



TWYNEO[®] PHASE 3 RESULTS



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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 Twynéo®, our anticipated NDA submission dates for Epsolay® and Twynéo®, 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 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.

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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 self-esteem; contributes to antibiotic resistance; systemic side effects

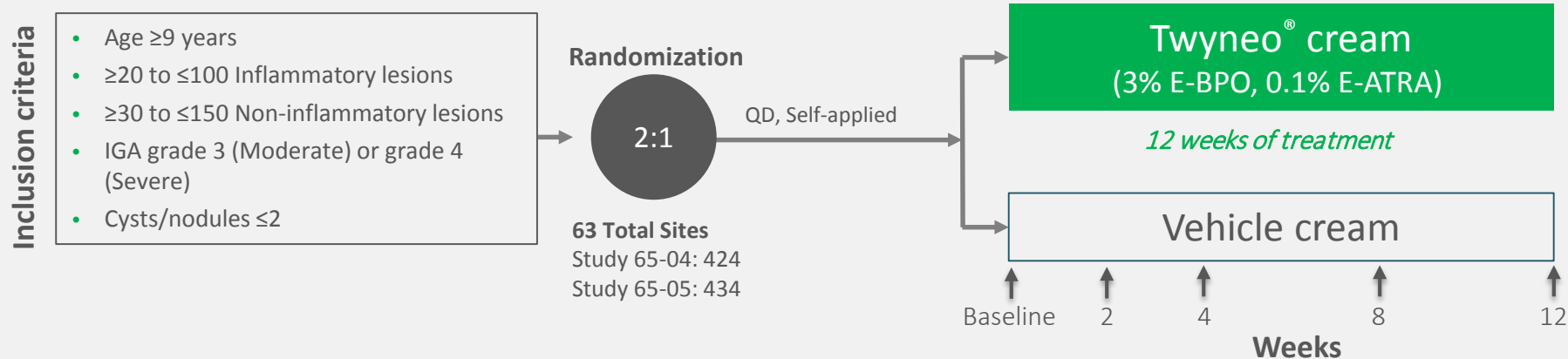
Our solution: **TWYNEO®**
E-BPO + E-ATRA Cream

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



TWYNEO[®] STUDY DESIGN

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



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;

WELL-BALANCED STUDIES AT BASELINE (ITT)



