Title:	**Report on an Open-Label, Multicenter, Single-arm Clinical Study, to Evaluate the Safety and Efficacy of eXXema Repair Cream for Treatment of Atopic Dermatitis: Twice Daily Treatments for 30 Days**
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Clinical Investigation Plan:	YM BI 2009
Relevant Standard:	Investigation was carried out in accordance with standard ISO 1415: 2010
Risk Assessment:	The sponsor has determined that this is a Non-Significant Risk study
Date of Report:	October 18, 2010
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Summary:

Objective: An open-label multicenter post-market surveillance (PMS) clinical trial was conducted to evaluate the safety and efficacy of eXXema Repair Cream a bio-active non-steroidal topical medical device, for the treatment of atopic dermatitis. **Methods**: The intent of the study was to determine therapeutic response of patients exhibiting dermatitis of light to moderate severity. A series of 227 patients of varying ages were enrolled in the study. Following baseline evaluations, all patients were placed on therapy with eXXema Repair Cream consisting of twice daily applications to a targeted area of atopic dermatitis. Two follow-up evaluations were scheduled, at 15 days, and at study termination at 30 days. The study initiation date was February 16, 2010, with final evaluation of the last patient on July 12, 2010. Baseline and follow-up evaluations consisted of clinical assessment using the EASI and SCORAD instruments to obtain severity scores. Dimensions (height, width) of the affected areas were measured with the aid of photographic image analysis. The occurrence of any adverse events during the course of the trial was also noted. **Results**: Statistically significant decreases in EASI (76.1 ± 31.6 %, $p < 0.0001$) and SCORAD (74.6 ± 29.6 %, $p < 0.0001$) scores were obtained over the study course. Likewise, significant reductions in the height (64.7 ± 37.2 %, $p < 0.0001$) and width (65.6 ± 38.7 %, $p< 0.0001$) of areas affected by dermatitis were recorded. Finally, there were no (0 %) adverse events of any type recorded in this trial. **Conclusions**: Twice-daily topical application of eXXema Repair Cream for 30 days provided a safe and effective treatment of

patients with light to moderate atopic dermatitis, in a study population of children and adults.

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1. INTRODUCTION

The skin is the largest of the body organs, covering all exposed body surfaces. Far from being a passive enclosure simply arranged to contain the internal body parts, skin actually serves a number of vital functions in its own right. Encompassing important attributes such as in protecting against injury, infection, heat, cold, and prevention of uncontrolled water loss, healthy skin is indeed a critical component of overall health. The human skin is an amazingly adaptable tissue capable of self-repair and complete turnover in a relatively short period of time. The skin is also tough enough to resist environmental assaults, yet endowed with finely tuned sensory elements capable of registering a variety of subtle environmental cues including temperature, humidity, or the passage of a gentle breeze. The barrier function of skin represents a first line of defense against possible invasion by bacteria and germs, while maintaining the body's internal temperature to within a few degrees of normal. The skin also secretes lubricants, and blocks entrance of toxic substances.

Any change to skin structure that impacts function poses a threat to overall health. One such condition is atopic dermatitis, a chronic skin disorder characterized by structural and functional breakdown of the skin. While a complete understanding of the causes of atopic dermatitis remains elusive, it is thought to involve both environmental sensitivity and genetic predisposition.[1] A defining aspect of atopic dermatitis is the local loss of skin integrity, particularly as relates to skin as a barrier to water permeability and microorganism invasion, protection from ultraviolet irradiation and oxidation, and regulatory and signaling functionality.

The disease is common, and most often begins in childhood. While up to 75% of cases can resolve by adolescence, a significant proportion of patients continue to have recurrent difficulties into adulthood. Symptoms include development of chronic dermal lesions which are frequently accompanied by severe pruritus and excoriations. Lesions may be dry and scaly, but can also exhibit weeping, crusting and exudation, reflective of secondary staphylococcal infection.[2]

A number of therapeutic means are available for reducing frequency and severity of dermatitis outbreaks, including topical anti-inflammatory agents, systemic antibiotics, emollients along with other means of skin hydration, and systemic antibiotic treatment aimed primarily towards opportunistic infection by *Staphylococcus aureus*. In addition, topical corticosteroids have a long history of use in management of atopic dermatitis, particularly for controlling acute flare-ups.[3] While being effective, there is a down side to the use of corticosteroids. Such agents can result in skin atrophy, a particularly troublesome outcome especially in elderly patients. The risk of side effects attendant with corticosteroids is an important concern with chronic usage, so therapeutic regiments are usually of short duration. Emollients are useful in treatment of atopic dermatitis, but in many cases such agents are not sufficient, especially in those subjects with severe pruritus.

Because of recognized limitations in available therapies for atopic dermatitis, a safe and effective alternative has been sought by medical practitioners. One such therapy is eXXema Repair Cream. The composition of the eXXema Repair Cream device arises from the interplay of several key therapeutic objectives. A primary intent is to naturally control the microenvironment of the dermatitis lesion in order to block colonization by microorganisms, particularly

S. aureus. An additional intent is to improve the overall condition of the skin. Importantly, the composition of eXXema Repair Cream is designed to enable safe long-term use, while avoiding any signs of skin atrophy.

Based on this, an open-label safety and efficacy clinical study was conducted consisting of twice daily treatments of targeted atopic dermatitis areas with eXXema Repair Cream. Results for the completed study are documented in this report.

2. MATERIALS AND METHODS

2.1. Device Description

The medical device evaluated in the clinical study reported here consisted of eXXema Repair Cream, a novel multi-component composition designed for topical treatment of atopic dermatitis. eXXema Repair Cream was filled in tubes, sized for convenient use by patients. The composition of eXXema Repair Cream is designed to mitigate the outward appearance and symptoms associated with atopic dermatitis. Key ingredients are directed towards reducing dryness, redness, and itch in skin areas afflicted with atopic dermatitis, while promoting a microenvironment resistant to colonization by bacteria.

2.2. Clinical Investigation Plan Summary

The investigation was organized as an open-label post-market surveillance clinical study to evaluate the safety and efficacy of eXXema Repair Cream for treatment of patients with atopic dermatitis. A copy of the Clinical Investigation Plan developed for this study can be found in Appendix 1 of this report. In accordance with the Clinical Investigational Plan, prospective patients of varying ages exhibiting atopic dermatitis were initially identified for

inclusion in the study. After having received information regarding the nature of the test therapy, the scope of the study, and the anticipated risks and benefits, patients were asked to sign an Informed Consent Form in order to determine eligibility for the study.

