M89, A COMBINATION OF 89% VICHY MINERALIZING WATER AND HYALURONIC ACID REINFORCES THE SKIN BARRIER AND SHOWS EFFICACY AND HIGH TOLERABILITY IN VARIOUS FACIAL INFLAMMATORY DERMATOSES AND ESTHETIC PROCEDURES AS ADJUNCT

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INTRODUCTION

The skin exposome comprises several external and internal factors including UV radiation, climatic conditions (heat and humidity), medications, pollution, stress, and dermatology procedures that may damage the skin barrier, induce skin diseases or accelerate skin ageing.[1-5]

Mineral 89 (M89, Vichy Laboratoires), containing 89% Vichy mineralizing water recognized to be a volcanic mineralizing water and hyaluronic acid, was developed to reinforce the natural skin barrier and to protect it against exposome factors.[6-9]

AIM OF THE STUDY

The aim of this study was to assess the efficacy and tolerability of M89 in subjects with facial inflammatory dermatoses including rosacea/sensitive/reactive skin, and in adult subjects undergoing dermatology procedures.

METHODS

Adults with facial inflammatory dermatoses or having undergone esthetic procedures applied M89 twice daily for 4 weeks as adjuvant to their standard treatment. Clinical evaluations took place at baseline and at the end of the study. A dermatologist assessed M89 efficacy in reducing the cutaneous clinical signs present at inclusion, such as erythema, desquamation and irritation, on a scale ranging from 0 (absent) to 4 (very intense).

Subjects assessed their cutaneous symptoms (dryness, burning sensation, itching, stinging/tingling) on a scale from 0 (absent) to 10 (most intense), at both the initial and the final visit. After 4 weeks of M89 daily use, physician global satisfaction was assessed on a scale from 0 (unsatisfied) to 3 (very satisfied); subject satisfaction was assessed using a visual scale (0 = very unsatisfied to 10 = very satisfied).

This poster presents results for the global study presentation as well as results for subjects with rosacea/sensitive/reactive skin.

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RESULTS

Global study population

A total of 1743 subjects were included; 1630 were suitable for statistical analysis. 67.5% (1101/1630) underwent a dermatology procedure and 32.5% (529/1630) had a dermatological condition including rosacea/sensitive/reactive skin. Mean age was 41.1 ± 11.3 years; 92.5% (1506/1628) were women. At study start, more than half (57.9%; 942/1627) of the subjects had dry skin, and 67.7% (1094/1617) had sensitive skin (Table 1).
A majority of subjects had erythema (56.7%; 922/1625), desquamation (56.1%; 912/1627), and skin irritation (57.5%; 934/1625) (Table 2).
After 4 weeks of M89 use, clinical signs (erythema, irritation, desquamation) were significantly less severe (p<0.0001; Figure 1). Skin hydration had increased in 74.6% (1186/1589) of subjects.
Patient symptoms such as dryness, burning, pruritus, and stinging/tingling had significantly improved (p<0.0001; Figure 2).
In the procedure group, erythema had resolved or improved in 72.5%, desquamation in 75.2%,and irritation in 88.1%. Dryness, burning, itching and stinging/tingling scores had decreased by 62.1%, 78.8%, 70.0% and 84.2%, respectively (all p≤0.0001); 74.1% considered that their skin was sufficiently hydrated.
At study end, a large majority of subjects (98.2%; 1591/1620) were satisfied with the texture of M89. The mean satisfaction score was 8.4 ± 1.8 out of 10 after applying M89 for one week and 9.0 ± 1.6 after 4 weeks.
In a large majority (97.4%; 1559/1600) of subjects, investigator's satisfaction was high or very high.
After applying M89 for one week, 91.9% (1496/1628) of subjects reported that their skin was soothed or very soothed; after 4 weeks, this percentage increased to 97.7% (1584/1622). M89 tolerability was excellent. Overall, M89 was well- or very well-tolerated by 98.5% (1602/1626) of subjects.

Table 1

DEMOGRAPHICS AND SKIN CHARACTERISTICS AT STUDY START

	Total		Rosacea Sensible/Reactive skin	
	n	%	n	%
Gender	**1628**	**100**	**308**	**100**
Female	1506	92.5	296	96.1
Male	122	7.5	12	3.9
Age	**1615**	**100**	**308**	**100**
Mean ± SD	41.1 ± 11.3		39.1 ± 11.2	
Median	41.0		39.0	
Min; Max	18;88		21;88	
Phototype	**1615**	**100**	**307**	**100**
I	136	8.4	29	9.4
II	739	45.8	160	52.1
III	621	38.5	101	32.9
IV	108	6.7	16	5.2
V	10	0.6	1	0.3
VI	1	0.1	0	0
Skin type	**1627**	**100**	**308**	**100**
Very dry	158	9.7	28	9.1
Dry	784	48.2	198	64.3
Normal	260	16.0	48	15.6
Combination	325	20.0	31	10.1
Oily	96	5.9	3	1.0
Very oily	4	0.2	0	0
Sensitive skin	**1617**	**100**	**307**	**100**
Yes	1094	67.7	277	90.2
No	523	32.3	30	9.8

