Sol-Gel
Advanced Topical Therapy

VERED Drug Product Candidate

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VERED Drug Candidate

Benzoyl peroxide is an oxidizing agent that successfully treats inflamed lesions

Encapsulation was designed to reduce irritation and is expected to contribute to patient compliance

- A once-daily cream containing encapsulated benzoyl peroxide (E-BPO), 5%

- VERED Phase II data demonstrated statistical significant improvement over the vehicle and dose-ranging efficacy

VERED Phase II Trial Design

Design	▪ A total of 92 subjects aged 18 and older were enrolled at 10 sites ▪ Participants were randomly assigned in a 1:1:1 ratio to receive once daily treatment with VERED 5%, with VERED 1% or with vehicle for 12 weeks ▪ Clinical evaluations were performed at weeks 2, 4, 8, and 12
Main inclusion criteria	▪ Facial rosacea with 12 or more inflammatory lesions ▪ Have a score of 2, 3 or 4 (“mild”, “moderate” or “severe”) on a 5-point IGA scale ranging from 0 (“clear”) to 4 (“severe”)
Co-primary efficacy endpoints	▪ For the primary measure of success at week 12, the proportion of subjects with successes and failures were tabulated ▪ Inflammatory lesion count change from Baseline at week 12 was summarized using descriptive statistics
Efficacy analysis	▪ Descriptive statistics were used to evaluate data trends and to establish the effect size of the difference VERED 1% and VERED 5%, and Vehicle groups with regard to success rate, IGA outcomes, inflammatory lesion counts, and inflammatory lesion erythema, rosacea erythema, and telangiectasia assessment scores
Cutaneous adverse events	▪ In order to assess tolerability, dryness, scaling, pruritus, stinging and burning were rated on a scale of 0 to 3 (“none”, “mild”, “moderate”, “severe”)
Related adverse events	▪ Any subject who experienced a tolerability assessment that was “moderate” or “severe” and the investigator deemed interruption of test medication, this tolerability assessment was recorded as an adverse event

VERED Phase II Baseline Characteristics (ITT)

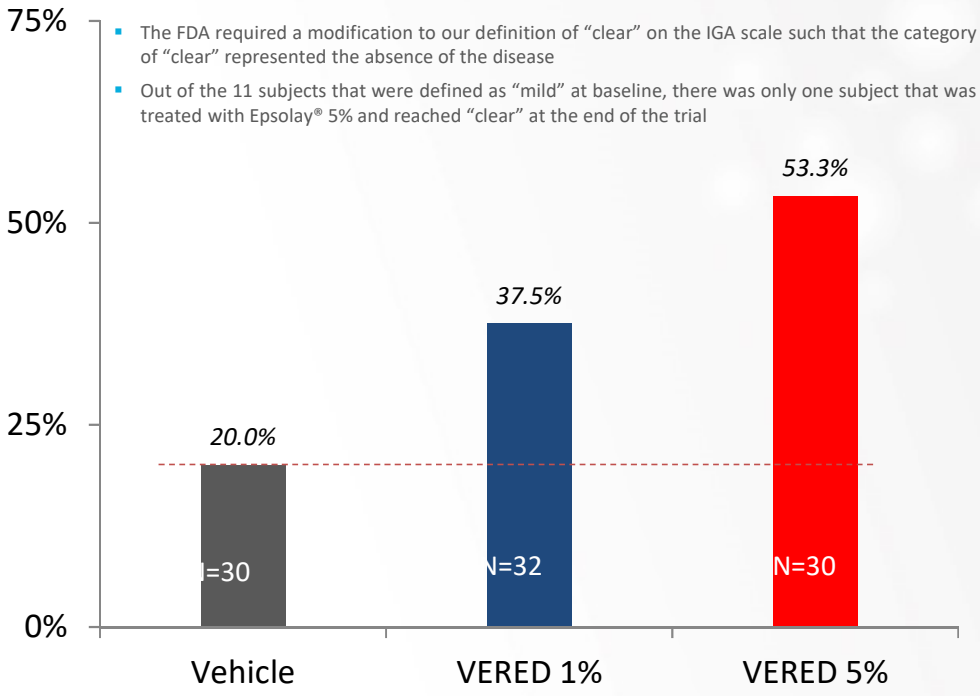
Summary of Subject Baseline Characteristics						
	Vehicle (N=30)		**VERED 1%** (N=32)		**VERED 5%** (N=30)	
Inflammatory Lesion Count						
Mean	19.9		28.6		22.9	
SD	8.64		27.76		16.89	
Median	17.5		17.5		18.0	
Min. to Max	12 to 52		12 to 130		12 to 104	
Investigator's Global Assessment						
0 – Clear	0	(0.0%)	0	(0.0%)	0	(0.0%)
1 – Almost Clear	0	(0.0%)	0	(0.0%)	0	(0.0%)
2 – Mild	4	(13.3%)	3	(9.4%)	4	(13.3%)
3 – Moderate	23	(76.7%)	24	(75.0%)	21	(70.0%)
4 – Severe	3	(10.0%)	5	(15.6%)	5	(16.7%)