Patient selection was based on a concise set of inclusion and exclusion criteria, as detailed in Table 1. After obtaining written informed consent, a Pre-Treatment phase was instituted to verify that patients completely met inclusion/exclusion criteria. Following this confirmation, study subjects were entered into the Treatment phase of the study that included receiving instruction on proper application of eXXema Repair Cream. Initial baseline evaluations were performed, after which twice daily treatments were carried out on targeted skin areas affected by atopic dermatitis. Two follow-up evaluations were designated; at 15 days, and at study termination at 30 days. During the course of the trial, concomitant application of systemic or topical therapies directed towards xerosis or dermatitis were to be avoided. Additional drugs were contraindicated, including neprotoxic agents such as aminoglycosides, amphotericin B, cisplatin, and cyclosporine. In addition, patients were to avoid taking systemic antifungal agents, clarithromycin, erythromycin, or systemic methylprednisolone. EASI (Eczema Area and Severity Index)[4] and SCORAD (SCORing Atopic Dermatitis)[5] severity scoring were selected as the instruments for clinical assessment, and represented the primary end point of the study. Dimensions (height, width) of skin areas affected by atopic dermatitis were measured with the aid of photographic image analysis, providing a secondary end point to the study. In addition, scoring of redness and itch intensity of atopic dermatitis areas targeted for treatment with eXXema Repair Cream was performed at baseline and follow-up, using a numerical rating scale. The

occurrence of any adverse events during the course of the trial was also documented.

Table 1

Inclusion Criteria	Exclusion Criteria
• Male and female, aged 5 years and older. • Fulfill diagnostic criteria of atopic dermatitis. • Outpatient or inpatient status. • Patients informed of study procedures and given written informed consent.	• Known sensitivity or allergy against eXXema Repair Cream ingredients. • Phototherapy or systemic immunosuppressive therapy within 1 month prior to initial treatment with eXXema Repair Cream. • Topical corticosteroids within 2 weeks prior to initial treatment with eXXema Repair Cream. • Chronic use or likely use of inhaled or oral steroids for asthma. • Malignancy or history of malignancy including skin cancer. • Presence of acute or chronic bacterial, viral or fungal skin diseases (including HIV). Subjects with tinea pedis or onychomycosis can be included. • Vaccination within 6 months prior to initial treatment with eXXema Repair Cream, or during, or within 4 weeks after end of treatment with eXXema Repair Cream. • Mental impairment with inability to comply with study requirements. • Participation in any clinical study involving an investigational drug within 8 weeks of initial treatment with eXXema Repair Cream. • History of drug or alcohol abuse within previous year. • Evidence of intent to be uncooperative with study requirements. • Any other condition deemed by investigator to render patient unsuitable for the study.

To assure a high level of quality in the study, investigators maintained responsibility for complete study records, including case report forms (CRFs), and source documents, as well as any lab reports along with patient-specific subject records and medical histories. A Clinical Monitor maintained overall responsibility for conduct and administration of the study, as well as on-site monitoring visits and data verification to ensure compliance with the study plan. Paul Bielderman MD. PhD. MBA. FARCP served as Clinical Monitor for the study. Two tubes of eXXema Repair Cream were allocated for each patient enrolled in the study, and accountability records for receipt, use, and disposition of the tubes were maintained. Additional oversight was directed towards timely receipt of study data, including standardized Case Report Forms, and verification of data completeness and accuracy.

2.3. Statistical Analysis

The Intent-to-Treat population of this study consisted of all subjects who received at least one usage of eXXema Repair Cream, for whom efficacy assessment post-baseline was available. The Per-protocol study cohort consisted of patients who completed the study without protocol violations. The Shapiro-Wilk test[6] was used for initial assessment of study data, as to whether results represented a normally distributed population, thus satisfying the null hypothesis. On the basis of that analysis, a Wilcoxon signed-rank test[7] was employed for statistical analysis of study results pertaining to the primary and secondary end points. P-values of 0.05 or less associated with statistical tests were considered evidence of statistical significance.

3. RESULTS

3.1. Study Administration

A multi-center, open-label, single-arm, post-market surveillance, prospective clinical study was carried out to evaluate safety and performance of topical eXXema Repair Cream as therapy for atopic dermatitis. A total of 227 patients met selection criteria, gave informed consent, and were enrolled into the study. The first patient received baseline evaluation in February, 2010, while the last patient underwent final evaluation in July, 2010, with completion of data analysis in July, 2010. Follow-up of patients was not extended beyond final evaluations at 30 days of treatment. All study data were recorded by authorized study personnel on case report forms developed for the study. Completed case report forms were signed and dated. In the course of auditing accuracy of data entered on case report forms, additional data clarification forms were used for any corrections necessary to the original case report forms. A dispense list was maintained to enable an accurate accounting of tubes containing eXXema Repair Cream. Unused tubes were collected and returned to the Sponsor at study termination.

3.2. Data and Analysis

Baseline demographics of the study population are shown in Table 2. A total of 227 patients with light to moderate atopic dermatitis were initially enrolled. Medical histories were collected for all patients, including histories concerning concomitant medications, identifying two such patients, who were removed from baseline and follow-up analysis of the primary and secondary end points. The patient population included children and adults, of which approximately

two-thirds were male. Ethnicity was completely Caucasian for this study. Approximately 11% of patients were smokers, and 26% regularly consumed alcohol.

Table 2

Baseline Patient Demographics (n=227)	
Age, (y)	
Mean±SD	28.5±15.2
Range	7.3 - 69.9
Sex, n (%)	
Male	150 (67)
Female	77 (33)
Race, n (%)	
Caucasian	227 (100)
Post-enrollment exclusion for concomitant medication, n (%)	
No	225 (99)
Yes	2 (1)
Smoker, n (%)	
No	200 (88.1)
Yes	25 (11.0)
Unknown	2 (0.9)
Cigarettes, quantity per day	
Mean±SD	11.6±5.5
Range	2 - 20
Alcohol consumption, n (%)	
No	167 (73.5)
Yes	58 (25.6)
Unknown	2 (0.9)
Alcohol, quantity of units per week	
Mean±SD,	3.53±2.05
Range	1.0 – 10.0
Photographic Documentation, n (%)	
No	120 (52.9)
Yes	106 (46.7)
Unknown	1 (0.4)

Baseline EASI and SCORAD scores, along with height and width dimensions of atopic dermatitis areas targeted for treatment with eXXema Repair Cream are shown in Table 3. In addition to the two patients excluded from baseline and follow-up analyses of primary and secondary endpoint parameters due to concomitant medication, baseline data for one additional patient were unavailable. Thus, baseline assessments in Table 3 represent data for the remaining 224 patients, who collectively exhibited EASI and SCORAD severity scores indicative of light to moderate atopic dermatitis.

Table 3

Baseline Assessment (n=**224**)	
EASI Score	
Mean±SD	1.95±1.45
Range	0.10 – 6.3
SCORAD score	
Mean±SD	27.34±14.27
Range	5.7 – 62.2
Height (end-to-end) (cm)	
Mean±SD	6.3±3.0
Range	1.0 – 13.5
Width (right to left) (cm)	
Mean±SD	6.2±2.6
Range	5.7 – 62.2

In addition to the three patients not included in baseline assessments in Table 3, 45 additional patients failed to complete the trial, representing 11 patients who were lost to follow-up, and 34 patients who experienced a protocol violation following baseline evaluations by concomitant use of cortisone. Thus, complete data at baseline and follow-up for primary and secondary end points was available for 179 patients at the end of the trial.

