Sol-Gel
Advanced Topical Therapy

TWIN Drug Product Candidate

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TWIN's Stability Challenge

- A major challenge in the development of TWIN was to make it stable. Scientific literature reports stability of approved tretinoin products Retin-A Micro® and Atralin® as limited to 7 hours and no stability of tretinoin gel when combined with BPO. As a result, no fixed-dose combination of BPO/tretinoin is available on the market

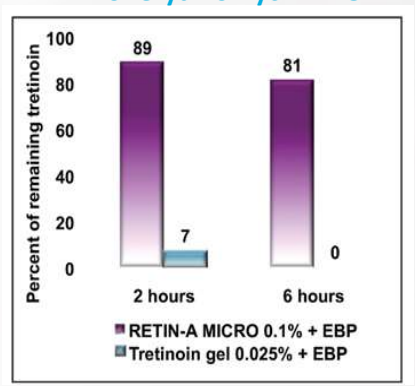
Limited stability of tretinoin in the presence of BPO (various works)

Table 3: BP/Clindamycin Tube Gel + Tretinoin Microsphere Gel 0.1%: 24-Hour Stability Data

Time Point	Percent Theoretical		
	Tretinoin	Benzoyl Peroxide	Clindamycin
0 hr	96%	99%	101%
1 hr	95%	100%	102%
2 hr	92%	100%	105%
4 hr	87%	104%	104%
6 hr	84%	105%	103%
24 hr	56%	102%	106%

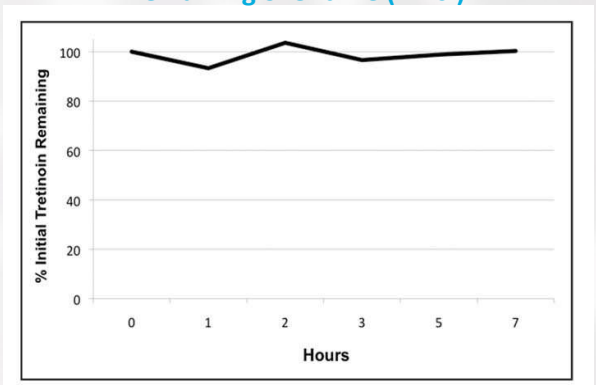
Source: Del Rosso, Cosmetic Dermatol., 2006

Stability in presence of erythromycin-BPO



Source: Kircik, JCAD Online, 2011

Percentage of initial tretinoin in Atralin® remaining over time (7hrs.)



Source: Del Rosso, JCAD Online, 2010

TWIN Drug Candidate

Major challenges in the development of TWIN were instability of tretinoin in the presence of BPO and irritation

Encapsulation allows stabilization and is also expected to contribute to patient compliance

- A once-daily cream containing a fixed-dose combination of encapsulated benzoyl peroxide (E-BPO) and encapsulated tretinoin (E-ATRA)

- Phase II data demonstrated statistical significant improvement over the vehicle regarding all three co-primary efficacy endpoints ($P<0.001$), dose-ranging efficacy and the numerical superiority of the combination over the monads

TWIN Phase II Trial Design

Design	▪ 726 subjects, aged 9 or older were enrolled at 36 sites in the U.S. ▪ Randomized 1:1:1:1:1:1 to receive once daily treatment with TWIN High, TWIN Low, encapsulated tretinoin (“E-ATRA”) high monad, E-ATRA low monad, encapsulated BPO (“E-BPO”) monad, and vehicle ▪ Clinical evaluations performed at weeks 2, 4, 8, and 12 ▪ Study Medical Monitor – Dr. Guy Webster
Main inclusion criteria	▪ Facial acne with >25 and <100 non-inflammatory lesions and >20 and <50 inflammatory lesions ▪ Score of 3 or 4 (“moderate” or “severe”) on a 5-point Investigator Global Assessment (“IGA”) scale ranging from 0 (“clear”) to 4 (“severe”) ▪ Two or fewer cysts or nodules
Co-primary efficacy endpoints	▪ Proportion of subjects with an assessment of “clear” or “almost clear” with at least a 2-grade improvement in IGA at week 12 based on the ITT population ▪ Mean absolute change from baseline in inflammatory and non-inflammatory lesion counts at week 12 based on the ITT population
Efficacy analysis	▪ Statistical superiority in efficacy as compared to the vehicle ▪ Numerical superiority in efficacy of TWIN as compared to encapsulated BPO and encapsulated tretinoin monads
Cutaneous adverse events	▪ Investigator assessment was used for rating of hyper- and hypo-pigmentation, erythema and scaling on a scale ranging from 0 (“none”) to 3 (“severe”) ▪ Patient reported outcome questionnaire was used for assessment of local tolerability rating itching, burning, and stinging on a scale ranging from 0 (“none”) to 3 (“severe”)
Safety assessment	▪ Electrocardiogram (12-lead ECG) was done at baseline, week 2 and week 12 or early termination ▪ Clinical chemistry, hematology and urinalysis were evaluated at baseline, week 8 and week 12 or early termination
Related and emerged adverse events (“AEs”)	▪ Related, probably related or possibly related AEs leading to study discontinuation ▪ Related, probably related or possibly related AEs, which are worsening of a condition present upon entry or noted as medical history