VERED Phase II Co-Primary Efficacy Results (ITT)

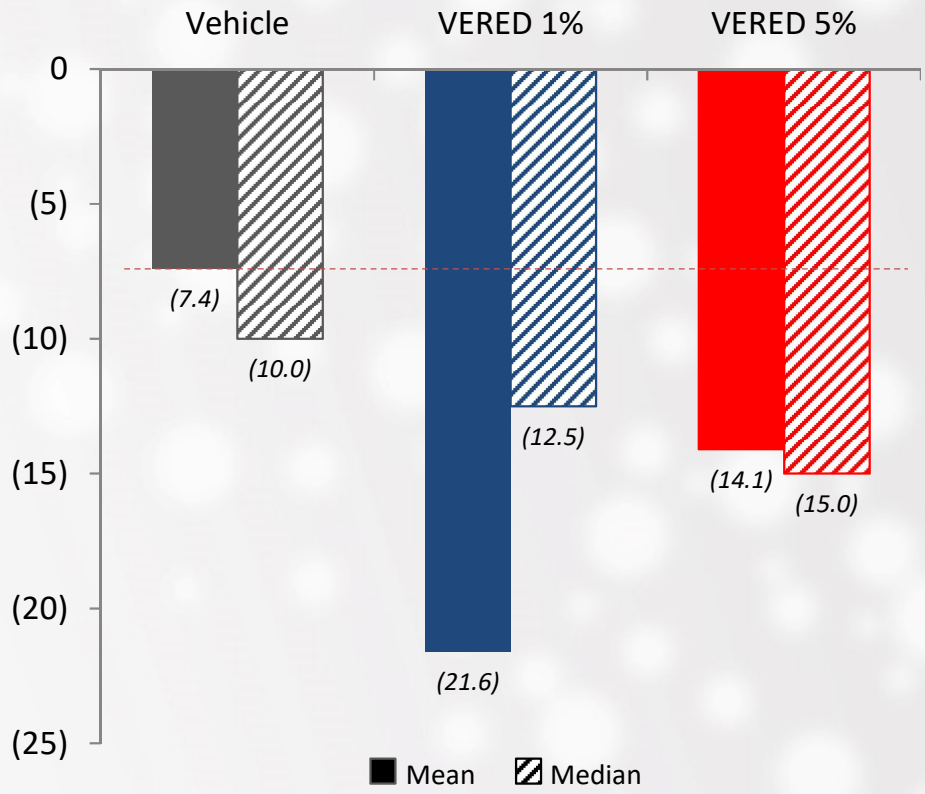
Success in Dichotomized IGA at Week 12

P-value vs. vehicle *0.0013*

- The FDA required a modification to our definition of "clear" on the IGA scale such that the category of "clear" represented the absence of the disease
- Out of the 11 subjects that were defined as "mild" at baseline, there was only one subject that was treated with Epsolay® 5% and reached "clear" at the end of the trial



Inflammatory Lesion Count – Change from Baseline at Week 12



VERED Phase II Cutaneous Tolerability Results

VERED 5% and VERED 1% were well-tolerated