ClarityMD™ Clinical Study

The safety and efficacy of twice-daily use of the ClarityMD Acne Solution (Deep Pore Cleanser and Clarifying Gel) was assessed in a 6-week open-label clinical study in 25 male and female volunteers, ages 12-35, having mild to moderate acne vulgaris. Efficacy was measured as a function of mean change from baseline in number of inflammatory and non-inflammatory acne lesions at weeks 1, 2, 4 and 6 as shown in Table 1.

Table 1: Mean percent change from baseline in acne lesions

	Week 1	Week 2	Week 4	Week 6
Inflammatory	**-59.06%** (± 31.38)	**-91.62%** (± 20.68)	**-90.85%** (± 16.23)	**-98.55%** (± 4.092)
p-value	< 0.0001	< 0.0001	< 0.0001	< 0.0001
Non - Inflammatory	**-13.54%** (±35.74)	**-38.95%** (± 28.53)	**-44.48%** (± 25.29)	**-56.10%** (± 28.77)
p-value	0.0520	< 0.0001	< 0.0001	< 0.0001

Visual improvements in acne were demonstrated using standardized digital photography using the Canfield Visia® CR photography system as shown in figure 1.

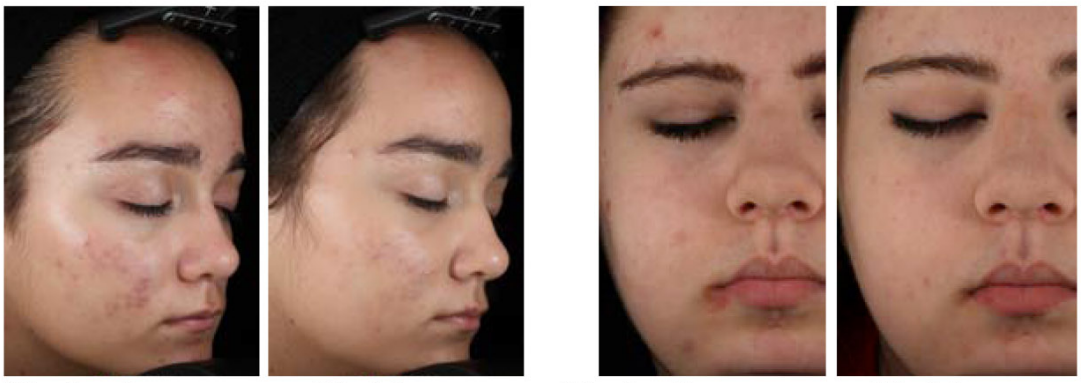

Figure 1: (*A*) Inflammatory acne lesions before and one week after twice-daily application of ClarityMD Acne Solution. (*B*) Inflammatory acne lesions before and six weeks after twice-daily application of ClarityMD Acne Solution.

The tolerability of the ClarityMD™ Acne Solution was assessed by a trained technician using a 4-point grading scale to measure the severity of erythema, dryness and edema in the facial skin of study volunteers, as shown in Figure 2, throughout the study.

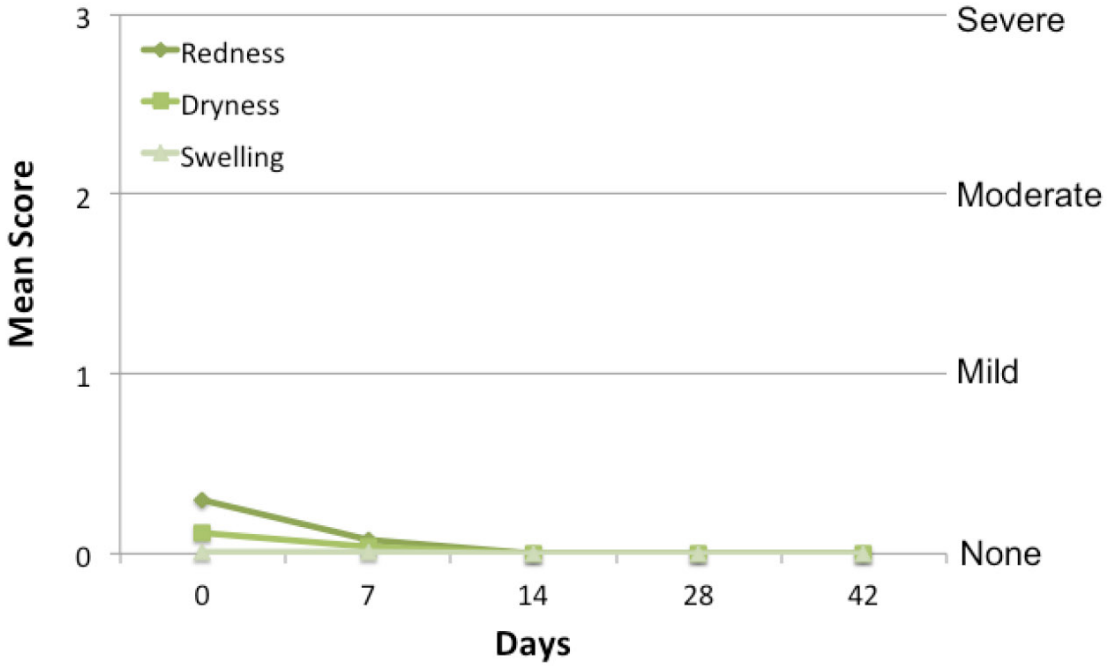

Figure 2: Mean tolerability scores are graphed as a function of time.

CONCLUSION

The results of this clinical study indicate that twice-daily use of the ClarityMD™ Acne Solution was well-tolerated by all study volunteers and that its onset of action is rapid, capable of producing over 50% reduction in inflammatory acne lesions in as little as 7 days.

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