TWIN Phase II Baseline Characteristics (ITT)

Summary of Subject Baseline Characteristics

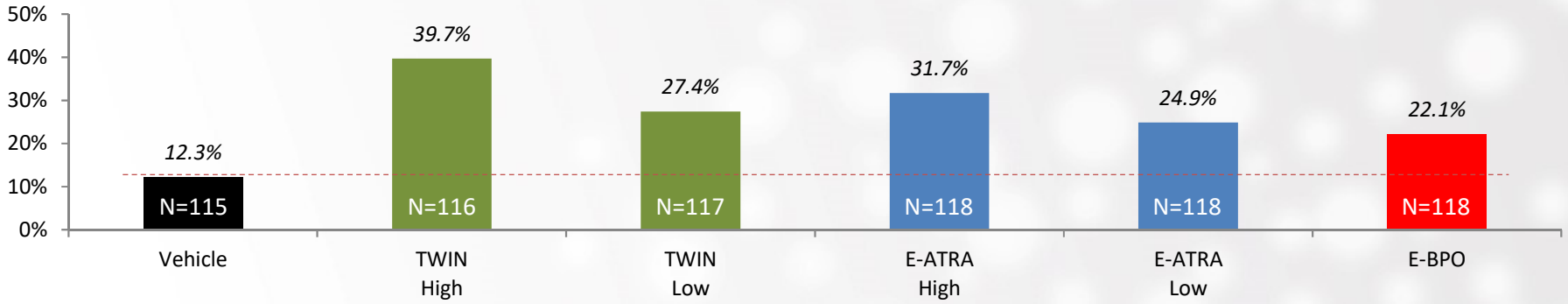
	Vehicle Cream (N=115)		TWIN High (N=116)		TWIN Low (N=117)		E-ATRA High (N=118)		E-ATRA Low (N=118)		E-BPO (N=118)	
Inflammatory Lesion Count												
N	115		116		117		118		118		118	
Mean	28.6		26.7		27.8		26.2		26.7		27.9	
SD	8.31		6.84		8.13		5.74		5.64		7.09	
Median	26.0		25.0		26.0		25.0		25.0		26.0	
Min. to Max.	18 to 50		16 to 49		20 to 86		18 to 48		19 to 46		18 to 50	
Non-Inflammatory Lesion Count												
N	115		116		117		118		118		118	
Mean	42.5		42.9		43.3		42.3		41.6		42.6	
SD	16.80		16.95		17.28		16.57		16.41		17.04	
Median	37.0		38.0		37.0		36.0		35.0		36.5	
Min. to Max.	25 to 98		25 to 98		25 to 100		25 to 91		25 to 96		25 to 96	
Investigator's Global Assessment												
N	115		116		117		118		118		118	
0 – Clear	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
1 – Almost Clear	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
2 – Mild	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
3 – Moderate	102	(88.7%)	102	(87.9%)	104	(88.9%)	107	(90.7%)	102	(86.4%)	101	(85.6%)
4 – Severe	13	(11.3%)	14	(12.1%)	13	(11.1%)	11	(9.3%)	16	(13.6%)	17	(14.4%)

Source: Clinical Study Report for SGT-EBPO1-09, December 2012

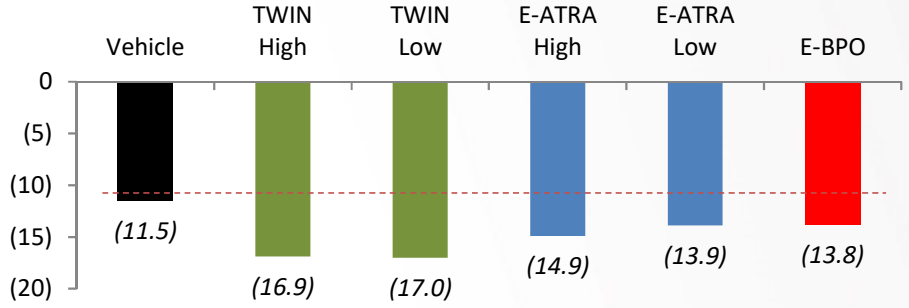
TWIN Phase II Trial Co-Primary Efficacy Results (ITT)