Table 4 records several details of the treatment regimen, from the first follow-up evaluation. Photographic records were obtained for slightly less than half of available patients at the 15 day follow-up. Approximately 92 % of patients were still using eXXema Repair Cream supplied from the first of two tubes, while approximately 8 % had finished use of the first tube and were using the second tube. A total of 36 patients had registered use of concomitant medication contraindicated for the study by the 15 day follow-up visit, and these patients were excluded from analysis at the end of the study. These 36 patients represented the 2 patients excluded prior to baseline assessments of primary and secondary end point parameters, and 34 additional patients with history of contraindicated medication during early follow-up. In addition, 12 other patients were permanently lost to follow-up.

Table 4

Follow-Up Assesment, Day 15	
Photographic documentation, n 227 (%)	
No	121 (53.3)
Yes	96 (42.3)
Unknown	10 (4.4)
Patients using 1 or 2 tubes, n (%)	
1	195 (86)
2	16 (7)
Unknown	16 (7)
Concomitant medications used, n (%)	
No	179 (83)
Yes	36 (17)
Lost to Follow-Up, n (%)	12 (5.3)

Table 5 records details of the treatment regimen from the 30 day follow-up evaluation. Photographic records were obtained for half of the available 179 patients at final evaluation.

By the end of treatment, 95 % of patients were using eXXema Repair Cream supplied from the second tube. Also by the 30 day follow-up, one additional patient of 179 total recorded use of concomitant medication. All12 patients lost to follow-up occurred prior to the first follow-up at 15 days of treatment.

Table 5

Follow-up Assessment, Day 30	
Photographic documentation, n 179 (%)	
No	89 (50)
Yes	90 (50)
Patients using 1 or 2 tubes, n (%)	
1	9 (5)
2	170 (95)
Concomitant medications used, n (%)	
No	178 (99)
Yes	1 (1)
Lost to Follow-up n (%)	12 (5.3)

3.3. Primary and Secondary End Points

The primary efficacy end point of the trial was an assessment of change in EASI and SCORAD severity scores following twice-daily treatment of targeted atopic dermatitis areas for 30 consecutive days. The secondary efficacy end point was evaluation of the change in dimensions (height and width) of the targeted atopic dermatitis areas, also following treatment for 30 consecutive days. Results from the initial and final follow-up examinations are recorded in Tables 6 and 7, and shown graphically in Figures 1 and 2.

Table 6

15 Day Assessment (n=210)	
EASI Score	
Mean±SD	1.13±1.09
Range	0.0 – 4.4
SCORAD score	
Mean±SD	15.93±11.50
Range	0.0 – 51.6
Height (end-to-end) (cm)	
Mean±SD	4.39±3.12
Range	0.0 – 12.6
Width (right to left) (cm)	
Mean±SD	4.50±2.89
Range	0.0 – 10.8

Table 7

30 Day Assessment (n=179)	
EASI Score	
Mean±SD	0.44±0.76
Range	0.0 – 4.4
SCORAD score	
Mean±SD	6.85±8.79
Range	0.0 – 46.1
Height (end-to-end) (cm)	
Mean±SD	2.17±2.64
Range	0.0 – 12.6
Width (right to left) (cm)	
Mean±SD	2.24±2.58
Range	5.7 – 62.2

The mean (mean±SD) EASI severity scores decreased from a baseline value of 1.95±1.45 (range 0.1–6.3) to 1.13±1.09 (range 0.0-4.4) at 15 days, and 0.44±0.76 (range 0.0-4.4) at 30 days of treatment (Figure 1). The results indicate a clear decrease in severity score in response to treatment with

eXXema Repair Cream. Likewise, as shown in Figure 2, a similar decrease in SCORAD severity score was also recorded. Mean SCORAD severity scores decreased from 27.3±14.3 (range 5.7-62.2) at baseline to 15.9±11.5 (range 0.0-51.6) at 15 days, and 6.9±8.8 (range 0.0-46.1) at 30 days of treatment.

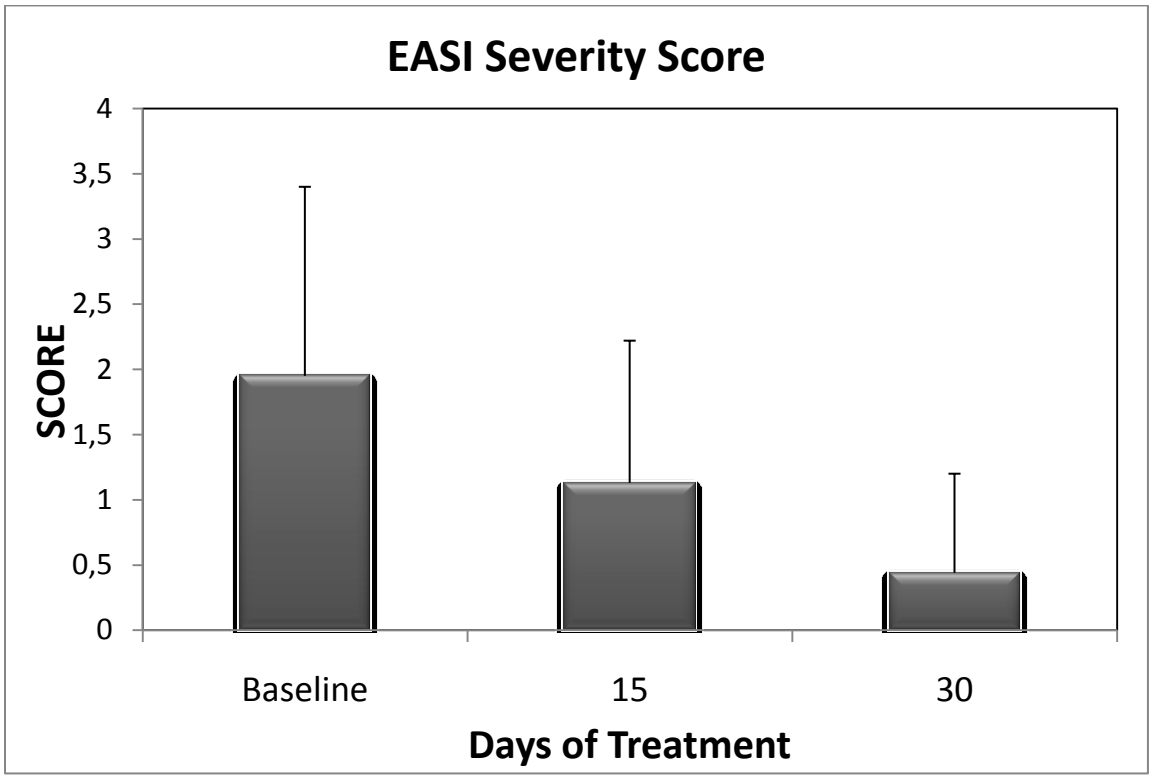

Figure 1. EASI severity scores for target areas of atopic dermatitis in patients at baseline (n=224), at 15 days (n=210) and at 30 (n=179) days of treatment with eXXema Repair Cream.