Study 65-04

Study 65-05

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

LOW DISCONTINUATION RATE ACROSS STUDIES



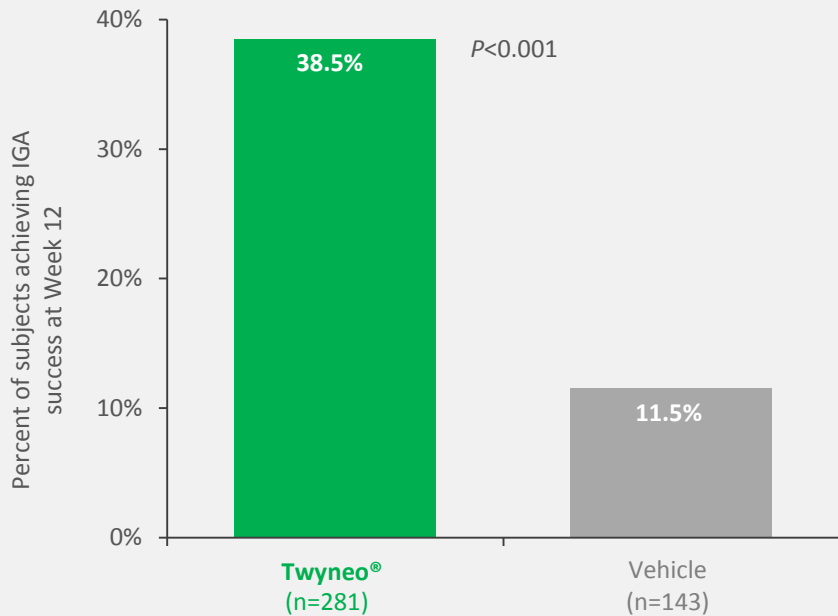
Study 65-04

Study 65-05

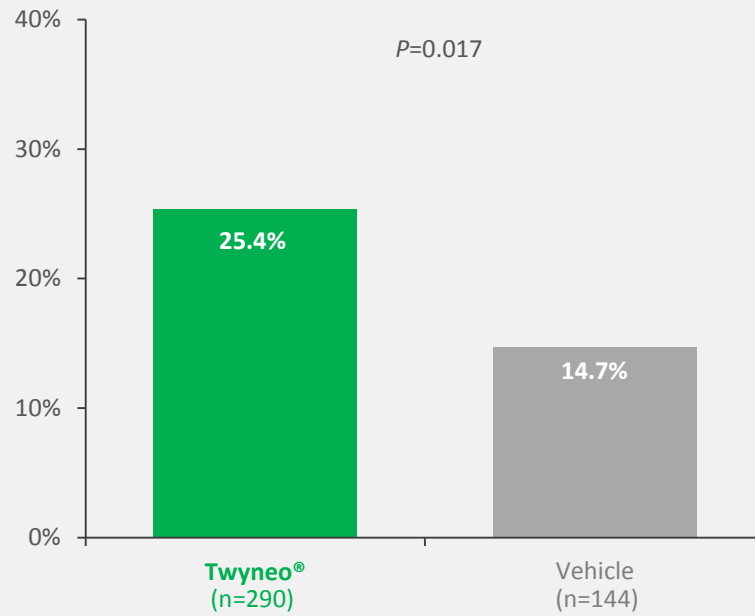
	Twyneo® (n=281)	Vehicle (n=143)	Twyneo® (n=290)	Vehicle (n=144)
Randomized Subjects				
Discontinued	32	12	48	12
Adverse events	4 (1.4%)	0	12 (4.1%)	0
