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Gdańsk, June 21, 2017

Study Report #16E2960 (version 1.0)

Related to quote #16D2960-5

CLINICAL EVALUATION OF THE CUTANEOUS TOLERANCE AND EFFICACY OF A COSMETIC PRODUCT

- USE TEST UNDER DERMATOLOGICAL CONTROL -



WELCOME HAIR – HAIR SERUM

Study coordination:

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Investigator:

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Report 1/1 including 44 pages

SUMMARY OF THE STUDY REPORT #16E2960

CLINICAL EVALUATION OF THE CUTANEOUS TOLERANCE AND EFFICACY OF A COSMETIC PRODUCT

- USE TEST UNDER DERMATOLOGICAL CONTROL -

Claim	<ul style="list-style-type: none">Hair growth.																																																																															
Objectives	To evaluate: <ul style="list-style-type: none">the cutaneous acceptability of the studied product by clinical examination by the technician in charge of the study under dermatological control,its efficacy on hair growth by scoring of the photographs of the vertex and gulfs by clinical score,subjectively the appreciation of its cosmetic acceptability and future use by analysis of the subjects’ answer to a subjective evaluation questionnaire.																																																																															
Methodology	<ul style="list-style-type: none">Open, intra-individual study; each subject is his/her own control,Before / After.																																																																															
Kinetics	<table><tr><td></td><td>Evaluation zone</td><td>D-X</td><td>D0</td><td>D0-D41</td><td>D42</td><td>D42-D83</td><td>D84</td></tr><tr><td>Information of the subject about study conditions and collection of his/her informed consent.</td><td rowspan="9">Scalp</td><td>•</td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>Verification of inclusion and non-inclusion criteria.</td><td>•</td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>Clinical examination under dermatological control to assess the cutaneous state of the scalp.</td><td></td><td>•</td><td></td><td></td><td></td><td>•</td></tr><tr><td>Standardized hair wash and hair cut by a hairdresser.</td><td></td><td>•</td><td></td><td>•</td><td></td><td>•</td></tr><tr><td>Realization of a photography of the scalp (vertex and gulfs) using Nikon® D90.</td><td></td><td>•</td><td></td><td></td><td></td><td>•</td></tr><tr><td>Scoring of the photographs by the technician.</td><td></td><td></td><td></td><td></td><td></td><td>•</td></tr><tr><td>Distribution / collection of the daily log and the studied product.</td><td></td><td>•</td><td></td><td></td><td></td><td>•</td></tr><tr><td>Application of the product by the subject at home.</td><td></td><td></td><td>•</td><td></td><td>•</td><td></td></tr><tr><td>Subjective evaluation questionnaire.</td><td></td><td></td><td></td><td></td><td></td><td>•</td></tr></table>									Evaluation zone	D-X	D0	D0-D41	D42	D42-D83	D84	Information of the subject about study conditions and collection of his/her informed consent.	Scalp	•						Verification of inclusion and non-inclusion criteria.	•						Clinical examination under dermatological control to assess the cutaneous state of the scalp.		•				•	Standardized hair wash and hair cut by a hairdresser.		•		•		•	Realization of a photography of the scalp (vertex and gulfs) using Nikon® D90.		•				•	Scoring of the photographs by the technician.						•	Distribution / collection of the daily log and the studied product.		•				•	Application of the product by the subject at home.			•		•		Subjective evaluation questionnaire.						•
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Dates	Products reception:	Study start:		Study end:		1 st results by e-mail:																																																																										
	January 20 and February 27, 2017	January 26, 2017		May 25, 2017		June 14, 2017																																																																										
Product	Reference:	Form:	Packaging:		Confidentiality procedure:		Storage temperature:																																																																									
	Welcome Hair – Hair Serum	Transparent brown solution	102 samples of 100 ml		Encoded		Room temperature																																																																									

