M89, A COMBINATION OF 89% OF VICHY VOLCANIC MINERALIZING WATER AND HYALURONIC ACID IMPROVES SIGNS AND SYMPTOMS OF SUBJECTS WITH ROSACEA/SENSITIVE/REACTIVE SKIN: RESULTS FROM AN OPEN-LABEL, OBSERVATIONAL, INTERNATIONAL STUDY

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INTRODUCTION

Rosacea is a common chronic inflammatory skin disease characterised by persistent erythema associated with periodic intensification or 'flares'.[1-3]

The syndrome of sensitive or reactive skin is characterized by abnormal and unpleasant sensations, such as burning, stinging, and itching, manifests as exaggerated responses to stimuli.[4, 5] Sensitive skin may occur in individuals with normal skin, with skin barrier disturbance, or as a part of the symptoms associated with rosacea, atopic dermatitis and psoriasis.[6]

M89 contains 89% Vichy volcanic mineralizing water and 0.4% hyaluronic acid in a minimalist formulation was developed to reinforce the skin barrier and to protect against exposome factors. It is hypoallergenic and contains no perfume, thus being suitable for subjects with rosacea. It reinforces the natural defences of the skin in restoring the natural skin barrier, stimulating antioxidant activity and reducing inflammation, which is commonly observed in subjects with rosacea.[7-10]

Recent interim analysis of this large international study conducted in subjects with inflammatory dermatoses or having undergone dermatological procedures confirmed the benefit and excellent tolerance of M89.[11]

AIM

The aim of this poster is to present the efficcacy and tolerability of M89 in a subgroup of adult subjects with rosacea/sensitive/reactive skin after 4 weeks of daily use.

METHODOLOGY

A large international, multicenter observational study has been conducted in subjects either with facial dermatoses or post procedures, who received M89 once or twice daily for 4 weeks. A subgroup of 510 subjects with rosacea/sensitive/reactive skin was analysed. Data about demographics, skin characteristics, subject efficacy perception, tolerance, and investigator satisfaction were collected after 4 weeks. Subjects scored their satisfaction after 1 and 4 weeks of use.

RESULTS

Overall, 93.3% of the subjects were women; the mean age was 39.3±11.2 years. 50.8% had phototype II and 31.9% phototype III. At baseline, 64.9% had dry or very dry skin and 92.1% sensitive skin. 78.2% had erythema, 56.4% desquamation and 47.2% irritation. On a scale from 0 to 10, subjects scored dryness 5.7±2.6, burning 3.6±2.8, itching 2.2±2.9 and stinging/tingling 3.1±2.7; 81.0% considered that their skin was insufficiently hydrated.

Subject demographics and skin characteristics are provided in Table 1. Incidence and severity of clinical signs are given at baseline in Table 2.

Figure 1 shows shifts from severity stages between study start and end of study for clinical signs of subjects with signs at baseline. After 4 weeks, dermatologists assessed that the proportion of subjects with erythema, irritation, desquamation at baseline who showed a significant improvement ($p<0.0001$) was 68.2%, 82.1%, and 92.2%, respectively.

Figure 2 shows mean symptom scores at study start and end of study for the same population. Scores for dryness, burning, itching and stinging/tingling when present at baseline, had decreased by 65.9%, 80.6%, 68.8% and 80.4%, respectively (all $p\leq0.0001$) after 4 weeks. Skin hydration had improved in 77.9% of subjects.

At study end, 98.4% were satisfied with the texture of M89 with a mean satisfaction score of 8.9±1.6 out of 10. After applying M89 for one week, 86.2% reported soothed or very soothed skin increasing up to 97.4% until week 4; investigator satisfaction was high or very high in 97.2% of subjects.

Tolerance was rated as good or very good by 98.6% of subjects.