Lost to follow-up	10 (3.6%)	7 (4.9%)	15 (5.2%)	7 (4.9%)
Lack of efficacy	0	0	0	0
Pregnancy	1 (0.4%)	0	1 (0.3%)	0
Protocol violation	2 (0.7%)	0	0	0
Withdrawal 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%)

CO-PRIMARY ENDPOINT (ITT)

IGA Treatment Success at Week 12



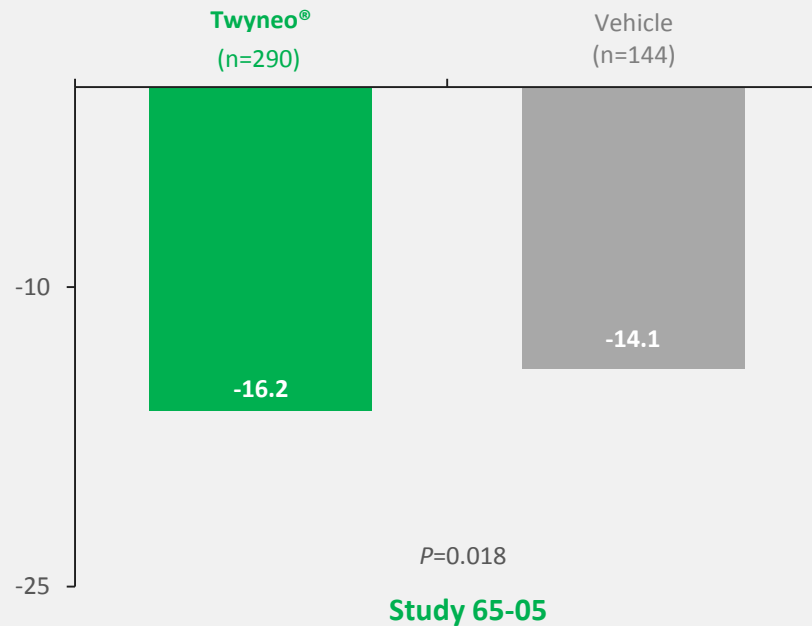
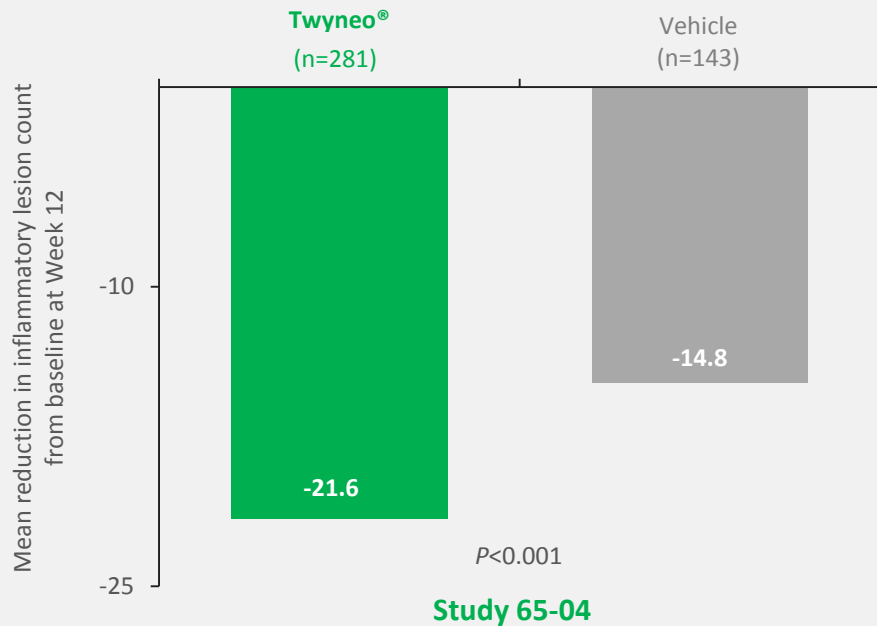
Study 65-04



