GLIABEAUTY – CRYOGEN FINAL REPORT

An Evaluation of Stem Cell Growth Factor Skin Care Regimens

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1. INTRODUCTION

Facial skin aging is an issue that eventually affects all humans. It is the result of many oxidative insults to the skin resulting in tissue and DNA damage. Growth factors may prevent and reverse some of this oxidative damage by instructing the skin to behave in a more youthful fashion and thus improving appearance. This research examined the appearance benefits of a mesenchymal stem cell growth factor-based skin care regimen.

2. STUDY OBJECTIVES

The objectives of this study were:

1. **To demonstrate the tolerability and efficacy of a skin care regimen in younger skin with acne.**
2. **To demonstrate the tolerability and efficacy of a skin care regimen in older skin with photoaging/hyperpigmentation/sunburn.**

3. SUMMARY

3.1 SAFETY ENDPOINT

The safety endpoint was the absence of significant adverse reactions. The safety endpoint was met.

3.2 PRIMARY EFFICACY ENDPOINT

The primary efficacy endpoint was the investigator assessed overall facial appearance improvement after 12 weeks of skin care regimen use. The primary efficacy endpoint was met. However, improvement in radiance, luminosity, softness, and smoothness **after 2 weeks of product use.**

3.3 SECONDARY EFFICACY ENDPOINT

The secondary efficacy endpoint was the subject assessed overall facial appearance improvement after 12 weeks of skin care regimen use. The secondary efficacy endpoint was met. However, improvement in radiance, luminosity, softness, and smoothness **after 2 weeks of product use.**

4. STUDY DESIGN OVERVIEW

Females of Fitzpatrick skin types I-VI who met all the inclusion criteria and none of the exclusion criteria and signed informed consent were enrolled. Subjects were asked to continue their self-selected colored cosmetics unchanged throughout the **12-week study**. Subjects used the study skin care products. No topical medications of any kind were used on the face. No facial skin care products other than the study products were allowed during the study.

The dermatologist investigator and subjects assessed the following facial efficacy parameters: fine lines, wrinkles, texture, radiance, luminosity, smoothness, softness, skin

tone evenness, firmness, pores, and overall facial appearance. The acne group also assessed acne severity. All assessments were made on a 5-point ordinal scale (0=none, 1=minimal, 2=mild, 3=moderate, 4=severe). The dermatologist investigator assessed tolerability in terms of peeling, dryness, redness, and swelling on the same 5-point ordinal scale. Finally, the subjects assessed tolerability in terms of itching, stinging, burning, and irritation on the same 5-point ordinal scale.

Subjects were asked to **return to the research center at week 2**, bringing diary and the test products. Subjects returned to the research center at week 2, week 4, week 8, and week 12 for the same assessments.

STUDY VISIT SCHEDULE

Procedures	Visit 1	Visit 2	Visit 3	Visit4	Visit 5
	BL	Week 2	Week 4	Week 8	Week 12
Informed Consent Procedure	X				
Inclusion/Exclusion Criteria	X				
Brief Medical History	X				
Investigator Clinical Grading for Tolerability	X	X	X	X	X
Investigator Clinical Facial Grading	X	X	X	X	X
Subject Clinical Grading for Tolerability	X	X	X	X	X
Subject Clinical Facial Grading	X	X	X	X	X
Photography (6 subjects)	X				X
Product Dispensing	X			X	
Subject Diary Assessment and Compliance Check		X	X	X	X
Subject Product Accountability and Study Completion					X

Subjects were provided with a daily compliance diary and study products appropriate for their group assignment, which was based on their skin care needs.

Group 1: Healthy female subjects 18-37 years of age with acne

Group 2: Healthy female subjects 37-65 years of age with mild to moderate photoaging

Subjects were assigned to one of two groups. The characteristics of the 2 groups are listed above.

5. INCLUSSION CRITERIA:

1. Females between **18-37 years of age with acne,** females **37-65 years of age** with photoaging/hyperpigmentation/sunburn
2. Subjects of all Fitzpatrick skin types.
3. Subjects with no known medical conditions that, in the investigator's opinion, may interfere with study participation.
4. Willingness to cooperate and participate by following study requirements.
5. Individuals must sign informed consent, photo release consent and confidentiality agreement.
6. Women of childbearing potential must be willing to use a form of birth control during the study. For the purpose of this study, the following are considered acceptable methods of birth control: oral contraceptives, Norplant®, Depo-Provera®, double barrier methods (e.g., condom and spermicide) and abstinence.