DEMOGRAPHICS AND SKIN CHARACTERISTICS

Table 1

	Total	
	n	%
Gender	**508**	**100**
Female	474	93.3
Male	34	6.7
Age	**503**	**100**
Mean ± SD	39.3 ± 11.2	
Median	39.0	
Min;Max	18.0;88.0	
Phototype	**508**	**100**
I	52	10.2
II	258	50.8
III	162	31.9
IV	34	6.7
V	2	0.4
Skin type	**507**	**100**
Very dry	46	9.1
Dry	283	55.8
Normal	75	14.8
Combination	87	17.2
Oily	15	3.0
Very oily	1	0.2
Sensitive skin	**507**	**100**
Yes	467	92.1
No	40	7.9

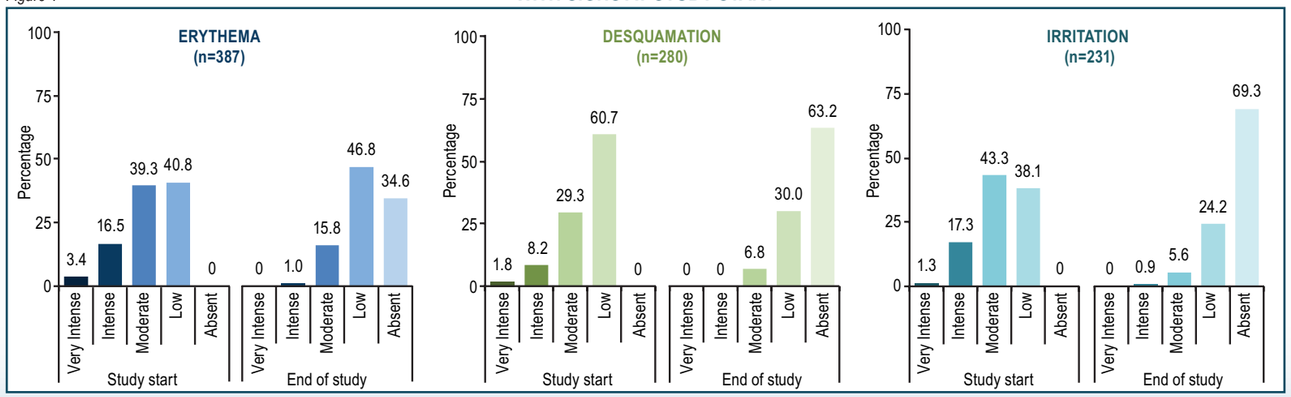
CLINICAL SIGNS ASSESSED BY THE INVESTIGATORS AT STUDY START

Table 2

	Total	
	n	%
Erythema	**503**	**100**
Very intense	13	2.6
Intense	65	12.9
Moderate	155	30.8
Low	159	31.6
Absent	111	22.1
Desquamation	**505**	**100**
Very intense	5	1.0
Intense	25	5.0
Moderate	82	16.2
Low	171	33.9
Absent	222	44.0
Irritation	**503**	**100**
Very Intense	3	0.6
Intense	41	8.2
Moderate	102	20.3
Low	88	17.5
Absent	269	53.5

SHIFT OF SEVERITY GRADES OF CLINICAL SIGNS (% OF SUBJECTS) FROM STUDY START TO STUDY END IN SUBJECTS WITH SIGNS AT STUDY START

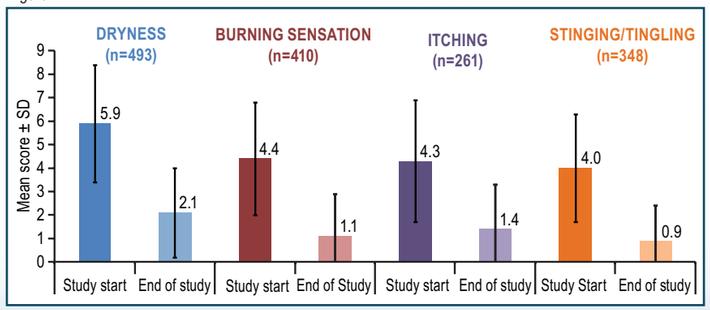
Figure 1



The difference in prevalence of subjects with improved clinical signs was statistically significant ($p<0.0001$) after 4 weeks compared to study start.

MEAN CLINICAL SYMPTOM SCORES AT STUDY START AND AT END OF STUDY FOR SUBJECTS WITH SYMPTOMS AT STUDY START

Figure 2



The decrease of mean scores at study end was statistically significant ($p<0.0001$).

CONCLUSION

M89 improves clinical signs and symptoms of subjects with rosacea/sensitive/reactive skin as an adjunct to standard management, with high tolerability and satisfaction.

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Conflict of interest

Delphine Kerob is an employee of Vichy Laboratories, France. Jerry Tan, Julieta Spada, Cecilia Orlandi, Martina Kerscher and Elena Araviskaia were Vichy Laboratories members of advisory boards organized by Vichy Laboratories France. The other authors have no conflict of interest to disclose.

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