Study 65-05

CO-PRIMARY ENDPOINT (ITT)

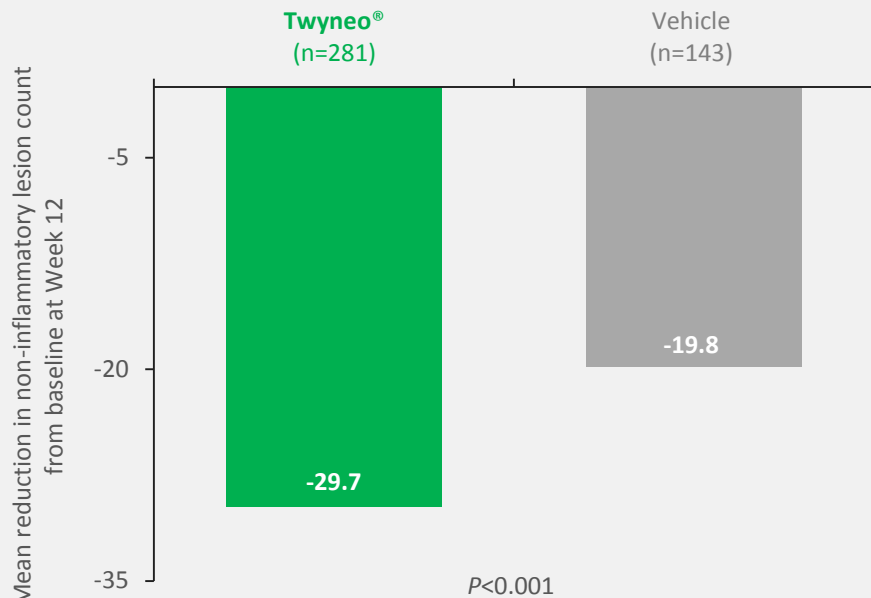
Absolute Mean Change From Baseline in Inflammatory Lesions at Week 12



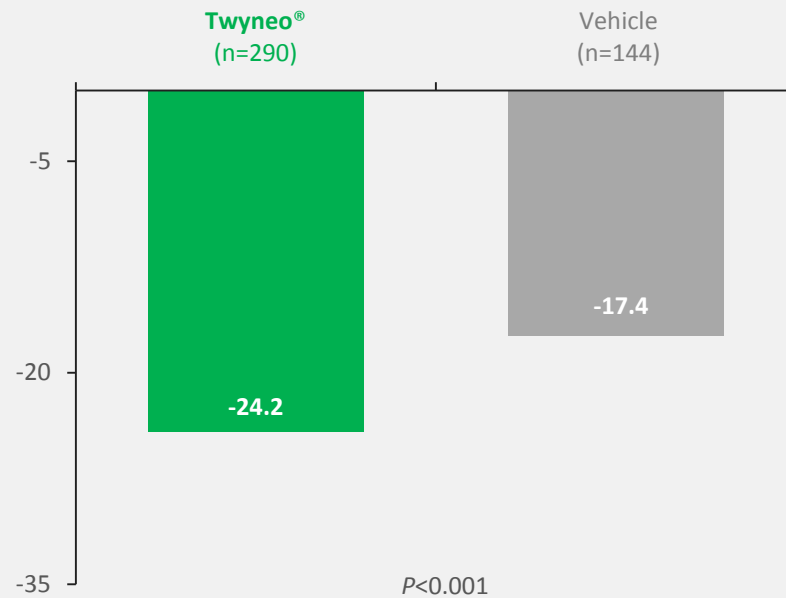


CO-PRIMARY ENDPOINT (ITT)

