# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

FORM 6-K

Report of Foreign Private Issuer Pursuant to Rule 13a-16 or 15d-16 Under the Securities Exchange Act of 1934

For the month of January 2020

Commission File Number 001-38367

#### **SOL-GEL TECHNOLOGIES LTD.**

(Translation of registrant's name into English)

7 Golda Meir Street Ness Ziona 7403650, Israel

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.					
Form 20-F ⊠	Form 40-F □				
Indicate by check mark if the registrant is submitting the Form 6-K in	paper as permitted by Regulation S-T Rule 101(b)(1): $\Box$				
Indicate by check mark if the registrant is submitting the Form 6-K in	paper as permitted by Regulation S-T Rule 101(b)(7): $\Box$				

#### INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

On January 8, 2020, Sol-Gel Technologies Ltd. (the "Company") issued a press release announcing that it will host a conference call today to discuss results from two Phase 3 clinical trials for Twyneo®, an investigational combination of microencapsulated tretinoin 0.1% and microencapsulated benzoyl peroxide 3% cream being studied in patients with acne vulgaris. The Company is also posting on its website a presentation titled "Twyneo® Phase 3 Results".

Attached hereto and incorporated by reference in this Report on Form 6-K are the following exhibits:

Exhibit 99.1: Press Release titled "Sol-Gel Hosts Investor Call to Discuss Positive Results from Twyneo® Phase 3 Program in Acne Vulgaris".

Exhibit 99.2: Corporate presentation titled "Twyneo® Phase 3 Results".

#### **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

#### SOL-GEL TECHNOLOGIES LTD.

Date: January 8, 2019

By: /s/ Gilad Mamlok

Gilad Mamlok Chief Financial Officer

## Sol-Gel Hosts Investor Call to Discuss Positive Results from Twyneo® Phase 3 Program in Acne Vulgaris

• Conference call with Sol-Gel management and U.S. key opinion leader today at 8:00 a.m. Eastern time

NESS ZIONA, Israel, January 8, 2020 – Sol-Gel Technologies, Ltd. (NASDAQ: SLGL) will host a conference call today to discuss results from two Phase 3 clinical trials for Twyneo®, an investigational combination of microencapsulated tretinoin 0.1% and microencapsulated benzoyl peroxide 3% cream being studied in patients with acne vulgaris. In the SGT-65-04 and SGT-65-05 clinical trials, Twyneo demonstrated statistically significant improvements in all co-primary endpoints, as compared to vehicle, and was found to be well-tolerated.

Sol-Gel management and U.S. key opinion leader Hilary Baldwin, M.D., will discuss results from the Phase 3 Twyneo clinical trial program via conference call and webcast today at 8:00 a.m. Eastern Time. Dr. Baldwin is past President of the American Acne and Rosacea Society, a Clinical Associate Professor of Dermatology at Rutgers Robert Wood Johnson School of Medicine, and Director of the Acne Treatment and Research Center.

The conference call can be accessed by dialing 877-282-0504 for participants in the U.S. or Canada and 270-215-9895 for international callers (conference ID: 5779723). The webcast and slide presentation can be accessed live via the Events & Presentations section of the Company's website at <a href="http://ir.sol-gel.com">http://ir.sol-gel.com</a>.

#### SGT-65-04 and SGT-65-05 Trials Design

To assess the efficacy and safety of Twyneo, 858 subjects, aged nine and older, with moderate-to-severe acne were enrolled in two multicenter, randomized, double-blind, parallel-group, vehicle-controlled trials (SGT-65-04 and SGT-65-05) at 63 sites across the U.S. Subjects were randomized at a 2:1 ratio to be treated once-daily with either Twyneo (n=571) or vehicle cream (n=287) for 12 weeks. The co-primary endpoints for both trials included: the proportion of patients who succeeded in achieving at least a two grade reduction from baseline and Clear (grade 0) or Almost Clear (grade 1) at Week 12 on a 5-point Investigator Global Assessment (IGA) scale; an absolute change from baseline in inflammatory lesion count at Week 12; and an absolute change from baseline in non-inflammatory lesion count at Week 12.