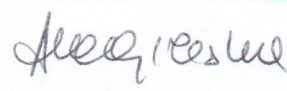
Application	Zone	Frequency	Mode
Welcome Hair – Hair Serum	Scalp	Twice daily (in the morning and in the evening).	Apply the serum in the morning and in the evening directly to the scalp and rub in for 1-2 minutes. Do not wash hair directly after application.
Studied population	Specific inclusion criteria		
	<ul style="list-style-type: none">• Sex: 10 female and 20 male.• Age: between 20 and 50 years old.• Phototype: I to IV.• Subjects presenting different types of hair loss/baldness (including androgenetic alopecia).• Subjects presenting hair loss confirmed by II-V stage on the Hamilton classification (for male subjects) and I-II stage on the Ludwig classification (for female subjects).• Female subjects with thin and thinning hair.		
	Number of subjects analyzed		Average age
	30		30±1 year (between 18 and 47 years old)
Results & Conclusion	<p>Under these study conditions, after 84 days of twice daily use, the product "Welcome Hair – Hair Serum":</p> <ul style="list-style-type: none">➤ was <u>very well tolerated on the cutaneous level</u>,➤ presented <u>a hair growth efficacy</u>, characterized by <u>a statistically significant increase in Total clinical score on D84 ($p = <0.001$)</u>. This effect was observed for 90% of the subjects.➤ was <u>appreciated</u> by the majority of the subjects for <u>its efficacy</u>. <p>The product "Welcome Hair – Hair Serum" induced a significant increase in hair growth.</p>		
Investigator	Name and job title	Date	Signature
	Agnieszka CEGIELSKA Dermatologist	21/06/2017	

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1. QUALITY CONTROL STATEMENT

DERMSCAN is certified ISO: 9001-2008.



The person responsible for the final quality control certifies that the study above was conducted as closely as possible to Good Clinical Practice (GCP-ICH), in compliance with the study protocol and Laboratoire DERMSCAN standard operating procedures and that the study report reflects raw data.

	QUALITY CONTROL ASSESSOR
Last name	CHABOWSKA
First name	Izabela
Date	21/06/2017
Signature	

2. STUDY PROCESS

The study is carried out on a cosmetic product whose safety has been assured by the Sponsor of the study. Its aim is to further confirm safety of the product which will be used by a large number of consumers under normal and reasonably foreseeable use conditions.

The European Directive 2001/20/CE, transposed in Polish Law (version of 07.08.2009, amended by the European Regulation of the European Parliament and Council (UE) #596/2009 dated on June 18, 2009 – Official Journal, #L188, page 14, dated on 18.7.2009) is not applicable. Therefore, this study is considered as non-interventional and does not require the Ethics Committee Approval and the Competent Authority Authorization.

This study was conducted under the following conditions:

2.1. POPULATION

2.1.1. Selection

INCLUSION CRITERIA
Specific
<ul style="list-style-type: none">• Sex: 10 female and 20 male.• Age: between 20 and 50 years old.• Phototype: I to IV.• Subjects presenting different types of hair loss/baldness (including androgenetic alopecia).• Subjects presenting hair loss confirmed by II-V stage on the Hamilton classification (for male subjects) and I-II stage on the Ludwig classification (for female subjects).• Female subjects with thin and thinning hair.
General
<ul style="list-style-type: none">• Healthy subject.• Subject having given his/her informed, written consent.• Subject willing to adhere to the protocol and study procedures.

NON-INCLUSION CRITERIA
<ul style="list-style-type: none">• Concerns women: pregnant or nursing woman or woman planning a pregnancy during the study.• Subjects with any systemic disorder or scalp condition (e.g. seborrheic dermatitis, alopecia, atopic dermatitis, dandruff, eczema, or psoriasis).• Subjects with alopecia areata, alopecia totalis, scarring alopecia, anagen effluvium, telogen effluvium etc.• Use of topical or systemic treatment during the previous weeks liable to interfere with the assessment of the tolerance of the studied product (according to the investigator's appreciation).• Subject using hair gel, hairspray or combing products the day of the visit at the laboratory.• Known allergic history to one of the components of the studied product.• Presence on the studied zone of white or blond hair.• Hair care as dying, bleaching, perm realized since less than one month or foreseen during of the study.• Subject foreseeing to modify his hair cleaning or styling habits and their frequencies (shampoo, conditioner, etc.).• Any topic or systemic medical treatment of the scalp during the three months preceding the inclusion (anti-dandruff, anti-seborrheic...) or stopped since less than three months.• Any topic or systemic medical treatment being able to affect the hair growth or the hair loss during the six months preceding the inclusion, in particular: chemotherapy, aromatase's inhibitors, anti-androgens, immuno-suppressors, retinoids, corticosteroids, rubefiant agents.