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



Study 65-04

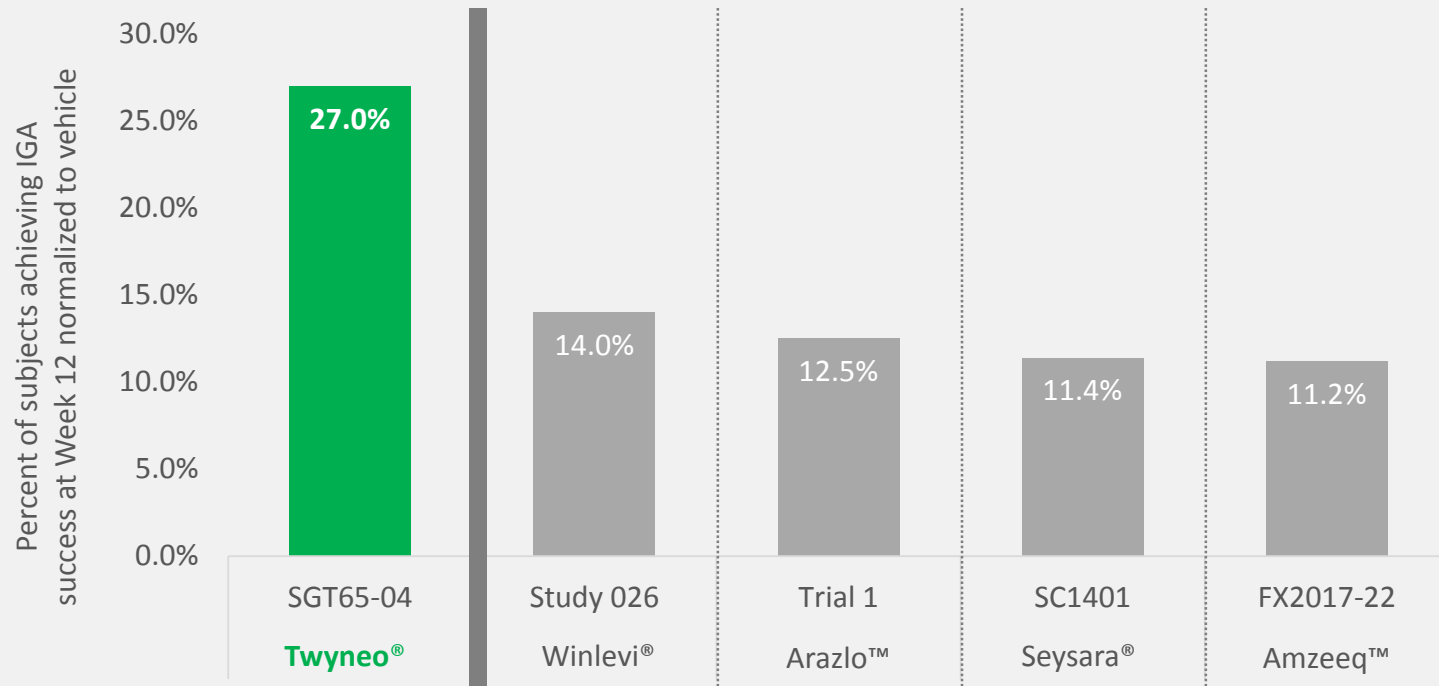


Study 65-05



SUCCESS IN IGA IN RECENT ACNE TRIALS*

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

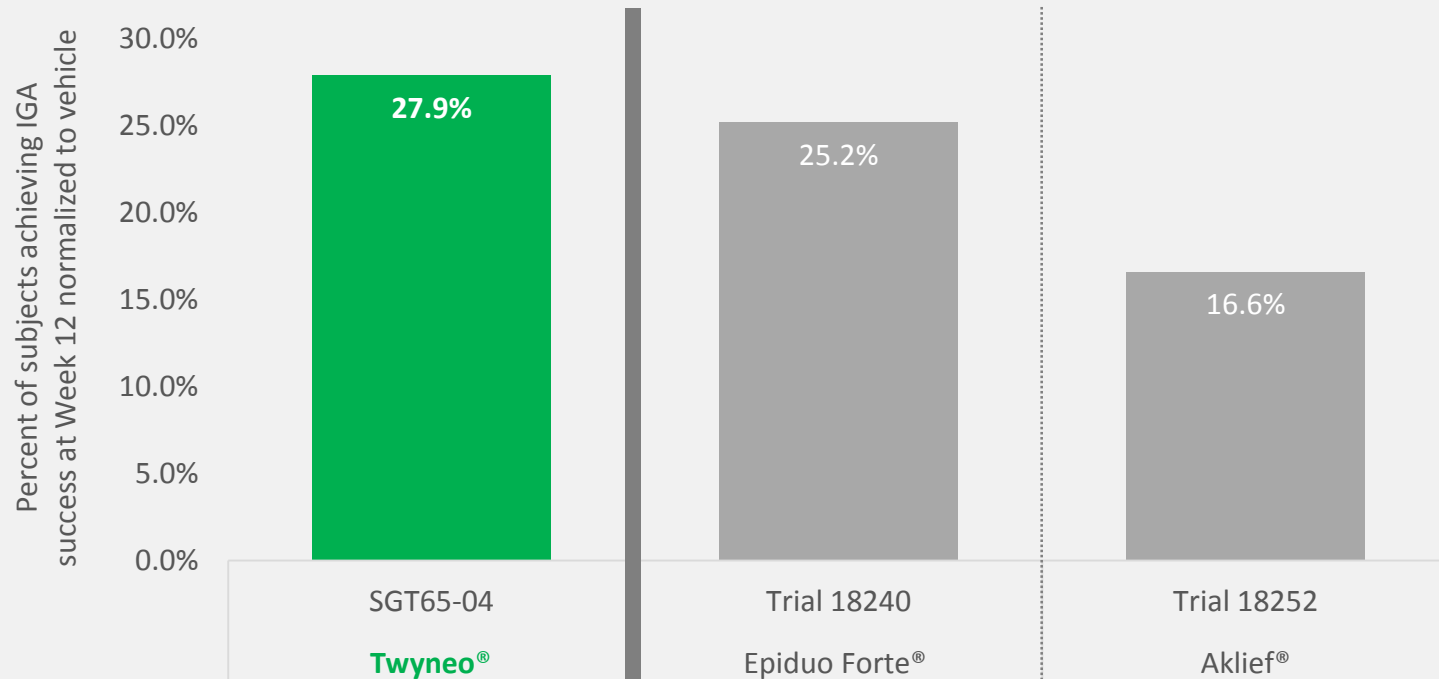


*Sol-Gel did not conduct a head-to-head comparison trial or study. The results described above are for illustrative purposes only and should not be construed as conclusions to be drawn as if we conducted a head-to-head comparison trial or study