#### **About Twyneo**

Twyneo is an investigational, antibiotic-free, fixed-dose combination of microencapsulated tretinoin 0.1% and microencapsulated benzoyl peroxide 3% cream. Benzoyl peroxide and tretinoin are widely prescribed and considered to be highly effective in the treatment for acne vulgaris; however, benzoyl peroxide causes degradation of the tretinoin, thereby reducing its effectiveness. Twyneo overcomes this degradation through the use of Sol-Gel's microencapsulation technology platform, thereby allowing for a stable drug combination, extending drug delivery time of the active ingredients, and reducing potential irritation caused by direct application of the drug to the skin.

#### **About Acne Vulgaris**

Acne vulgaris is a common multifactorial skin disease that according to the American Academy of Dermatology affects approximately 40 to 50 million people in the United States. The disease occurs most frequently during childhood and adolescence (affecting approximately 80% of all adolescents) but it may also appear in adults. Acne patients suffer from the appearance of lesions on areas of the body with a large concentration of oil glands, such as the face, chest, neck and back. These lesions can be inflamed (papules, pustules, nodules) or non-inflamed (comedones). Acne can have a profound effect on the quality of life of those suffering from the disease. In addition to carrying a substantial risk of permanent facial scarring, the appearance of lesions may cause psychological strain, social withdrawal and lowered self-esteem.

#### **About Sol-Gel Technologies**

Sol-Gel is a clinical-stage dermatology company focused on identifying, developing and commercializing branded and generic topical drug products for the treatment of skin diseases. Sol-Gel leverages its proprietary microencapsulation technology platform for Twyneo®, for the treatment of acne vulgaris, and Epsolay®, for the treatment of papulopustular rosacea. The Company's pipeline also includes SGT-210, an early-stage topical epidermal growth factor receptor inhibitor for the treatment of punctate palmoplantar keratoderma. For additional information, please visit <a href="www.sol-gel.com">www.sol-gel.com</a>.

#### Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements. These forwardlooking statements include information about possible or assumed future results of our business, financial condition, results of operations, liquidity, plans and objectives. In some cases, you can identify forward-looking statements by terminology such as "believe," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," "predict," "potential," or the negative of these terms or other similar expressions. Forward-looking statements are based on information we have when those statements are made or our management's current expectation, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important risks and uncertainties that could cause such differences include, but are not limited to, risks and uncertainties relating to the timing of the submission of an NDA for Twyneo and the timing of availability of Twyneo to patients, as well as the following risks and uncertainties: (i) the adequacy of our financial and other resources, particularly in light of our history of recurring losses and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives; (ii) our ability to complete the development of our product candidates; (iii) our ability to find suitable co-development partners; (iv) 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; (v) our ability to commercialize our pharmaceutical product candidates; (vi) our ability to obtain and maintain adequate protection of our intellectual property; (vii) our ability to manufacture our product candidates in commercial quantities, at an adequate quality or at an acceptable cost; (viii) our ability to establish adequate sales, marketing and distribution channels; (ix) acceptance of our product candidates by healthcare professionals and patients; (x) the possibility that we may face third-party claims of intellectual property infringement; (xi) 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; (xii) intense competition in our industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do; (xiii) potential product liability claims; (xiv) potential adverse federal, state and local government regulation in the United States, Europe or Israel; and (xv) 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 21, 2019 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 press release. Any such forward-looking statements represent management's estimates as of the date of this press release. Except as required by law, we undertake no obligation to update publicly any forward-looking statements after the date of this press release to conform these statements to changes in our expectations.

For further information:

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Source: Sol-Gel Technologies Ltd.