- Any anti-hair loss cosmetic or medical treatment taken in the three months preceding the inclusion.
- Excessive exposure to sunlight or UV-rays within the previous month.
- Subject enrolled in another clinical trial during the study period (concerns the studied zone).
- Subject considered by the investigator to be likely not compliant to the protocol.

2.1.2. Restrictions during the study

DURING THE STUDY, THE SUBJECTS		
HAVE TO	MUST NOT	ARE ALLOWED TO USE
<ul style="list-style-type: none">• comply with dates and hours of evaluation and hairdresser visits,• follow the conditions of use of the study product at home,• complete the daily-log and bring it back with test product at the end of the study,• avoid excessive UV exposure (including artificial UV).	<ul style="list-style-type: none">• apply any product to test areas the days of the visits to the lab,• apply any other similar product to test areas (hair and scalp serum),• modify their usual hygiene or care products and/or use new products,• allow the use of the investigation product by another person than himself/herself• use the service of a hairdresser except for the planned visits.	<ul style="list-style-type: none">• usual cleansing products (shampoo, conditioner),• usual styling products (hair gel, hairspray).

2.1.3. Compliance assessment

A protocol deviation can be defined as any non-adherence to the final protocol, including:

- wrong inclusion (inclusion criteria or non-inclusion criteria not fulfilled),
- start of a prohibited concomitant treatment,
- the non-adherence of the subjects to the study schedule (missed or postponed visit),
- the missing data for one or several evaluation criteria,
- aberrant values,
- low compliance of the subject to the treatment,
- premature study end or untraceable subject,
- no respect of the constraints envisaged by the protocol.

In case of minor protocol deviation, the technician or the investigator repeats the instructions and reminds the subject to follow protocol requirements / study procedures. In case of persistent or major protocol violations, the subject is declared non-compliant and withdrawn from the study because of non-compliance.

The compliance is controlled by checking the daily log (see **Appendix 7.6**).

2.1.4. Protocol non-adherences

Subject #	Description of the non-adherence	Type of non-adherence (minor / major)	Data kept into the analysis (yes/no)
1	The subject used the product once instead of twice on D42.	minor	yes
(2)*	<i>The subject did not use the studied product on D15, D23, D24, D36, D38, D48, D49 D50, D51, D62, D63, D74, D75. The subject used the product once instead of twice on D16, D37, D47, D59, D60, D61.</i>	major	no
3	The subject used the product once instead of twice on D42.	minor	yes
5	The subject used the product once instead of twice on D42.	minor	yes
6	The subject used the product once instead of twice on D42.	minor	yes
7	The subject used the product once instead of twice on D42.	minor	yes
8	The subject returned on D83 instead of D84. The subject used the product on D83.	minor	yes
11	The subject used the product once instead of twice on D42.	minor	yes
12	The subject used the product once instead of twice on D42.	minor	yes
13	The subject did not use the studied product on D38, D39, D51, D52, D60. The subject used the product once instead of twice on D58 and D59.	minor	yes
14	The subject did not use the product on D42.	minor	yes
19	The subject did not use the product on D26 and D27. The subject used the product once instead of twice on D25, D28, D60, D73 and D74.	minor	yes
23	The subject used the product three times instead of two times on D3.	minor	yes
24	The subject used the product once instead of twice on D18, D42, D59 and D60.	minor	yes
25	The subject used the product once instead of twice on D42.	minor	yes
28	The subject was 18 years old at the inclusion instead of 20 years old minimum.	minor	yes
	The subject used the product once instead of twice on D42.	minor	yes
29	The subject used the product once instead of twice on D11, D27, D59, D65, D72 and D73.	minor	yes
(31)*	<i>The subject got pregnant during the study.</i>	major	no
34	The subject returned on D85 instead of D84.	minor	yes