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*

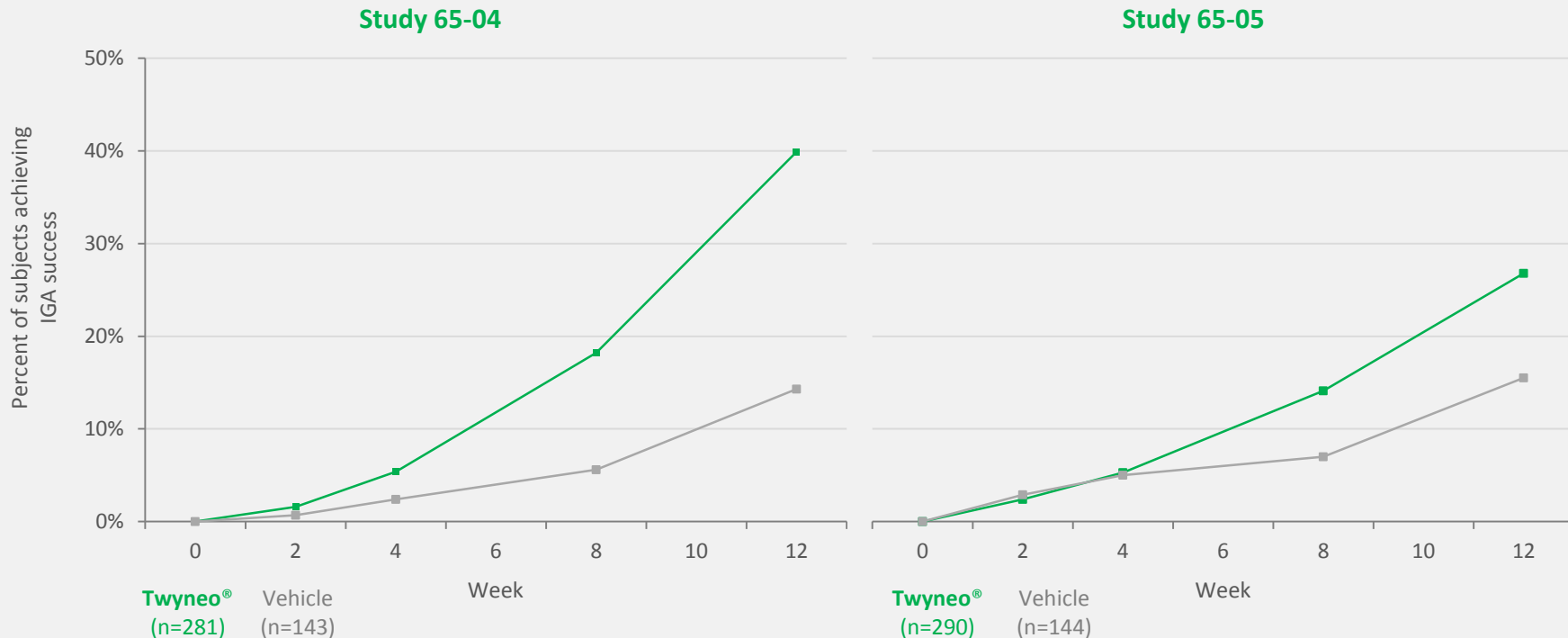


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SUPPORTIVE EFFICACY ANALYSIS* (ITT)

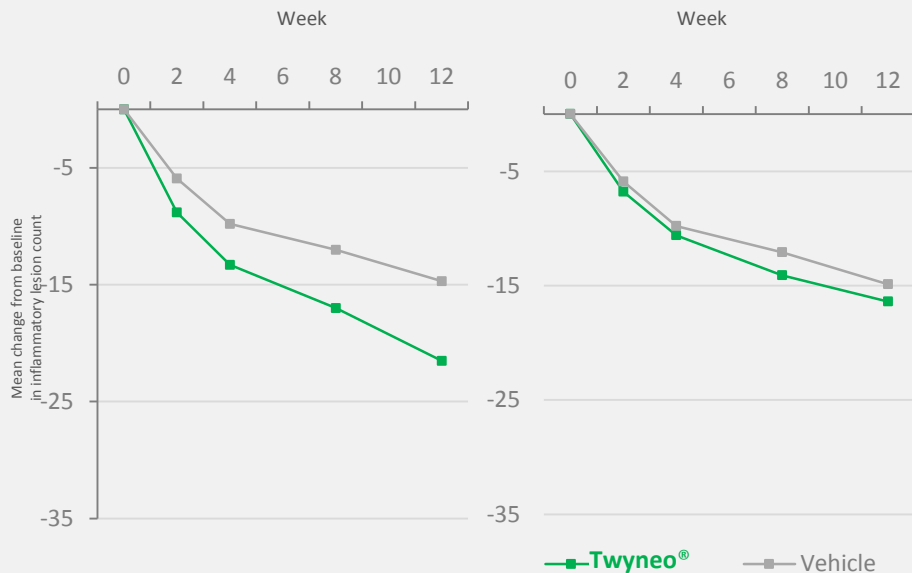
IGA Treatment Success Over Time



*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

SUPPORTIVE EFFICACY ANALYSIS* (ITT)