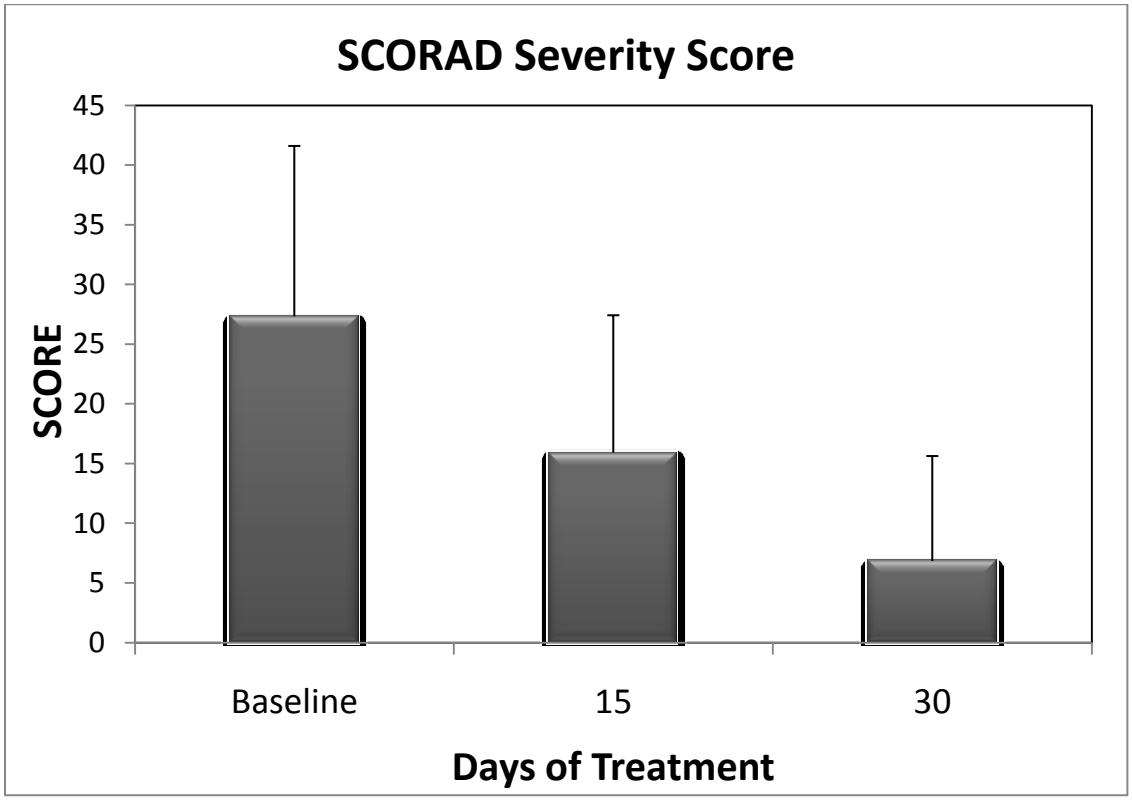

Figure 2. SCORAD severity scores for target areas of atopic dermatitis in patients at baseline (n=224), at 15 days (n=210) and at 30 (n=179) days of treatment with eXXema Repair Cream.

Decreases in dimensions (height and width) of targeted atopic dermatitis treatment areas were observed in response to eXXema Repair Cream treatment, as indicated in Tables 6 and 7, shown graphically in Figures 3 and 4. Mean height decreased from 6.3±3.0 cm (range 1.0-13.5) at baseline to 4.4±3.1 cm (range 0.0-12.6) at 15 days, and 2.2±2.6 cm (range 0.0-12.6) at 30 days of treatment. Likewise, mean width decreased from 6.2±2.6 cm (range 1.6-13.2) at baseline to 4.5±2.9 cm (range 0.0-10.8) at 15 days and 2.2±2.6 cm (range 0.0-10.2) at 30 days of treatment.

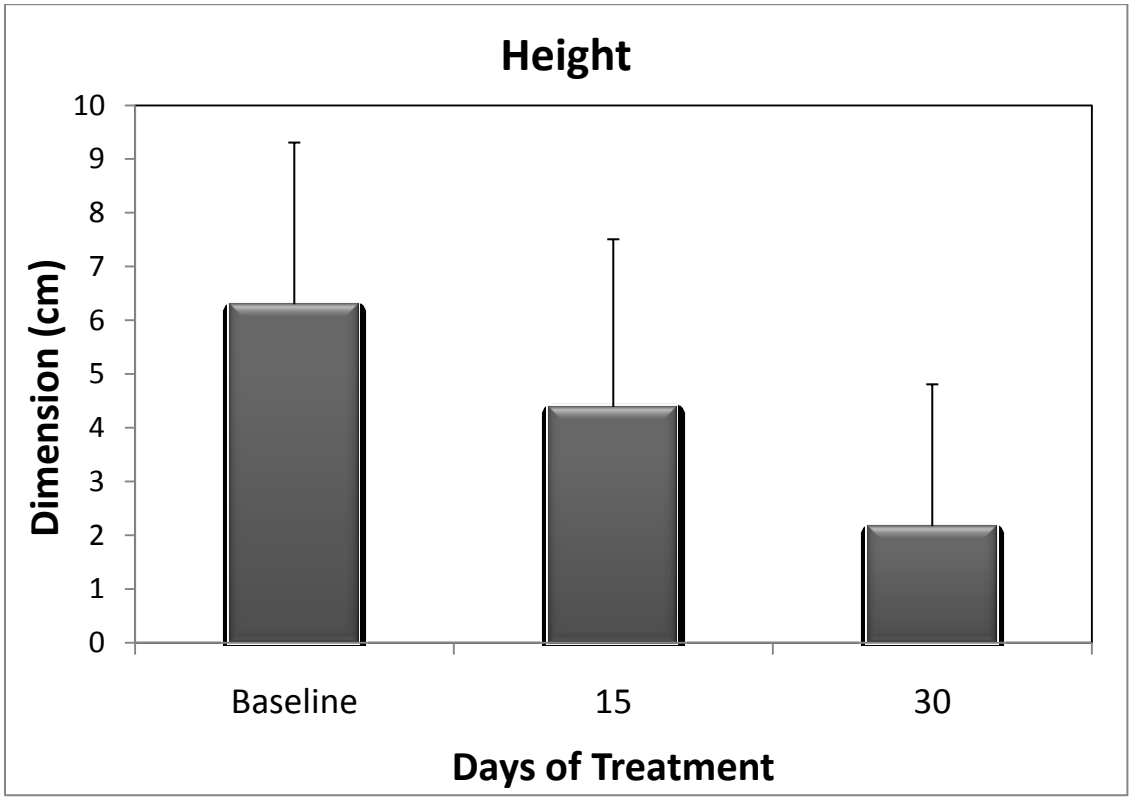

Figure 3. Height (cm) of atopic dermatitis target area at baseline (n=224), at 15 days (n=210), and at 30 days of treatment (n=179) with eXXema Repair Cream.