Legend:

(*)*: not included in data analysis

The protocol non-adherences of the subjects #1, 3, 5, 6, 7, 8, 11, 12, 13, 14, 19, 23, 24, 25, 28, 29 and 34 do not invalidate the data obtained for these subjects.

However, the protocol non-adherences of the subjects #2 and 31 invalidate the data obtained for these subjects.

2.1.5. Concomitant treatments

None of the concomitant medications invalidate the data obtained for the concerned subjects.

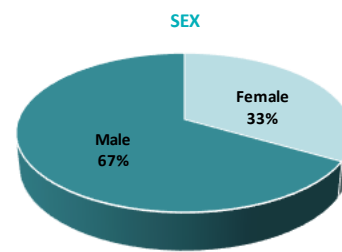
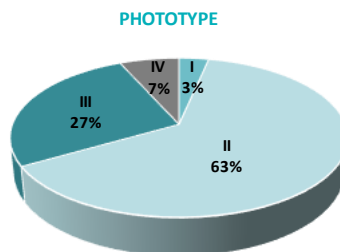
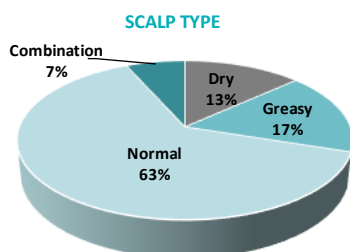
See the concomitant medications in **Appendix 7.2**.

2.1.6. Follow-up

	NUMBER OF SUBJECTS				
	INCLUDED	COMPLETING THE STUDY	ANALYZED	NOT COMPLETING THE STUDY	NON-ANALYZED
Cutaneous tolerance / Clinical score / Subjective evaluation questionnaire	34	32	30	Subjects #20 and 21: consent withdrawal.	Subjects #2 and 31: excluded from data analysis due to a major protocol non- adherence.

2.1.7. Demographic data

ANALYZED SUBJECTS	SEX	AGE (IN YEARS)			SCALP TYPE	PHOTOTYPE	EVENT OR MEDICAL TREATMENTS	COMMENTS AND DETAILED DATA
		Mean ± SEM	Min.	Max.				
30	Female: 10 Male: 20	30±1	18	47	Dry: 4 Greasy: 5 Normal: 19 Combination: 2	I: 1 II: 19 III: 8 IV: 2	See Appendix 7.2	See Appendix 7.1



2.2. PRODUCT

2.2.1. Labelling

Example of labelling of each product by DermScan and translation:

DERMSCAN Badanie nr	DERMSCAN Study #
Nr Ochotnika:	Subject#:
W nagłej potrzebie: 58 732 02 90	Emergency tel. number: 58 732 02 90
Nr DermScan:	DermScan ref.:
Warunki przechowywania:	Conservation:
Przechowywać z dala od dzieci i ich zasięgu wzrokowego. Stosować pod kontrolą medyczną tylko dla potrzeb badania.	Keep out of reach and sight of children. To be used only under strict medical supervision for clinical trial.

2.2.2. Storage

Products are kept at room temperature in a dedicated air-conditioned room, which is locked and access controlled until the beginning of the study.

2.2.3. Attribution to the subjects

→ *Product*

All the subjects receive the same product reference.

→ *Randomization of the application zones*

Not applicable.

2.2.4. Handing-out

The products are delivered to the subjects by the technician or investigator with an explanation of the application conditions.

2.2.5. Future

As far as possible, one sample of the studied product is kept by the laboratory for a period of six months after its receipt.