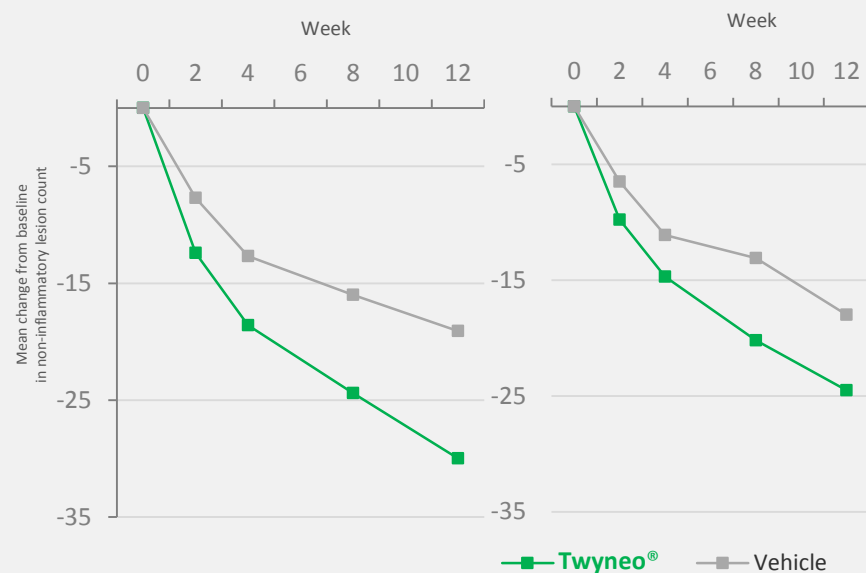
Mean Reduction in Inflammatory Lesion Count Over Time



Study 65-04

Study 65-05

Mean Reduction in Non-Inflammatory Lesion Count Over Time



Study 65-04

Study 65-05

*Mean change from baseline in inflammatory and non-inflammatory lesion counts from baseline to Week 2

SAFETY & TOLERABILITY

Study 65-04

Study 65-05

Most frequent non-cutaneous TEAEs (≥1% in any treatment arm), n (%)	Study 65-04		Study 65-05	
	Twynéo®	Vehicle	Twynéo®	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 Twynéo® and 0 in vehicle
- No treatment-related SAEs were identified in either study
- 2 subjects reported SAEs in Study 65-05; (1) Twynéo® subject reported depression

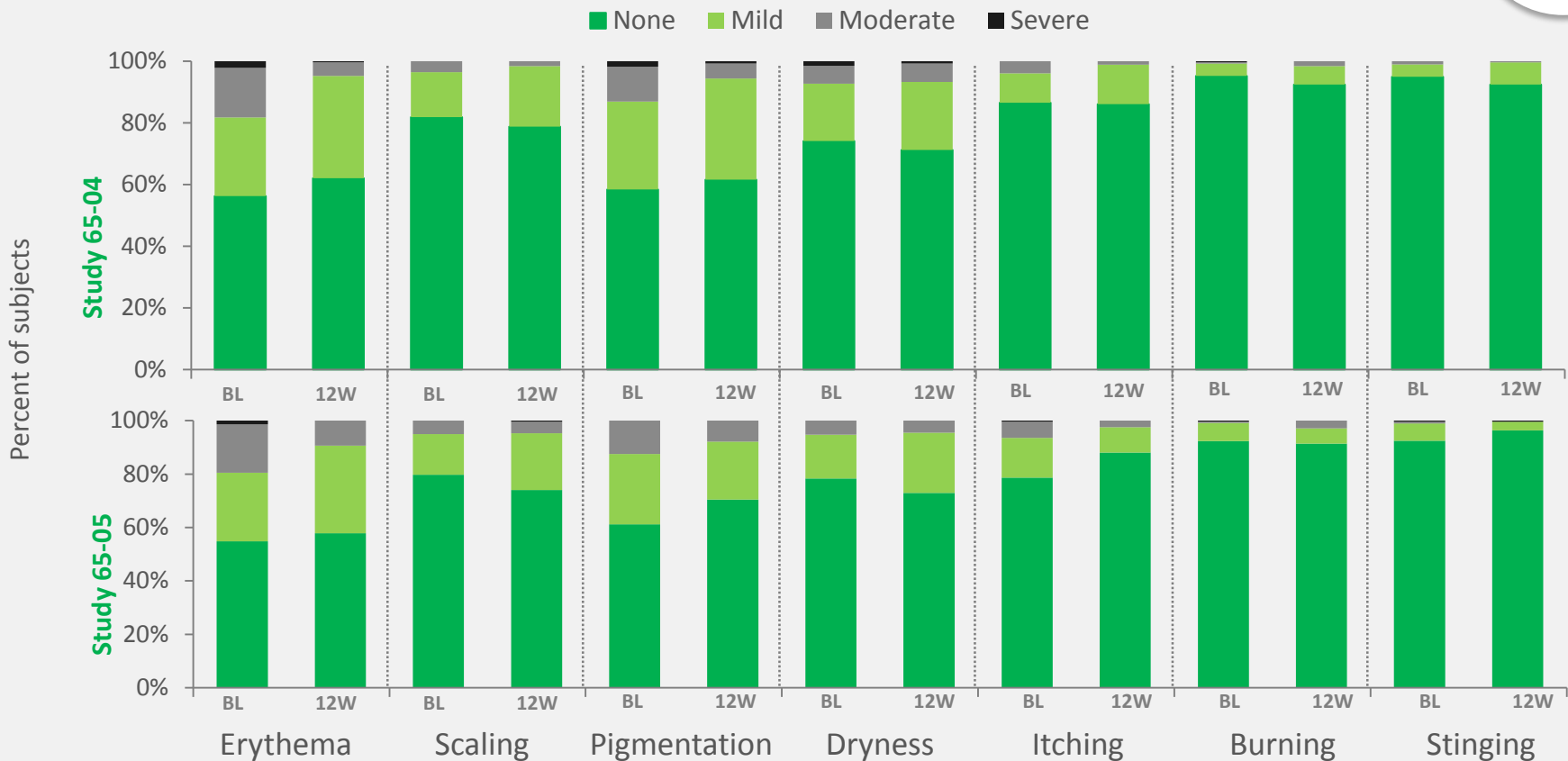
LOCAL SKIN TOLERABILITY ASSESSMENT* AT WEEK 12