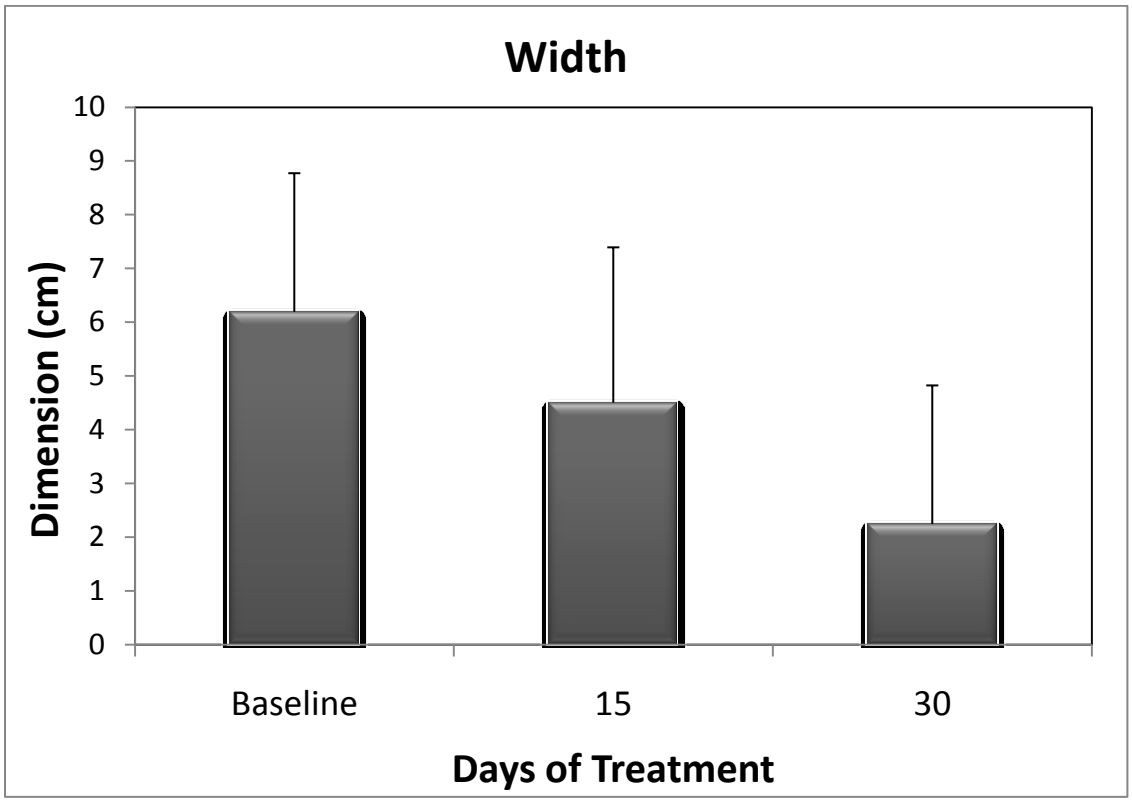

Figure 4. Dimension (width, cm) of atopic dermatitis area at baseline (n=224), at 15 days (n=210), and at 30 days of treatment (n=179) with eXXema Repair Cream.

In addition to primary and secondary end point assessments, two additional clinically relevant parameters of atopic dermatitis severity were evaluated, namely change in lesion redness and itch intensity. Complete patient records for assessment of redness or itch intensity at baseline and follow-up evaluations at 15 days and study termination at 30 days were available for 186 patients. Decreases in redness and itch intensity of targeted atopic dermatitis areas treated with eXXema Repair Cream are shown in Figures 5 and 6. As can be seen, similar degrees of reduction in redness and itch intensity occurred in response to the treatment regimen.

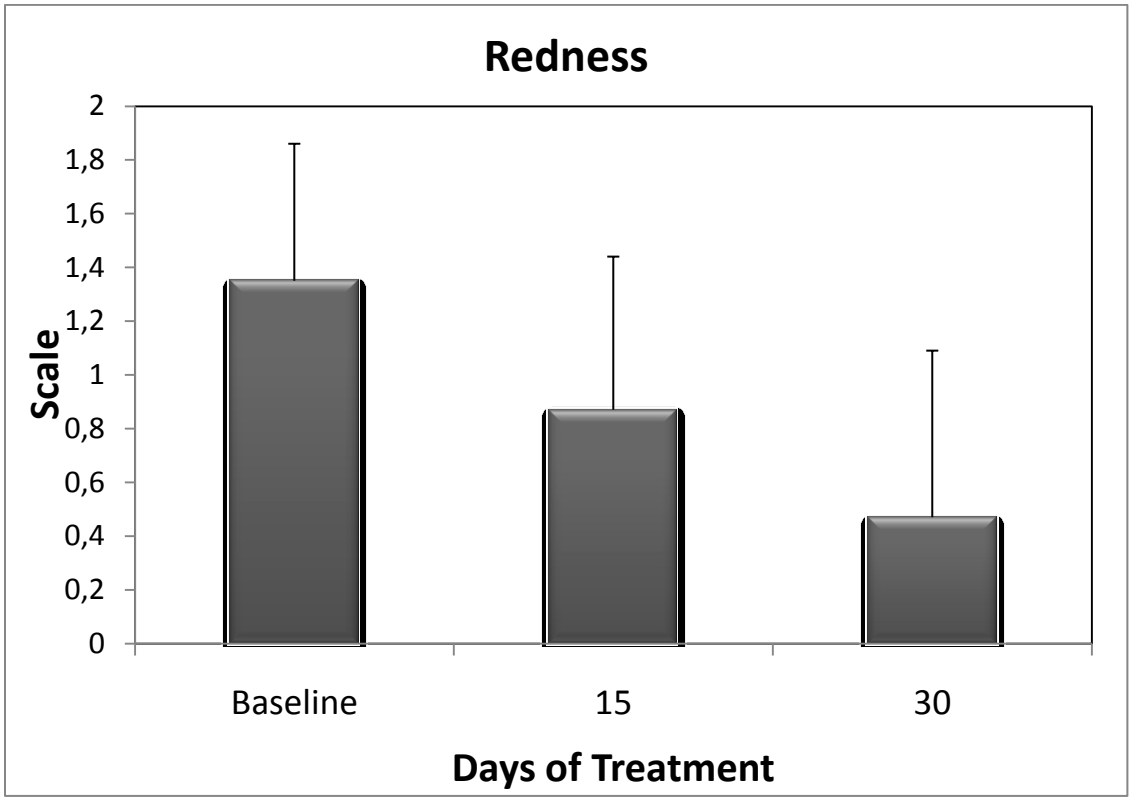

Figure 5. Redness of atopic dermatitis area targeted for treatment with eXXema Repair Cream at baseline and at 15 days and 30 days of treatment (n=186).

