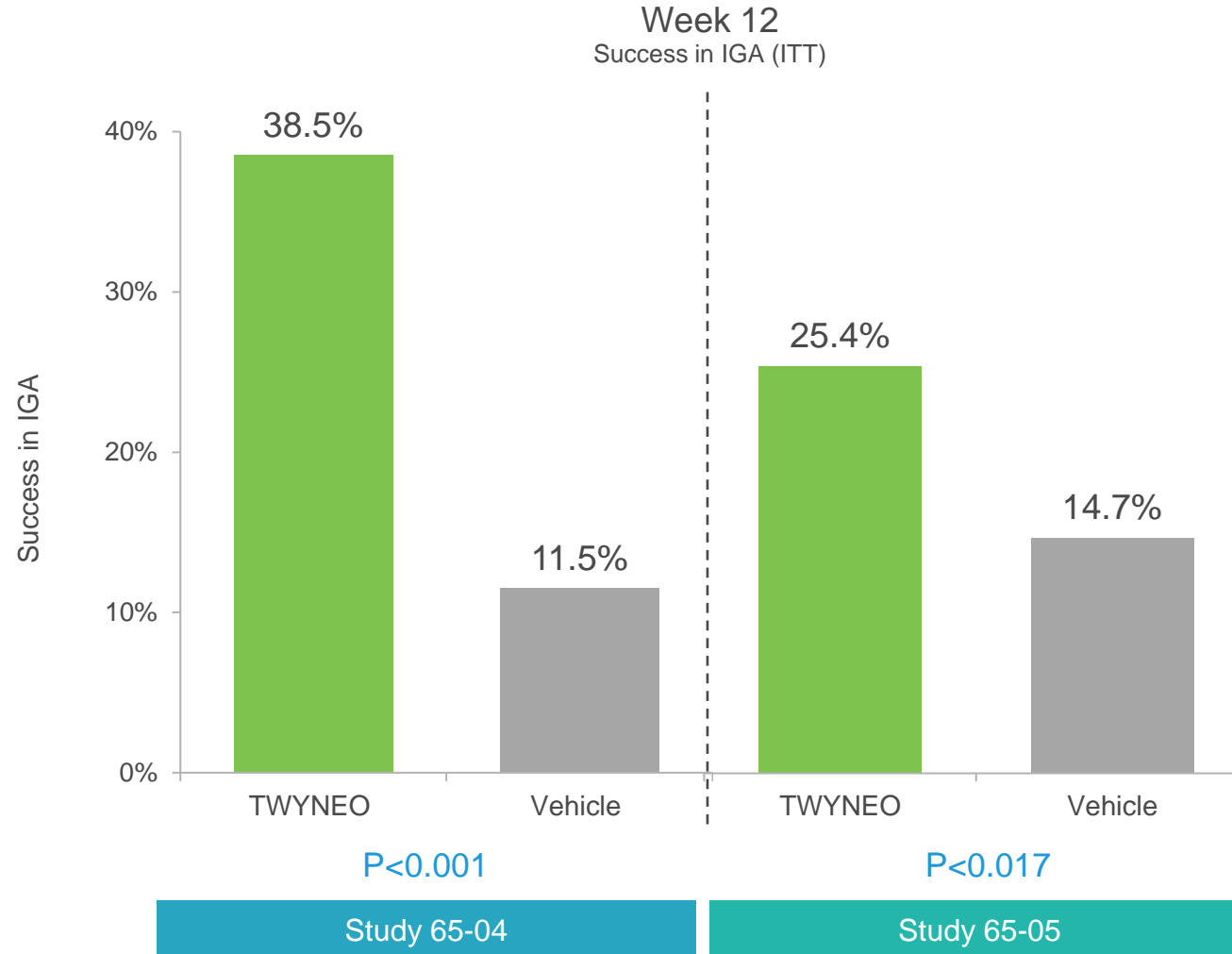
## PHASE III STUDIES

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