Study 65-04	Twynéo® (n=274) %				Vehicle (n=139) %			
	None	Mild	Moderate	Severe	None	Mild	Moderate	Severe
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

*Safety population

LOCAL SKIN TOLERABILITY ASSESSMENTS OVER TIME



Safety population for Study 65-04 (n=274). Safety population for Study 65-05 (n=281). BL=baseline; 12W=12 weeks



TWYNEO® PHASE 3
RESULTS

- Successfully met all primary efficacy endpoints demonstrating statistically significant improvements over vehicle
- No treatment-related serious adverse events
- Safe and 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.

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

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

Baseline



Week 12



Subject: 518-010. Age: 18 years old. Gender: Female. Race: Hispanic or Latino, white

TWYNEO[®] PER-PROTOCOL “FAILURE” IN IGA AND SUCCESS IN INFLAMMATORY LESION COUNT REDUCTION

Baseline



Week 12



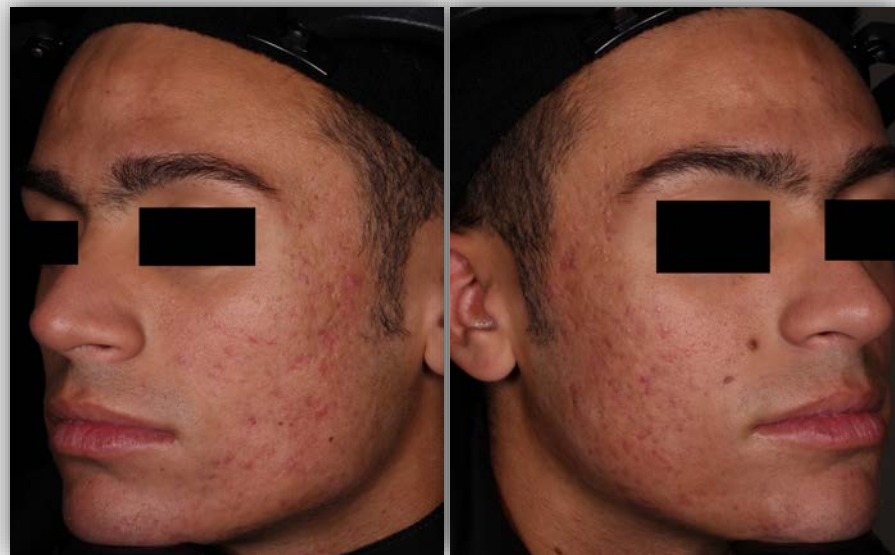
Subject: 507-003. Age: 18 years old. Gender: Female. Race: Hispanic or Latino, white

TWYNEO® PER-PROTOCOL “FAILURE” IN IGA AND SUCCESS IN INFLAMMATORY LESION COUNT REDUCTION

Baseline



Week 12



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



QUESTIONS