# TWYNEO® PHASE 3 RESULTS

Twynep® Phase 3 Results I January 8, 2020

#### CAUTIONARY NOTE ON 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 commencement of our planned bioequivalence study for a generic product candidate, our expected date to report top-line data from our pivotal Phase III clinical program for Twyneo®, our anticipated NDA submission dates for Epsolay® and Twyneo®, 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: 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 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 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, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing, and sales, distribution and personnel resources than we do; potential product liability claims; potential adverse federal, state, and local government regulation in the United States, Europe, or Israel; 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 21, 2019, 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 press release. Any such forward-looking statements 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

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.

#### ACNE VULGARIS



#### Multifactorial disease requiring powerful combination treatments

What is 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, antibiotics, and their combinations; isotretinoin and antibiotics are mainstays of systemic therapy

What are the current treatment shortfalls?

Insufficient efficacy negatively affects selfesteem; contributes to antibiotic resistance; systemic side effects

E-BPO + E-ATRA Cream

Encapsulation allows combining 2 highly effective APIs, BPO and ATRA, that have complementary mechanisms of action Encapsulation may reduce the irritation of both BPO and ATRA Potential to be more effective than existing topical treatments



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### TWYNEO® STUDY DESIGN



#### Two Phase 3, Double-blind, Randomized, Vehicle-controlled Studies

Twyneo<sup>®</sup> cream Inclusion criteria Age ≥9 years Randomization · ≥20 to ≤100 Inflammatory lesions (3% E-BPO, 0.1% E-ATRA) ≥30 to ≤150 Non-inflammatory lesions QD, Self-applied 2:1 12 weeks of treatment IGA grade 3 (Moderate) or grade 4 (Severe) Cysts/nodules ≤2 Vehicle cream 63 Total Sites Study 65-04: 424 Study 65-05: 434 4 8 12 Baseline Weeks

#### **Co-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

#### Safety Endpoints

· Cutaneous safety assessment, local tolerability assessment, adverse event reporting

E-ATRA=microencapsulated tretinoin; E-BPO=microencapsulated benzoyl peroxide; IGA=Investigator's Global Assessment; QD=once daily;

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## WELL-BALANCED STUDIES AT BASELINE (ITT)



Study 65-05

### Study 65-04

Number of sites	3	32	31		
	Twyneo®	Vehicle	Twyneo®	Vehicle	
Age, years Mean (SD)	(n=281) 20.9 (8.48)	(n=143) 21.4 (8.62)	(n=290) 20.1 (6.96)	(n=144) 20.3 (6.67)	
Median (range)	18.0 (11-67)	18.0 (10-57)	18.0 (10-51)	18.5 (9-42)	
Sex, n (%) Male Female	106 (37.7%) 175 (62.3%)	60 (42.0%) 83 (58.0%)	117 (40.3%) 173 (59.7%)	67 (46.5%) 77 (53.5%)	
Ethnicity, n (%) Hispanic/Latino Not Hispanic or Latino Unknown/Not Reported	102 (36.3%) 178 (63.3%) 1 (0.4%)	44 (30.8%) 98 (68.5%) 1 (0.7%)	85 (29.3%) 204 (70.3%) 1 (0.3%)	56 (38.9%) 87 (60.4%) 1 (0.7%)	
IGA severity Moderate Severe	251 (89.3%) 30 (10.7%)	132 (92.3%) 11 (7.7%)	262 (90.3%) 28 (9.7%)	133 (93.0%) 10 (7.0%)	
Inflammatory lesion count Mean (SD) Median (range)	33.5 (14.62) 28.0 (20-92)	33.5 (14.69) 28.0 (20-90)	28.2 (8.70) 25.0 (20-62)	27.5 (8.52) 25 (20-75)	
Non-inflammatory lesion count Mean (SD) Median (range)	48.6 (20.24) 42.0 (30-148)	47.1 (19.97) 41.0 (30-140)	44.6 (18.03) 39.0 (23-149)	44.9 (18.82) 38.0 (30-123)	

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## LOW DISCONTINUATION RATE ACROSS STUDIES