6. EXCLUSSION CRITERIA

1. Any dermatological disorder, which in the investigator's opinion, may interfere with the accurate evaluation of the subject's skin characteristics, except for the study indication.
2. Subjects who are not willing to use the assigned study products to their face as instructed.
3. Subject who has had any facial treatments in the past 6 months and are not willing to withhold all facial treatments during the study including facials, facial peels, photo facials, laser treatments, dermabrasion, botulinum toxin (Botox), injectable filler treatments, intense pulsed light (IPL), acid treatments, tightening treatments, facial plastic surgery.
4. A subject with any **UNCONTROLLED** systemic disease. A potential subject in whom therapy for a systemic disease is not yet stabilized will not be considered for entry into the study.
5. A subject with a significant history or current evidence of a medical, psychological or other disorder that, in the investigator's opinion, would preclude enrollment into the study.
6. A subject with a known hypersensitivity to any of the components of the study product.
7. A subject using any topical product containing a *retinoid, retinol, or other vitamin A derivative within 3 months* prior to or during the study period.
8. A subject using any systemic steroid therapy within 6 months prior to or during the study period.
9. A subject using any topical medicated creams, lotions, powders, etc. on the treatment areas during the study period, other than the study treatment regimen.
10. A subject using any topical sunless tanning products containing dihydroxyacetone (DHA) on the treatment areas for at least 7 days prior to the start of the study as well as throughout the entire course of the study.
11. A subject that undergoes facial waxing, bleaching, or depilatory cream use within 30 days prior to entering the study as well as throughout the entire course of the study.
12. A subject has used any topical products containing alpha-hydroxy acids, salicylic acid, or vitamin C on the face for at least 7 days prior to the start of the study, as well as throughout the entire course of the study.
13. Subjects, who are pregnant, breast feeding, or planning a pregnancy.

14. Subjects who are unwilling or unable to comply with the requirements of the protocol.
15. Subjects who have history of a psychological illness or condition that would interfere with their ability to understand and follow the requirements of the study.
16. Subjects currently participating in any other clinical trial.
17. Subjects having started hormone replacement therapies (HRT) or hormones for birth control less than 3 months prior to the study entry or who plan on starting, stopping or changing doses of HRT or hormones for birth control during the study.

DEMOGRAPHIC LOG

A study termination form was completed for each study subject who received study product. This included subjects who completed the study or who withdrew or were withdrawn from study. The subjects successfully completed the study. The demographic log for the study is presented below.

Subject #	Age	Young/Mature	Gender	Fitz	Race
1	32	Young	F	I	C
2	23	Young	F	III	O
3	36	Young	F	VI	AA
4	37	Young	F	II	C
5	28	Young	F	I	C
6	19	Young	F	II	C
7	30	Young	F	II	C
8	27	Young	F	II	C
9	33	Young	F	I	C
10	37	Young	F	I	C
11	23	Young	F	V	AA
12	33	Young	F	I	C
13	35	Young	F	I	C
14	36	Young	F	II	C
15	21	Young	F	II	C
16	62	Mature	F	I	C
17	43	Mature	F	III	C
18	64	Mature	F	IV	AA
19	43	Mature	F	V	AA
20	64	Mature	F	I	C
21	43	Mature	F	II	C
22	60	Mature	F	II	C
23	50	Mature	F	II	C
24	58	Mature	F	III	C
25	53	Mature	F	II	C
26	64	Mature	F	I	C
27	50	Mature	F	V	H
28	39	Mature	F	IV	AA
29	53	Mature	F	II	C
30	62	Mature	F	II	C

7. STATISTICAL METHODS

Along with descriptive statistics (means, standard deviations and percentages), investigator and subject ordinal nonparametric data were analyzed using the Wilcoxon signed rank test. Change was considered significant at a p value of less than 0.05.

Photography: 6 subjects participated in the photography sub study (3 from each group). VISIA-CR images were taken of the front, right, and left face with standard lighting 1 at baseline and week 12.

Week 12	
Statements	**Per Cent Agreement**
1. The products leave my skin feeling hydrated.	96.6%
2. My feels supple, soft, and more elastic.	100%
3. My skin texture has improved.	93.1%
4. My skin looks lifted and tighter.	79.3
5. My skin looks healthier than before.	96.6%
6. My skin looks younger than before.	75.9%
7. My fine lines and wrinkles appear reduced.	86.2%
8. My skin texture has improved.	93.1%
9. My brown spots and age spots are reduced	62.1%

7.1 SIGNIFICANCE LEVEL

Significance was defined at the $p<0.05$ level based on a two-sided test.

The investigator assessed statistically significant **(p<0.001)** improvement in radiance, luminosity, softness, and smoothness **after 2 weeks of product use.** Improvement continued into week 4 with statistically significant improvement lines, roughness, radiance, luminosity, smoothness, softness, evenness, firmness, and overall appearance. In addition, there was statistically significant **(p=0.008)** improvement in acne in the younger acne cohort. This cumulative improvement continued into week 8 with the following parameters showing statistically significant results: lines, roughness, radiance, luminosity, smoothness, softness, evenness, firmness, pigmentation, and overall appearance. The acne improvement continued to be statistically significant. Similar results were seen at week 12, with all parameters indicating statistically significant improvement: lines, wrinkles, roughness, radiance, luminosity, smoothness, softness, evenness, firmness, pigmentation, acne, and overall appearance. The investigator noted excellent anti-aging appearance benefits with the skin care regimen.