PHASE III RESULTS

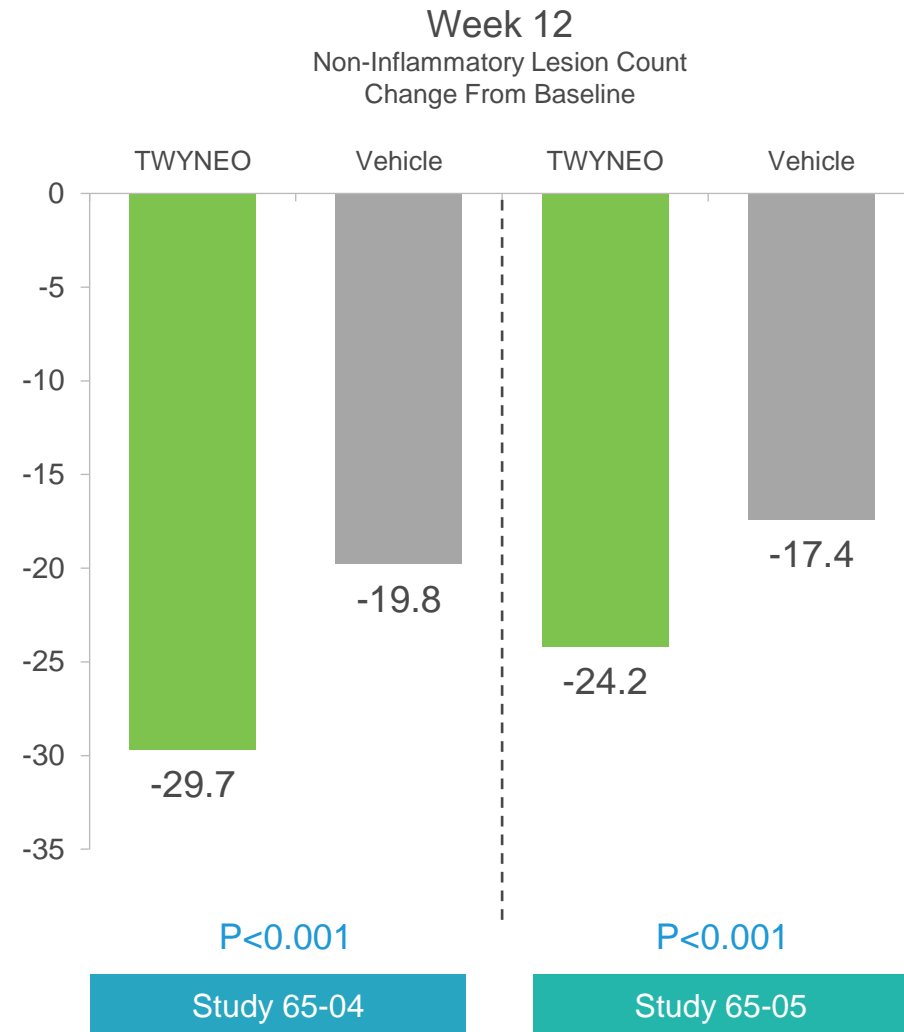
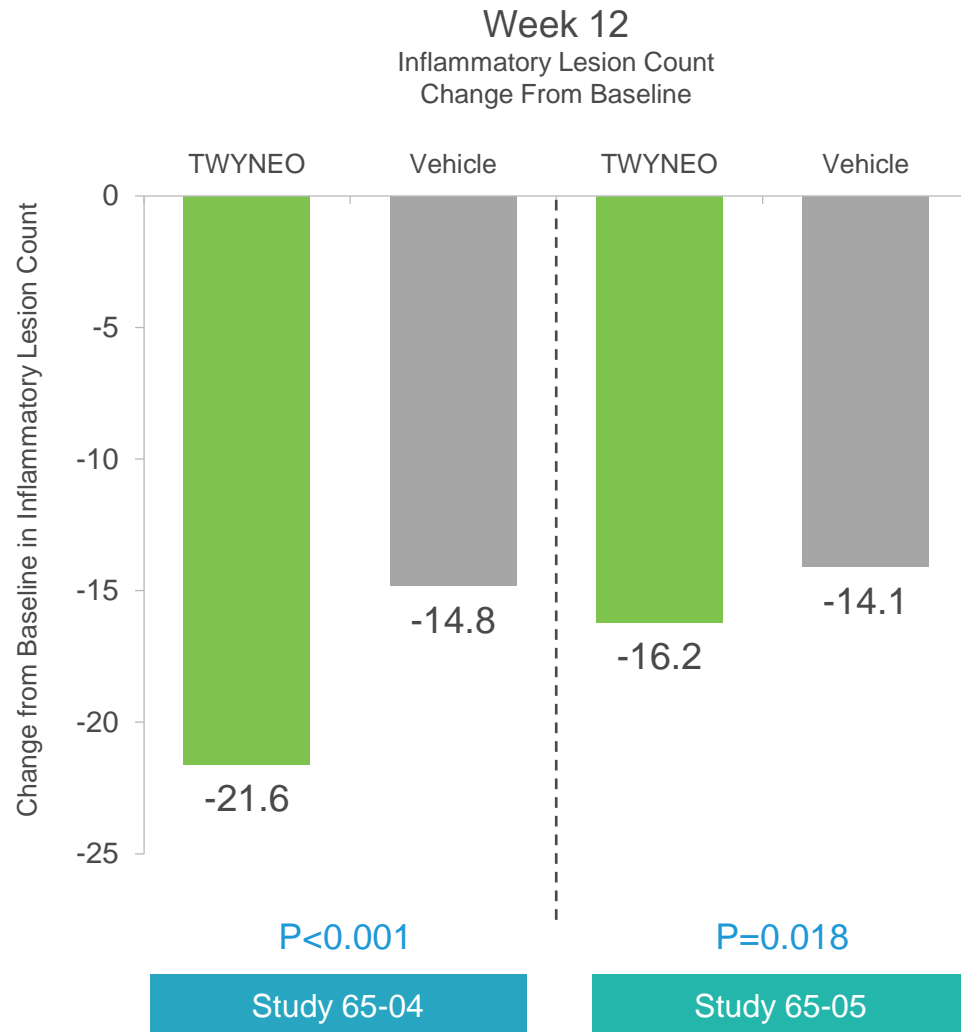
# SUCCESS IN IGA