Success in Dichotomized IGA at Week 12

	Vehicle	TWIN High	TWIN Low	E-ATRA High	E-ATRA Low	E-BPO
P-value vs. vehicle		*<0.001*	*0.006*	*0.001*	*0.015*	

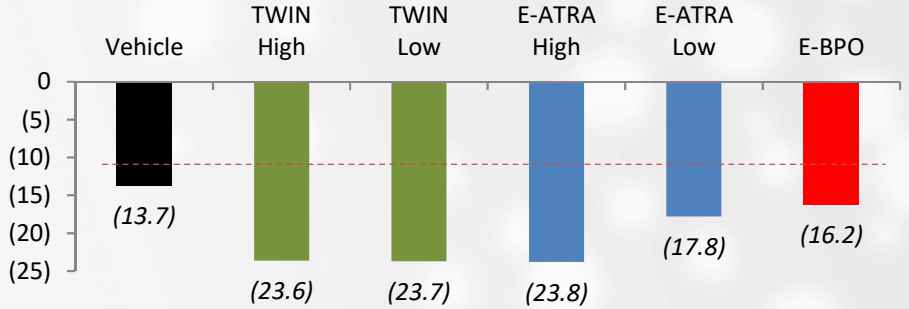


Inflammatory Lesion Mean Absolute Change from Baseline at Week 12



	Vehicle	TWIN High	TWIN Low	E-ATRA High	E-ATRA Low	E-BPO
P-value vs. vehicle		*<0.001*	*<0.001*	*0.003*	*0.060*	

Non-Inflammatory Lesion Mean Absolute Change from Baseline at Week 12



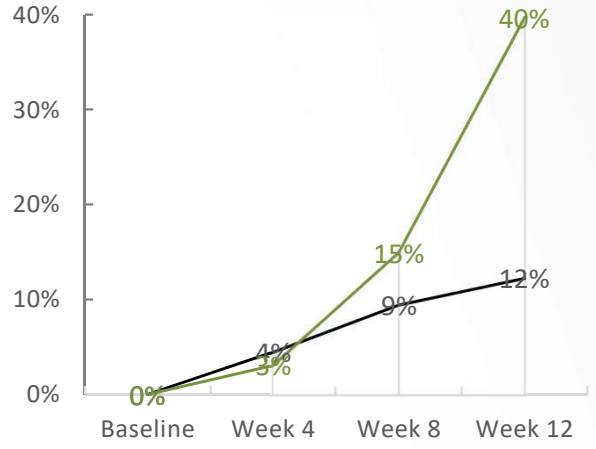
	Vehicle	TWIN High	TWIN Low	E-ATRA High	E-ATRA Low	E-BPO
P-value vs. vehicle		*<0.001*	*<0.001*	*<0.001*	*0.002*	

TWIN Co-Primary Efficacy Results Over Time (ITT)

The success in IGA at week 12, the decrease from baseline in inflammatory lesions at week 8 and12 and for non-inflammatory lesion count at weeks 4, 8 and 12, respectively, were statistically significantly greater than for vehicle