The products (used and not used) are send back to the sponsor at the end of the study.

2.3. STUDY STAGES

ON D-X (pre-inclusion):

- The subjects come to the laboratory without having applied any product to the hair and scalp since the previous evening.
- They are informed about the trial objectives, the procedures and the risks of the study.
- They must sign two copies each of the Consent Form.
- Verification of inclusion and non-inclusion criteria.
- Final inclusion of the subjects who meet all the inclusion criteria.

ON D0 (for included subjects):

- The subjects come to the laboratory without having applied any product to the hair and scalp since the previous evening.
- Standardized hair wash and hair cut by a hairdresser.
- Clinical examination of the initial cutaneous state of the scalp by the technician in charge of the study under dermatological control and asking the subjects about their usual unpleasant sensations.
- Realization of a photography of the scalp (vertex and gulfs) using Nikon® D90.
- The product is distributed to the subjects. They use it twice daily (in the morning and in the evening) on the scalp during 84 days under normal conditions of use.
- The subjects receive a daily log in order to write down their potential intolerance sensations or others felt and observed during the study (see **Appendix 7.6**).

ON D42:

- Standardized hair wash and hair cut by a hairdresser.

ON D84 (the last product application is done in the evening on the day before the visit):

- The subjects come to the laboratory without having applied any product to the hair and scalp since the previous evening.
- The subjects bring back their daily log and the remaining product.
- Standardized hair wash and hair cut by a hairdresser.
- New clinical examination of the final cutaneous state of the scalp by the technician in charge of the study under dermatological control and asking the subjects about the unpleasant sensations they felt during the study to assess the cutaneous tolerance of the product.
- New realization of a photography of the scalp (vertex and gulfs) using Nikon® D90.
- Scoring of hair growth effect by two independent technicians.
- The subjects fill in the subjective evaluation questionnaire (see **Appendix 7.5**).

2.4. DATA ANALYSIS

The following data are analyzed:

	Parameter(s)	Unit(s)	Variation(s) DX-D0 ±SEM	Variation(s) DX-D0 in %	p	Expected result(s)
Cutaneous tolerance	Functional, physical and clinical signs	/	D84-D0 (without variations)		/	
Hair growth effect (score by technician)	Items	/	D84-D0		≤0.05	Increase
Questionnaire	Questions	%	D84		Majority of positive answers	

2.4.1. Calculation formulas

The raw variations (and in percentage) of the different studied parameters are calculated according to the following formulas:

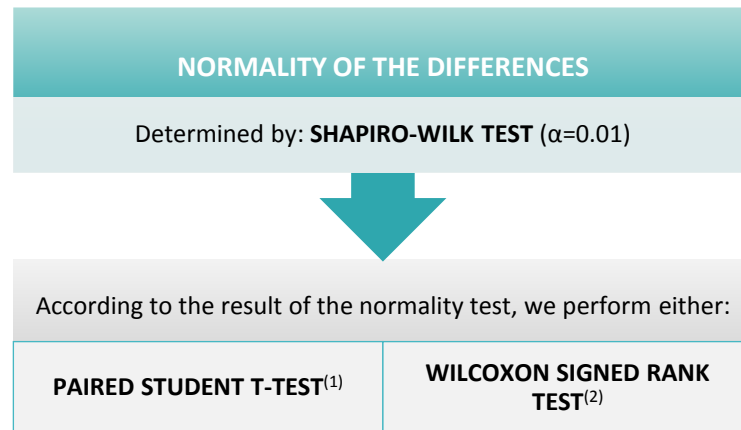
$$\Delta = (TZ_{ti} - TZ_{t0})$$

$$\Delta\% = \frac{(TZ_{ti} - TZ_{t0})}{TZ_{t0}} \times 100$$

with:

TZ: value obtained on the treated zone(s)
t0: before application
ti: at each measurement time after application

2.4.2. Statistical method



Analysis conditions	p-value	H0	Conclusion
Type I error (α) = 5% in bilateral / unilateral mode	$p \leq 0.05$	Rejected	Statistically significant difference
Null hypothesis (H0) = no difference between means ⁽¹⁾ or medians ⁽²⁾	$p > 0.05$	Not rejected	No statistically significant difference

2.4.3. Statistical software

The software used is Excel 2016 and PASW® statistics 24 (SPSS®).