## 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 INTELLECTUAL PROPERTY ESTATE



- EPSOLAY is protected until 2032 by granted patents, and until 2040 by allowed patents
- TWYNEO is protected until 2038 by granted patents and until 2041 by pending patent applications
- 25 patent applications for erlotinib, tapinarof and roflumilast in various skin conditions (as of February 26, 2021)



# EPSOLAY & TWYNEO ARE COMPELLING ENOUGH TO DRIVE PAYOR COVERAGE

EPSOLAY®



TWYNEO®

- “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”

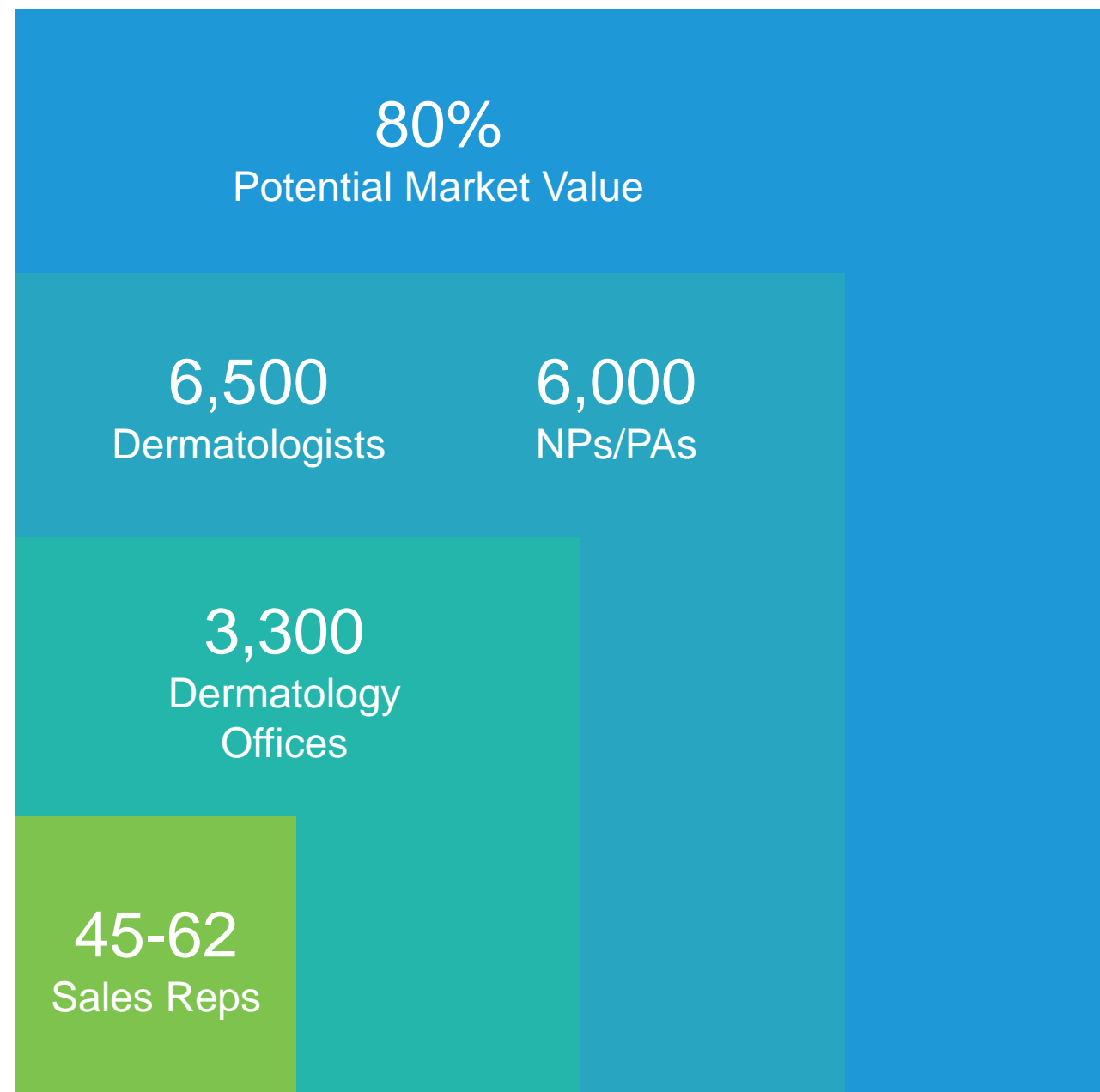
- “Unique MOA will qualify it for formulary addition, price will determine its position”