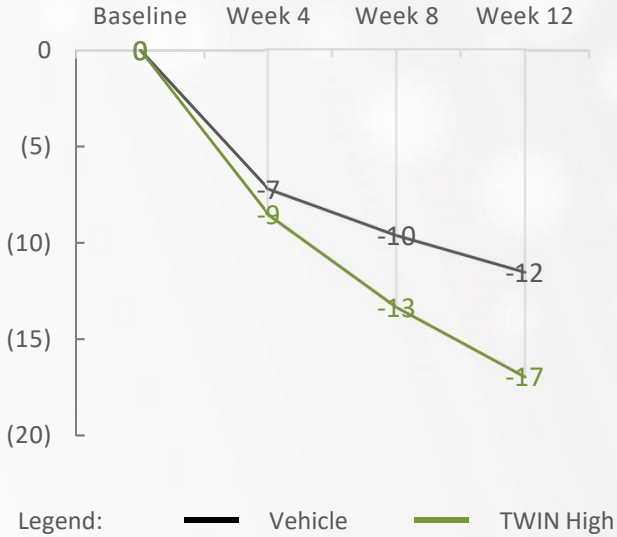
Success in IGA

P-value vs. vehicle *<0.001*



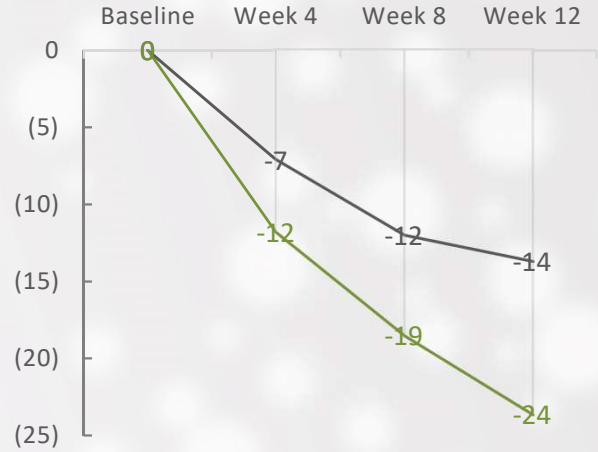
Change in Inflammatory Lesion Count

P-value vs. vehicle *0.001* *<0.001*



Change in Non-Inflammatory Lesion Count

P-value vs. vehicle *0.011* *<0.001* *<0.001*

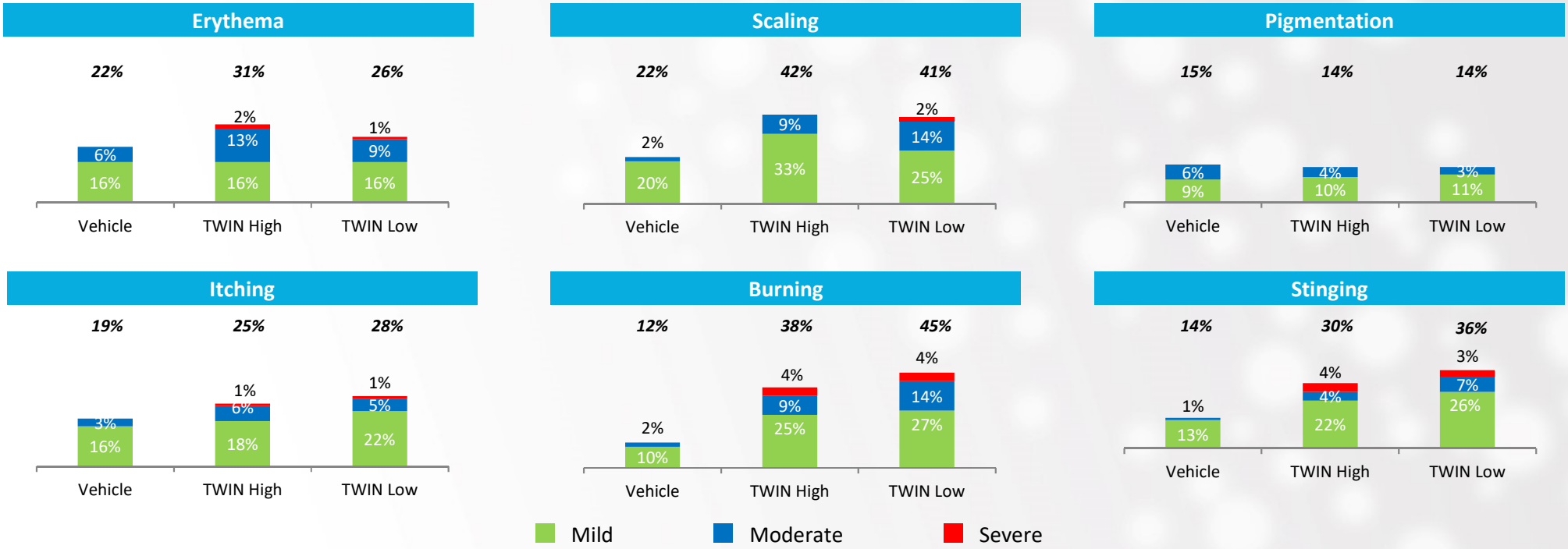


TWIN Phase II Cutaneous Tolerability Results

TWIN was generally well-tolerated. Majority of the cutaneous adverse events were mild

Proportion of Subjects with Post-Baseline Worsening of Cutaneous Side Effects (Safety Population)

Max. Post-Baseline > Baseline



Epiduo Forte®: Erythema (44%), scaling (48%), dryness (62%), and stinging/burning (65%)

Source: Clinical Review #207917