Table 2

CLINICAL SIGNS ASSESSED BY THE INVESTIGATORS AT STUDY START

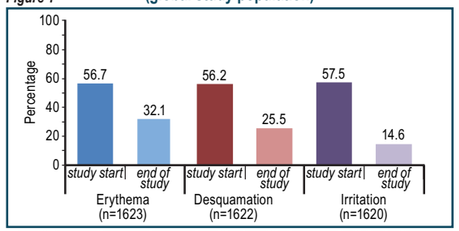
	Total		Rosacea Sensible/Reactive skin	
	n	%	n	%
Erythema	**1625**	**100**	**309**	**100**
Yes	922	56.7	239	77.3
No	703	43.3	70	22.7
Grade	1609	100	307	100
Very intense	43	2.7	11	3.6
Intense	141	8.8	32	10.4
Moderate	356	22.1	72	23.5
Low	366	22.7	122	39.7
Absent	703	43.7	70	22.8
Desquamation	**1627**	**100**	**308**	**100**
Yes	912	56.1	212	68.8
No	715	43.9	96	31.2
Grade	1622	100	308	100
Very intense	31	1.9	4	1.3
Intense	102	6.3	17	5.5
Moderate	297	18.3	59	19.2
Low	477	29.4	132	42.9
Absent	715	44.1	96	31.2
Irritation	**1625**	**100**	**308**	**100**
Yes	934	57.5	109	35.4
No	691	42.5	199	64.6
Grade	1612	100	307	100
Very Intense	26	1.6	1	0.3
Intense	113	7.0	12	3.9
Moderate	540	33.5	46	15.0
Low	242	15.0	49	16.0
Absent	691	42.9	199	64.8

Subjects with rosacea/sensitive/reactive skin

At study start, 19.0% (309/1630) of subjects had rosacea and/or sensitive and/or reactive skin as diagnosed by the dermatologist. Mean age was 39.1 ± 11.2 years; 96.1% (296/308) were women. Overall, 73.4% (226/308) of subjects had dry or very dry skin and 90.2% (277/307) had sensitive skin (Table 1). A majority in this subpopulation had erythema (77.3%; 239/309), desquamation (68.8%; 212/308), and skin irritation (35.4%; 109/308) at baseline. Most subjects (85.8%; 260/303) had poorly or very poorly hydrated skin (Table 2).
After 4 weeks of M89, clinical signs (erythema, irritation, desquamation) were significantly less severe (p<0.0001; Figure 3), and skin hydration had significantly improved (77.3%; 231/299) (p<0.0001).
Patient symptoms such as dryness, burning, pruritus, and stinging/tingling had significantly improved (p<0.001; Figure 4).
A large majority of subjects (98.7%; 301/305) were satisfied with M89 texture. The mean satisfaction score was 8.7 ± 1.6 out of 10 after applying M89 after one and 9.0 ± 1.5 after 4 weeks of daily use. In a large majority of subjects (98.3%; 292/297) was high or very high.
After applying M89 for one week, 94.5% (292/309) reported that their skin was soothed or very soothed; after 4 weeks this increased to 98.4% (304/309).
M89 tolerability was excellent. Overall, M89 was well- or very well-tolerated by 99.7% (308/309) of subjects with rosacea/sensitive/reactive skin.

PREVALENCE OF SUBJECTS WITH CLINICAL SIGNS AT STUDY START AND AT END OF STUDY (global study population)

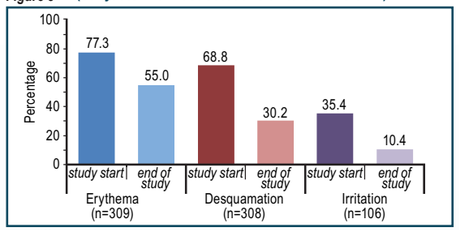
Figure 1



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

PREVALENCE OF SUBJECTS REPORTING CLINICAL SIGNS AT STUDY START AND AT END OF STUDY (subjects with rosacea/sensitive/reactive skin)

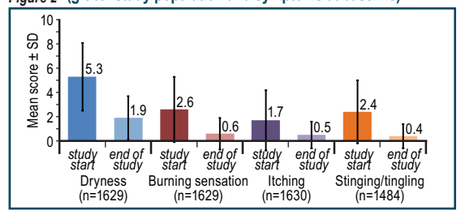
Figure 3



The difference in prevalence of subjects with improved clinical signs at week 4 was statistically significant (p≤0.0001) compared to baseline.

MEAN CLINICAL SYMPTOM SCORES AT STUDY START AND AT END OF STUDY (global study population and symptoms at baseline)

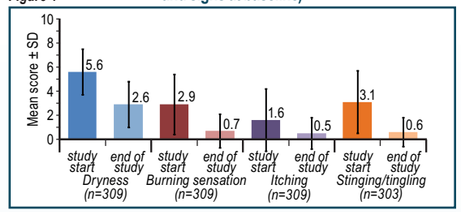
Figure 2



The mean score for skin dryness had decreased by 62.6%, for burning sensation by 79.9%, for itching sensation by 70.3% and for stinging/burning tingling by 84.5%. The decrease was statistically significant (p<0.0001).

MEAN CLINICAL SYMPTOM SCORES AT BASELINE AND AT STUDY START AND AT END OF STUDY (subjects with rosacea/sensitive/reactive skin and signs at baseline)

Figure 4



Mean symptom scores for skin dryness had decreased by 68.2%, for burning sensation by 85.5%, for itching sensation by 64.3% and for stinging/tingling sensation by 87.0%. The decrease was statistically significant (all p<0.0001).

CONCLUSIONS

M89, a combination of 89% VMW and hyaluronic acid significantly improves skin signs and symptoms after 4 weeks of continued use with no tolerance issues in subjects with dermatological indications such as rosacea, sensitive and reactive skin, as well as in subjects who had recently undergone esthetic procedures. M89 was well-tolerated and provided high subject and investigator satisfaction.

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