2.5. AUDIT AND TRIAL MONITORING VISIT

An audit and/or trial monitoring visit may be carried out at the sponsor's request or by the appropriate regulatory authority. The aim of the monitoring visit is to verify that the study is conducted according to the determined protocol and current regulations.

No monitoring visit occurred during this study.

3. PRINCIPLES AND RESULTS

3.1. CUTANEOUS TOLERANCE

3.1.1. Principle

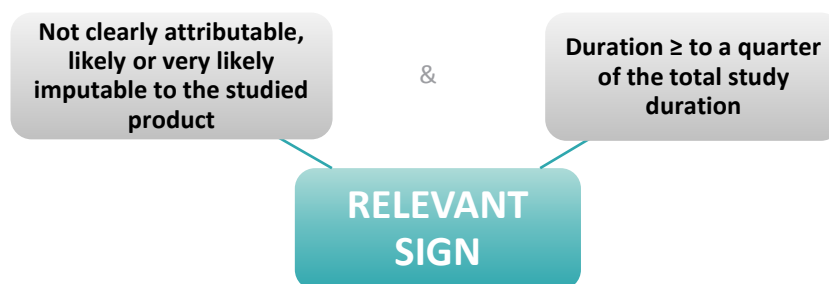
Before and after 84 days of the product use, the subjects' scalp is examined by the technician in charge of the study under dermatological control and each of the following parameters is assessed:

	NONE	VERY MILD	MILD	MODERATE	SEVERE
Erythema	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dryness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Desquamation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Seborrhea	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dandruff	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Others	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Please define:				

On D0, the subjects are also asked about their sensations (usual ones and felt on D0):

	NONE	VERY MILD	MILD	MODERATE	SEVERE
Tightness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Stinging	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Itching	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Warm sensation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Burning sensation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Others	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Please define:				

On D84, the cutaneous tolerance of the product is assessed by taking into account the relevant elements reported by the subject (functional and physical signs) as well as those noted during the examination (clinical signs). The confrontation of these signs is used to conclude the final cutaneous tolerance of the studied product.



This rule of relevance excludes signs of excluded or unlikely relationship with the product as well as signs that last only a few days during the study (especially at the beginning of the study).

All not clearly attributable, likely or very likely imputable signs that appear during the final days of the study are retained, providing there is no ulterior follow-up.

3.1.2. Results

The individual results of the dermatological examination are presented in the following table (relevant signs appear in bold):

Subject #	Signs reported by the subjects		Clinical signs observed on D84
	Functional signs	Physical signs	
1	None	None	None
(2)*	<i>(Moderate itching on the whole scalp ten minutes after the product application during three hours on D1 (unlikely imputable).)*</i>	<i>(None)*</i>	<i>(None)*</i>
3	None	None	None
4	None	None	None
5	None	None	None
6	None	None	None
7	None	None	None
8	None	None	None
9	None	None	None
10	None	None	None
11	None	None	None
12	None	None	None
13	None	None	None
14	None	None	None
15	None	None	None
16	None	None	None
17	None	None	None
18	None	None	None
19	None	None	None
(20)*	<i>(Consent withdrawal)*</i>		
(21)*	<i>(Consent withdrawal)*</i>		
22	None	None	None
23	None	None	None
24	None	None	None
25	None	None	None
26	None	None	None
27	None	None	None
28	None	None	None
29	None	None	None
30	None	None	None
(31)*	<i>(None)*</i>	<i>(None)*</i>	<i>(None)*</i>
32	None	None	None
33	None	None	None
34	None	None	None

Legend:

()*: not included in data analysis



After 84 days of use of the product "Welcome Hair – Hair Serum", no functional nor physical sign was reported. Moreover, no clinical sign was observed on D84.