- “If you price it like Epiduo, it will be managed like Epiduo”
- “If similarly priced with better tolerability, it would become preferred brand”

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



# PRUDENT COMMERCIALIZATION APPROACH

We are in advanced negotiations with a potential partner regarding the commercialization of EPSOLAY<sup>®</sup> and TWYNEO<sup>®</sup>



\* EPSOLAY & TWYNEO are investigational. Safety and efficacy have not been established

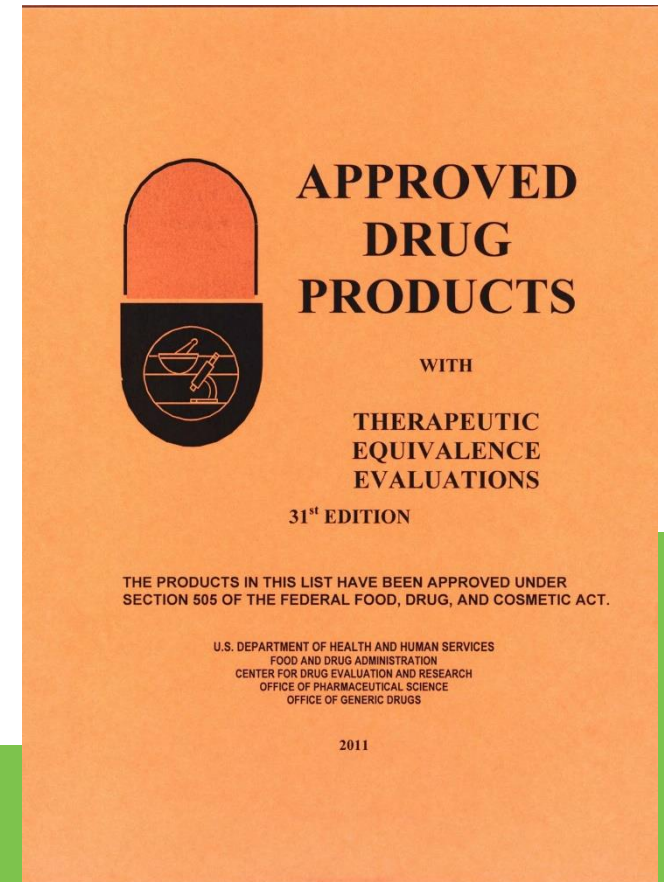
Source: Syneos Health (Morrisville, NC), Sol-Gel Market Analysis, June 2019