Study 65-04 Study 65-05

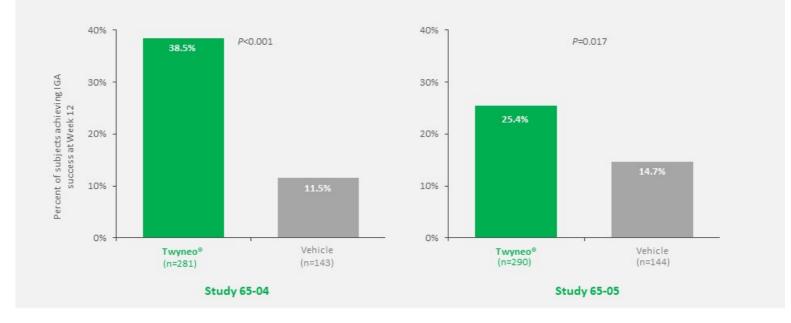
Randomized Subjects	Twyneo <sup>®</sup> (n=281)	<b>Vehicle</b> (n=143)	Twyneo <sup>⊗</sup> (n=290)	Vehicle (n=144)	
Discontinued	32	12	48	12	
Adverse events	4 (1.4%)	0	12 (4.1%)	0	
Lost to follow-up	10 (3.6%)	7 (4.9%)	15 (5.2%)	7 (4.9%)	
Lack of efficacy	0	0	0	0	
Pregnancy	1 (0.4%)	0	1 (0.3%)	0	
Protocol violation	2 (0.7%)	0	0	0	
Withdrawal by parent/guardian	4 (1.4%)	1 (0.7%)	4 (1.4%)	0	
Withdrawal by patient	9 (3.2%)	4 (2.8%)	14 (4.8%)	5 (3.5%)	
Physician decision	1 (0.4%)	0	1 (0.3%)	0	
Condition worsened	0	0	0	0	
Other	1 (0.4%)	0	1 (0.3%)	0	
Completed	249 (88.6%)	131 (91.6%)	242 (83.4%)	132 (91.7%)	

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## CO-PRIMARY ENDPOINT (ITT)



#### IGA Treatment Success at Week 12



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## CO-PRIMARY ENDPOINT (ITT)



### Absolute Mean Change From Baseline in Inflammatory Lesions at Week 12

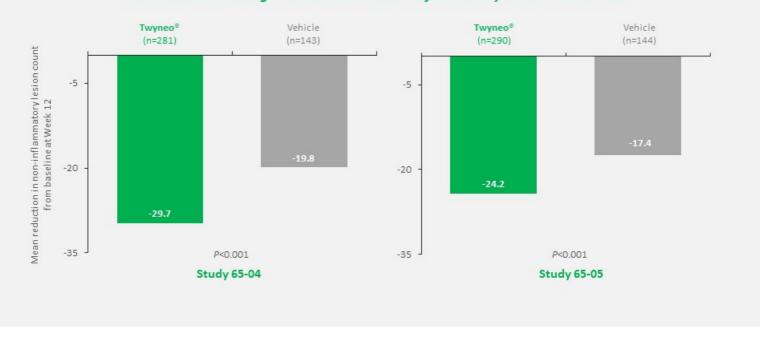


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### CO-PRIMARY ENDPOINT (ITT)



### Absolute Mean Change From Baseline in Non-Inflammatory Lesions at Week 12



Fwyneo\* Phase 3 Results | January 2020

### SUCCESS IN IGA IN RECENT ACNE TRIALS\*



#### Trials With Highest Difference in IGA Between the Active Arm and the Vehicle Arm



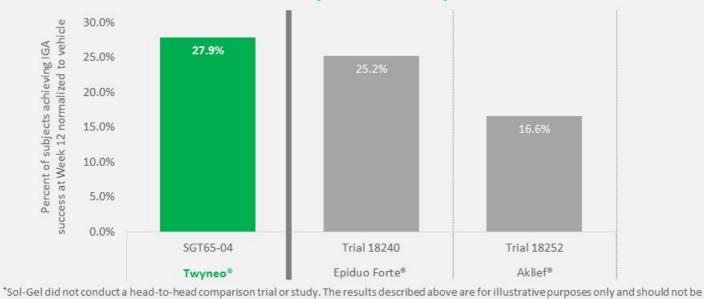
<sup>\*</sup>Sol-Gel did not conduct a head-to-head comparison trial or study. The results described above are for illustrative purposes only and should not be construed as conclusions to be drawn as if we conducted a head-to-head comparison trial or study