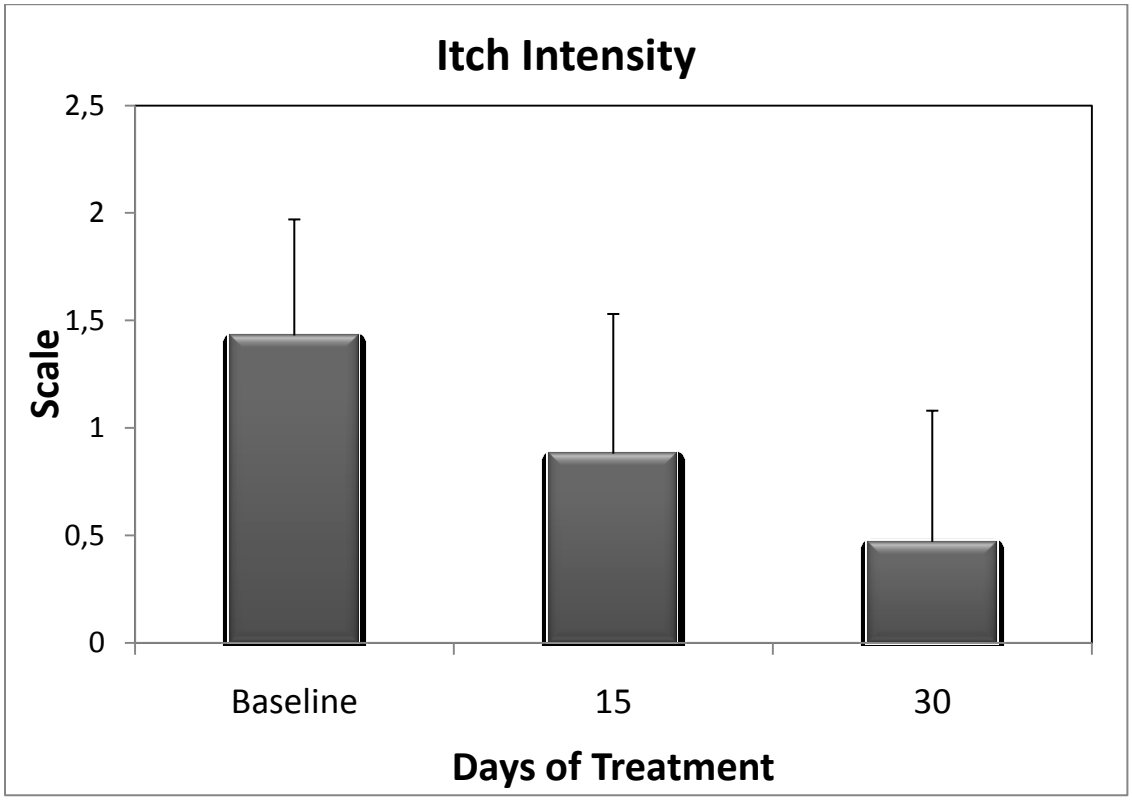

Figure 6. Itch intensity of atopic dermatitis area targeted for treatment with eXXema Repair Cream at baseline and at 15 days and 30 days of treatment (n=186).

Statistical evaluations were carried out on parameters designated as the primary and secondary end points of the study, namely changes in EASI and SCORAD severity scores, as well as the height and width of atopic dermatitis areas treated with eXXema Repair Cream during the study. Inputs into the analysis included data from patients for which a complete data set was available at baseline assessment and study termination. This consisted of 179 patients. The remaining 48 patients originally enrolled in the study were not included in this evaluation. A total of 12 of these patients were lost to follow-up during the study, while 36 others were excluded for protocol violation (cortisone treatment). The Shapiro-Wilk test for normality was initially applied. This test, when utilized for evaluation of small to medium sample sizes, provides

guidance for determining appropriateness of using either parametric or non-parametric statistical analysis methods on study data. Results from the Shapiro-Wilk analyses showed that p-values for reductions in primary and secondary end points over the course of treatment were all $p < 0.0001$. On that basis, the null hypothesis for normal distribution was rejected and the reductions in these parameters were assessed statistically with a non-parametric Wilcoxon signed-ranks test. Results showed that the percent reductions for all primary and secondary end point parameters were statistically significant at the $p < 0.0001$ level, as represented in Table 6 and Figures 7-10.

Table 8

Parameter	Reduction, Mean±SD (%)	p-value
EASI Severity Score	76.1±31.6	< 0.0001
SCORAD Severity Score	74.6±29.6	< 0.0001
Target Area Height	65.6±38.7	< 0.0001
Target Area Width	64.7±37.2	< 0.0001

The data in Table 6 were derived as follows. Percent reduction values for primary and secondary end point parameters were calculated individually for each patient by the formula:

% Reduction = (1- (30 day follow-up value/ baseline value)) X 100%

The Mean and standard deviation values were then calculated for the entire available patient cohort (n=179). This data also supplied input for the statistical evaluation of significance by the Wilcoxon signed-ranks test, and resulting p-value determinations.

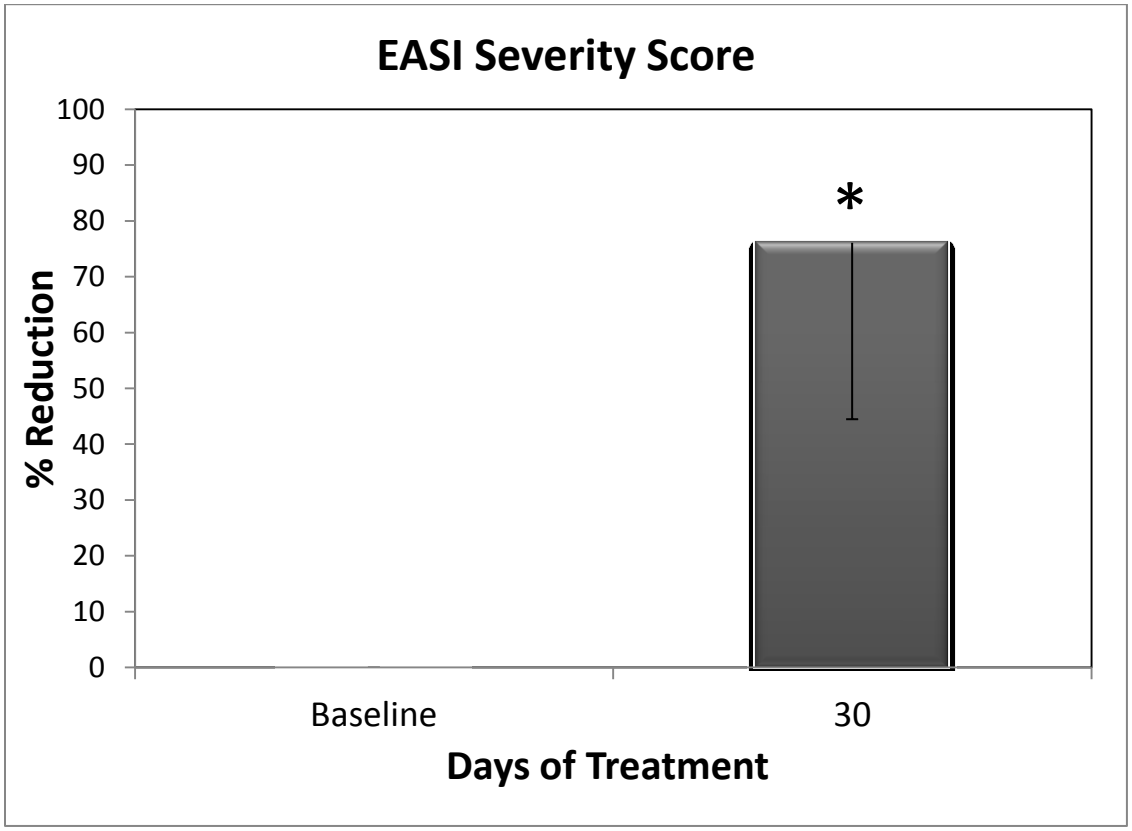

Figure 7. Percent reduction in EASI severity score from baseline to 30 days of treatment of target atopic dermatitis area with eXXema Repair Cream. *A significant reduction in EASI severity score occurred ($p < 0.0001$).