# LUCRATIVE GENERIC PIPELINE

## 12 collaborations with Perrigo – with 50/50 gross profit sharing

- In June 2021, Perrigo launched ivermectin cream, 1%
- In February 2019, Perrigo launched acyclovir cream, 5%
- In June 2020, Perrigo was first-to-file a Paragraph IV Certification for Duobrii®
- In January 2020, Perrigo filed a Paragraph IV Certification for Bryhali®







# 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
- 23,028,264 Ordinary Shares as of March 31, 2021
- \$8.7 million net revenues from generic products in 2020 and \$0.7 million net revenues from generic products in 1Q/21
- \$46.9 million in cash and investments as of March 31, 2021
- Under our operational model which assumes partnership regarding the commercialization of EPSOLAY® and TWYNEO® with a dermatology company that has a strong market presence, we expect that our cash resources will enable funding of operational and capital expenditure requirements into the third quarter of 2022



WHAT'S AHEAD

SGT-210

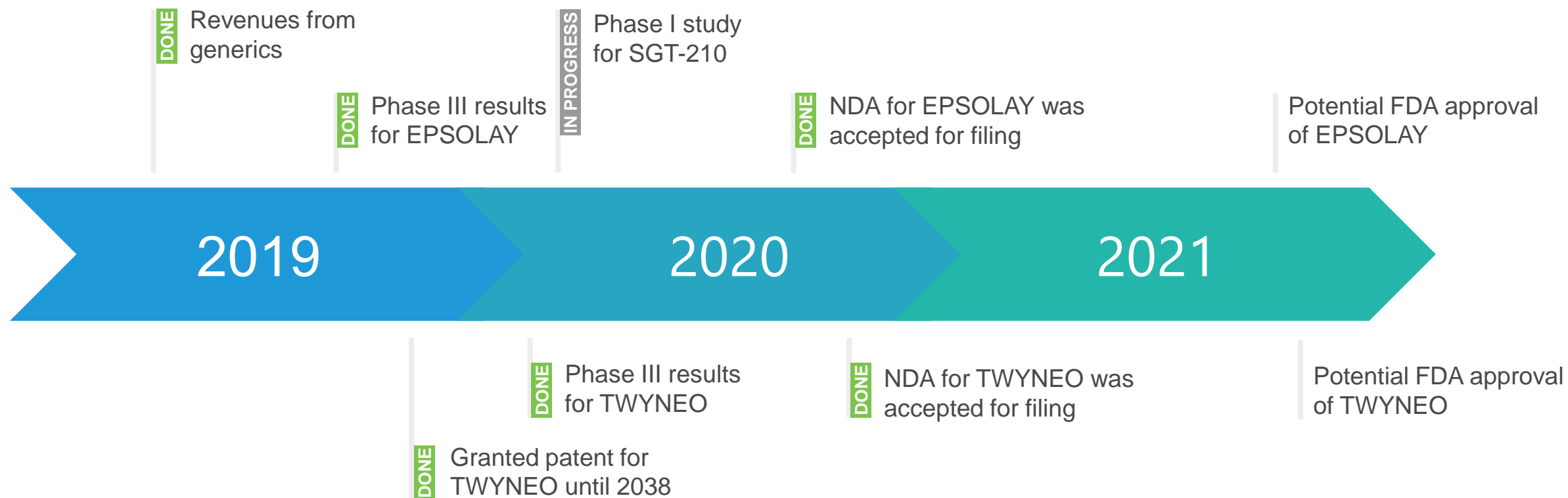
# PALMOPLANTAR KERATODERMA



**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



# RECENT MILESTONES & NEXT STEPS





# Sol-Gel

Advanced Topical Therapy

NASDAQ: SLGL