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### SUCCESS IN IGA IN MODERATE SUBJECTS\*



### Trials With Highest Difference in IGA Between the Active Arm and the Vehicle Arm Moderate Subjects at Baseline Only



construed as conclusions to be drawn as if we conducted a head-to-head comparison trial or study

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## SUPPORTIVE EFFICACY ANALYSIS\*(ITT)



#### IGA Treatment Success Over Time



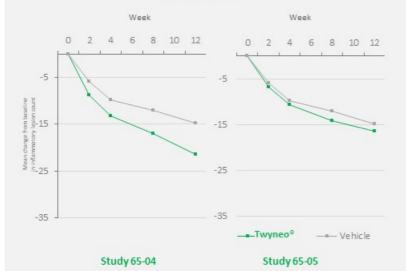
\*Percent of subjects with an assessment of clear or almost clear and with at least a 2-grade improvement in IGA from baseline, at Weeks 2, 4 and 8

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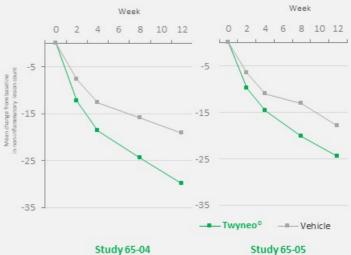
## SUPPORTIVE EFFICACY ANALYSIS\* (ITT)



#### Mean Reduction in Inflammatory Lesion Count Over Time



## Mean Reduction in Non-Inflammatory Lesion Count Over Time



 $<sup>^{</sup>ullet}$ Mean change from baseline in inflammatory and non-inflammatory lesion counts from baseline to Week 2

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### SAFETY & TOLERABILITY



Study 65-04

Study 65-05

Most frequent non-cutaneous TEAEs (≥1% in any treatment arm), n (%)	Twyneo®	Vehicle	Twyneo®	Vehicle
Safety population	n=274	n=139	n=281	n=138
Upper respiratory tract infection	6 (2.2%)	3 (2.2%)	1 (0.4%)	2 (1.4%)
Headache	3 (1.1%)	1 (0.7%)	1 (0.4%)	0
Nasopharyngitis	1 (0.4%)	0	4 (1.4%)	0
Attention deficit hyperactivity disorder	0	2 (1.4%)	0	0
Viral upper respiratory tract infection	0	0	1 (0.4%)	2 (1.4%)

- Nearly all AEs were mild or moderate in severity
- Total of 18 subjects discontinued from Studies 65-04 and 65-05 due to a TEAE: 18 (2%) in Twyneo° and 0 in vehicle
- No treatment-related SAEs were identified in either study
- 2 subjects reported SAEs in Study 65-05; (1) Twyneo® subject reported depression

SAE=serious adverse event; TEAE=treatment-emergent adverse event

yrieo" Phase 3 Results | January 2020

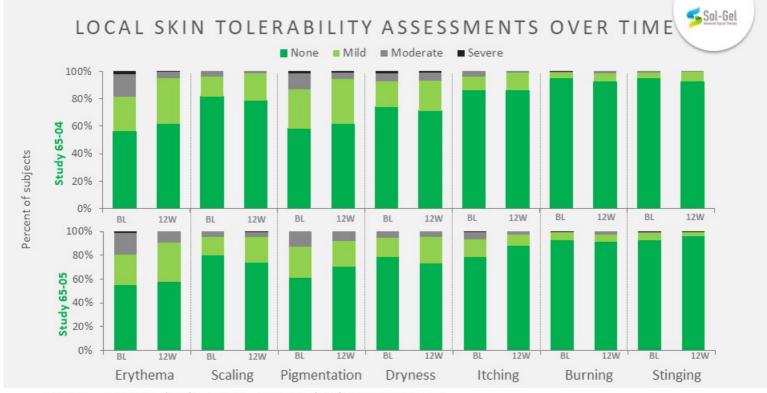
## LOCAL SKIN TOLERABILITY ASSESSMENT\* AT WEEK 12