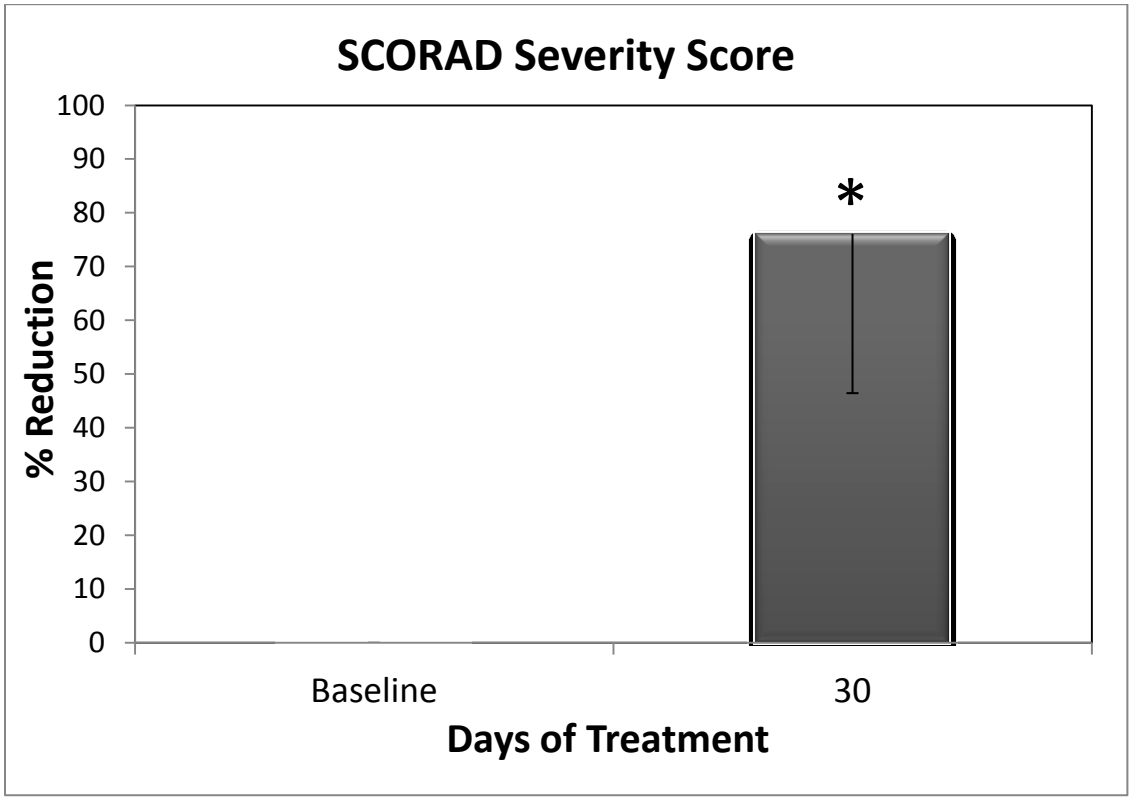

Figure 8. Percent reduction in SCORAD severity score from baseline to 30 days of treatment of target atopic dermatitis area with eXXema Repair Cream.
*A significant reduction in SCORAD severity score occurred ($p < 0.0001$).

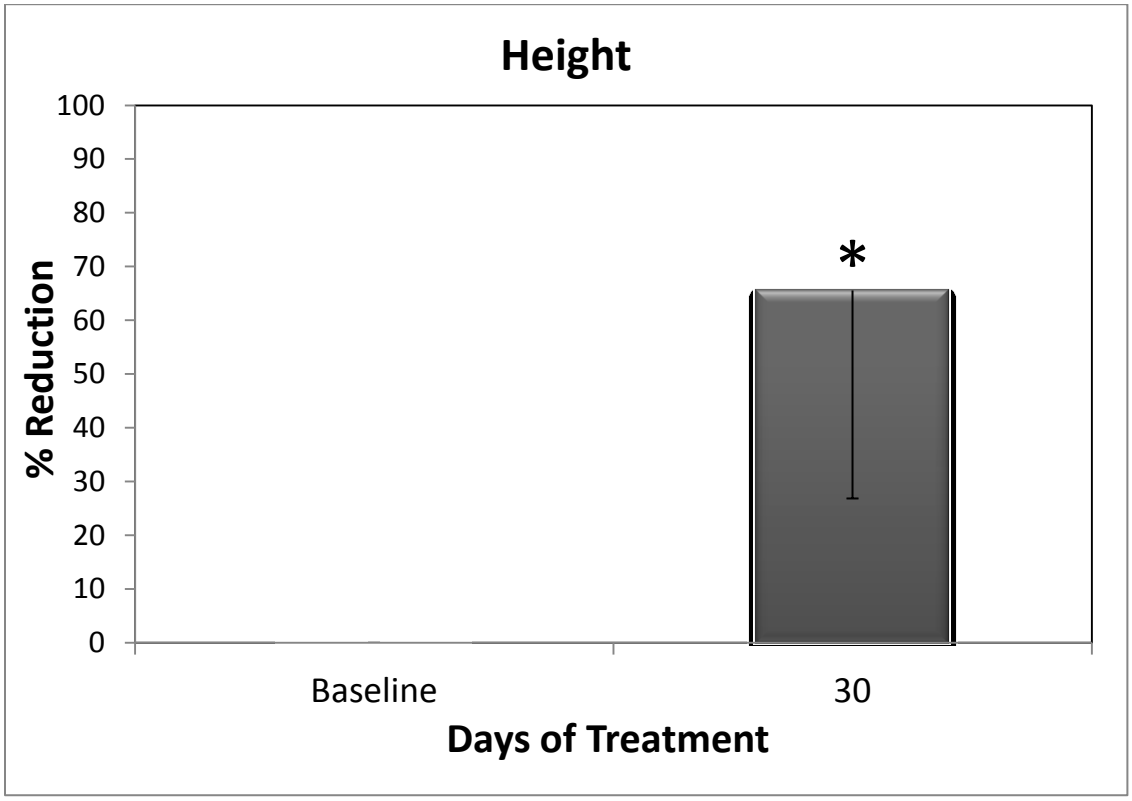

Figure 9. Percent reduction in height of target atopic dermatitis area treated with eXXema Repair Cream, from baseline to 30 days of treatment. *A significant reduction in height occurred ($p < 0.0001$).