Under these study conditions, after 84 days of twice daily use, the product "Welcome Hair – Hair Serum" was very well tolerated on the cutaneous level.

3.2. HAIR GROWTH EFFECT

3.2.1. Principle

A photography of the subjects' scalp (vertex and gulfs) is taken on D0 and on D84.

The digital camera used is a camera of the type Nikon® D90.

The photographs are taken in standardized, indirect light. Aperture, speed and distance of the camera are also standardized.

Then two independent technicians realize a visual score of the product's efficacy based on the photographs using 7-point structured scale presented below:

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
-3	-2	-1	0	1	2	3
marked aggravation (less dense)	moderate aggravation	slight aggravation	no change	slight improvement	moderate improvement	marked improvement (much denser)

The variations (D84-D0) are calculated for the studied parameter. Descriptive statistics are performed to determine the significance of each parameter. The percentages of improvement, aggravation and stagnation are calculated.

3.2.2. Results

A synthesis of the results is presented in the table below.
Individual results are presented in the **Appendix 7.3**.
Statistical analysis is presented in the **Appendix 7.4**.

A significant increase of clinical scores presents a hair growth effect.

Parameter	Kinetic	Variation (mean±SEM)			p	Type of statistical test	Significance
Hair growth Score gulf left side	Mean ΔD84	0.8	±	0.1	<0.001	Wilcoxon	Yes
Hair growth Score right gulf side	Mean ΔD84	0.9	±	0.1	<0.001	T-test	Yes
Hair growth Score Vertex	Mean ΔD84	0.9	±	0.2	<0.001	T-test	Yes
Hair growth TOTAL SCORE	Mean ΔD84	0.9	±	0.1	<0.001	T-test	Yes



Under these study conditions, after 84 days of twice daily use, the product "Welcome Hair – Hair Serum" presented a hair growth efficacy, characterized by a statistically significant increase in:

- Score on the gulf left side on D84 (p= <0.001). This effect was observed for 80% of the subjects.
- Score on the gulf right side on D84 (p= <0.001). This effect was observed for 80% of the subjects.
- Score on the vertex on D84 (p= <0.001). This effect was observed for 77% of the subjects.
- Total clinical score on D84 (p= <0.001). This effect was observed for 90% of the subjects.

3.2.3. Illustrations

Example of the results obtained with the studied product is presented below for the subjects #4 and 5.