		Twyne o <sup>®</sup> (n=274) %			Vehicle (n=139) %			
Study 65-04	None	Mild	Moderate	Severe	None	Mild		
Erythema	62.0%	33.2%	4.4%	0.4%	65.9%	25.8%	8.3%	0
Scaling	78.8%	19.6%	1.6%	0	83.3%	15.9%	0.8%	0
Pigmentation	61.6%	32.8%	4.8%	0.8%	67.4%	27.3%	5.3%	0
Dryness	71.2%	22.0%	6.0%	0.8%	78.0%	18.9%	3.0%	0
Itching	86.0%	12.8%	1.2%	0	89.4%	7.6%	3.0%	0
Burning	92.4%	6.0%	1.6%	0	95.5%	3.8%	0.8%	0
Stinging	92.4%	7.2%	0.4%	0	94.7%	3.8%	1.5%	0
Study 65-05								
Erythema	57.8%	32.8%	9.4%	0	64.4%	28.0%	7.6%	0
Scaling	83.2%	13.1%	3.7%	0	89.4%	9.8%	0.8%	0
Pigmentation	70.5%	21.7%	7.8%	0	70.5%	25.8%	3.8%	0
Dryness	73.0%	22.5%	4.5%	0	84.1%	14.4%	1.5%	0
Itching	88.1%	9.4%	2.5%	0	87.9%	9.8%	2.3%	0
Burning	91.4%	5.7%	2.9%	0	96.2%	3.0%	0.8%	0
Stinging	96.7%	3.3%	0.0%	0	99.2%	0.0%	0.8%	0

<sup>\*</sup>Safety population

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Safety population for Study 65-04 (n=274). Safety population for Study 65-04 (n=281). BL=baseline; 12W=12 weeks

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- Successfully met all primary efficacy endpoints demonstrating statistically significant improvements over vehicle
- No treatment-related serious adverse events
- Well-tolerated, with results similar to vehicle at 12 weeks



## INTRODUCING HILARY BALDWIN, MD

Past President of the American Acne and Rosacea Society, Clinical Associate Professor of Dermatology at Rutgers Robert Wood Johnson School of Medicine, and Director of the Acne Treatment and Research Center.

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# TWYNEO® IGA TREATMENT SUCCESS AND SIGNIFICANT REDUCTION IN INFLAMMATORY LESION COUNT



#### Baseline



Week 12



Subject: 417-004. Age: 19 years old. Gender: Male. Race: Hispanic or Latino, white

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# TWYNEO® IGA TREATMENT SUCCESS AND SIGNIFICANT REDUCTION IN INFLAMMATORY LESION COUNT



Baseline





Week 12



 ${\it Subject:}~518\hbox{-}010.~{\it Age:}~18~{\it years\,old.}~{\it Gender:}~{\it Female.}~{\it Race:}~{\it Hispanic\,or\,Latino,white}$ 

Twyneo\* Phase 3 Results | January 2020

### TWYNEO® PER-PROTOCOL "FAILURE" IN IGA AND SUCCESS IN INFLAMMATORY LESION COUNT REDUCTION





Week 12



Subject: 507-003. Age: 18 years old. Gender: Female. Race: Hispanic or Latino, white

Sol-Gel

# TWYNEO® PER-PROTOCOL "FAILURE" IN IGA AND SUCCESS IN INFLAMMATORY LESION COUNT REDUCTION

### Baseline Week 12





Sol-Gel

Subject: 501-015. Age: 16 years old. Gender: Male. Race: Hispanic or Latino, white

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