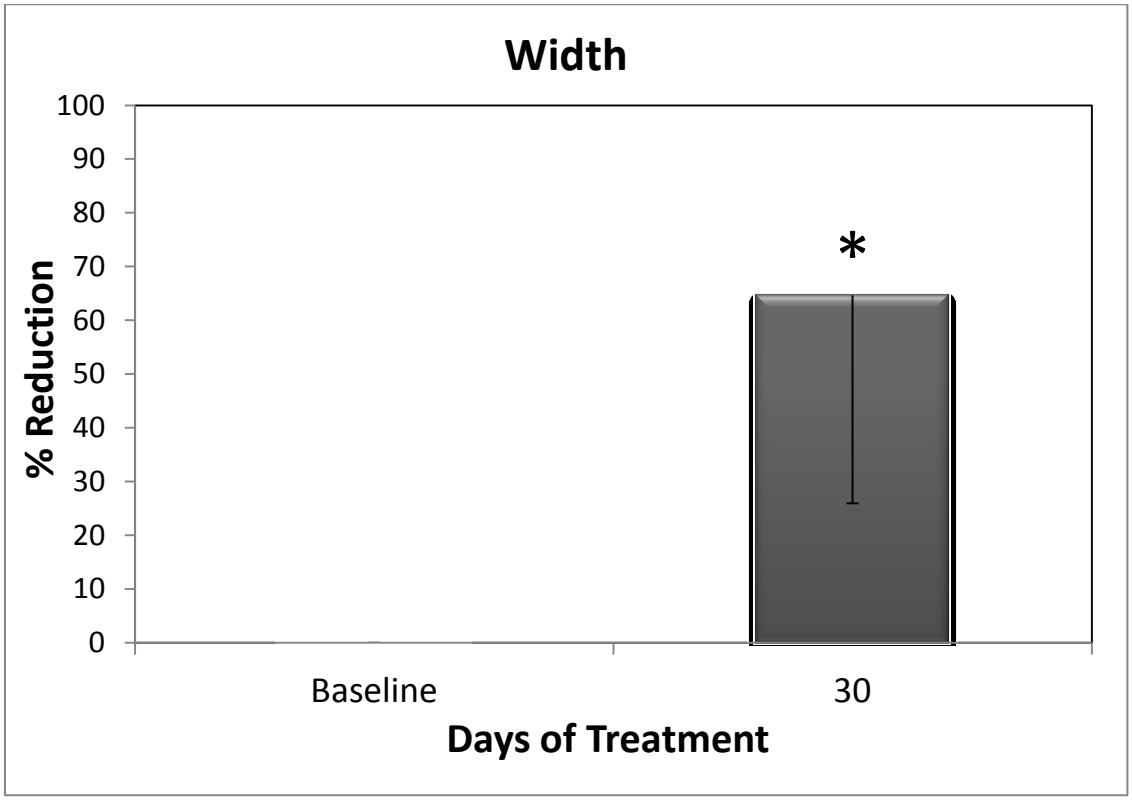

Figure 10. Percent reduction in width of target atopic dermatitis area treated with eXXema Repair Cream, from baseline to 30 days of treatment. *A significant reduction in height occurred ($p < 0.0001$).

3.4. Safety

There was a complete absence of any type of adverse event, be it mild or severe, for any patient in this trial. No indications of skin atrophy or bruising, or of skin irritation or of any overall adverse response occurred with any patient in the series, throughout the 30 day treatment period. No patient deaths were recorded in the trial.

4. DISCUSSION AND OVERALL CONCLUSIONS

4.1. Discussion

Results of this 30 day open-label multicenter study in a mixed population of children and adults with light to moderate atopic dermatitis demonstrated that a twice-daily topical regimen of eXXema Repair Cream was both safe and therapeutically effective. Over the study time course, patients experienced a statistically significant reduction in both severity and size of targeted atopic dermatitis areas in response to therapy, thus satisfying the primary and secondary end points of the trial. Average reductions in disease severity of 76.1% and 74.6 % were recorded via the EASI and SCORAD clinical instruments, respectively. Likewise, the dimensions of targeted atopic dermatitis areas treated with eXXema Repair Cream were reduced by an average of 65.6 % and 64.7 % for height and width, respectively. Similar reductions in redness and itch intensity of the treated skin areas were also recorded.

There was a complete absence of adverse events of any type in this trial, with no reports of any adverse reactions of the targeted skin areas, or involving patients as a whole.

EXXema Repair Cream thus appears to be an attractive therapeutic option for treatment of light to medium severity atopic dermatitis. The composition of the Cream has been judiciously chosen to provide effective therapy, while minimizing the safety risk profile, especially for longer-term exposure. The mode of action of eXXema Repair Cream may provide therapeutic advantages in comparison to other available therapeutic modalities. While simple

emollients serve a purpose in increasing water content in skin, they show little or no evidence of improving atopic dermatitis directly. Topical corticosteroids certainly have been used successfully for treating atopic dermatitis, though such treatments may also result in irreversible thinning of the skin.[8] Likewise, antibiotics have been used, but the presence of antibiotic-resistant bacterial strains can limit their effectiveness.[9] Results of the current trial indicate that eXXema Repair Cream is able to overcome limitations such as indicated for other treatment modalities, without incurring any novel safety risk.

4.2. Overall Conclusions

Topical application of eXXema Repair Cream applied twice daily for 30 days is a safe and effective treatment for light to moderate atopic dermatitis in a mixed population of children and adults. Statistically significant decreases in atopic dermatitis severity were achieved for targeted disease areas following treatment with eXXema Repair Cream. The size of those treated areas also declined significantly. Such benefits were achieved alongside a complete absence of adverse events of any type. EXXema Repair Cream thus appears to be a very useful therapeutic option for clinicians and their patients.

5. ABBREVIATED TERMS AND DEFINITIONS

EASI: Eczema Area and Severity Index

SCORAD: SCORing Atopic Dermatitis

CRF: Case Report Form

GCP: Good Clinical Practice

6. ETHICS

The Clinical Investigation Protocol for this study was reviewed and approved by the Ethics Committee at Academic Hospital Antwerp, Belgium prior to study initiation. All information and data developed during the study and forwarded to the Monitor and/or Sponsor, concerning patients or their participation in this study was considered confidential. All data used in the analysis and reporting of this study were expressed in a manner without reference to patient identities. The study was conducted in conformity with the current revision of the Declaration of Helsinki, and relevant Good Clinical Practices (GCPs).

7. ADMINISTRATIVE STRUCTURE

The study was organized as a multi-institutional post-market investigation of the safety and efficacy of eXXema Repair Cream for treatment of atopic dermatitis. Patients were enrolled from five private practices, with study administration and data collection and management by:

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8. SIGNATURE PAGE

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