Subject #4
Left side



D0



D84

Right side



D0

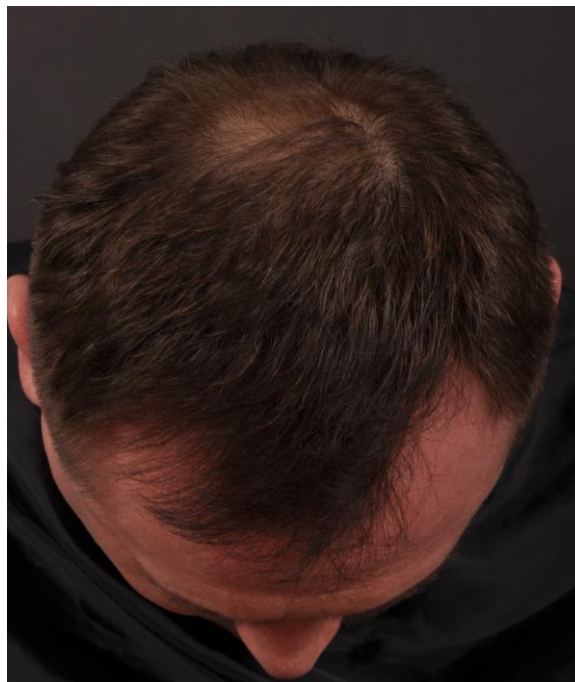


D84

Vertex

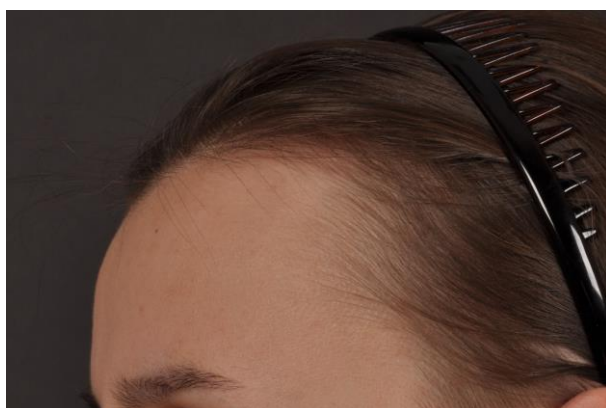


D0



D84

Subject #5
Left side

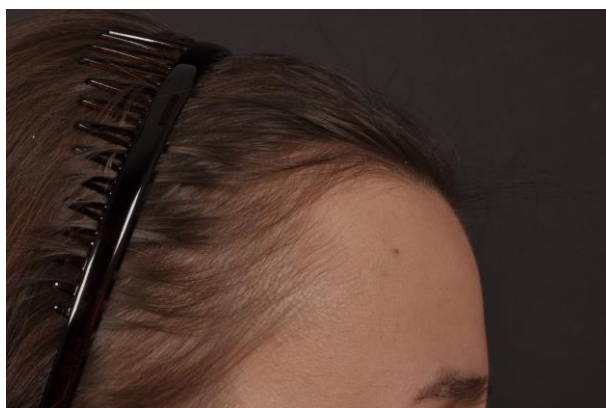


D0

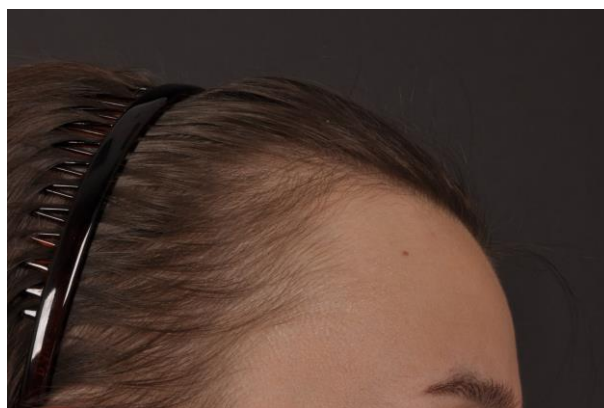


D84

Right side



D0

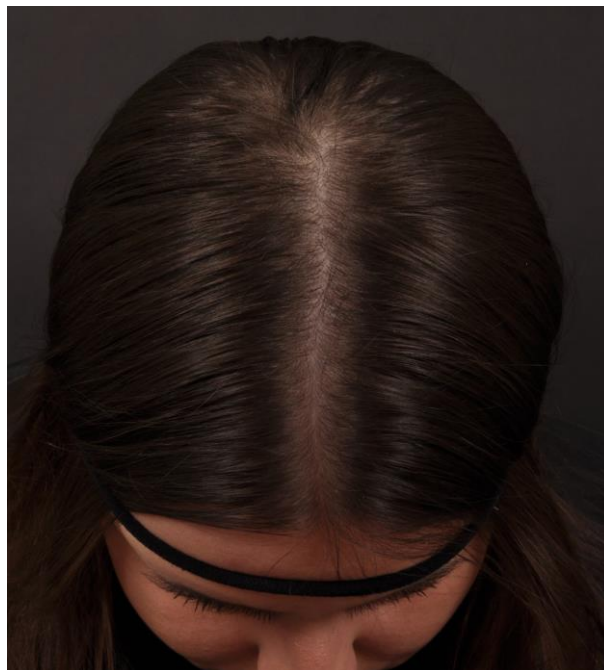


D84

Vertex



D0



D84

3.3. SUBJECTIVE EVALUATION QUESTIONNAIRE

3.3.1. Principle

A subjective evaluation questionnaire, prepared by the clinical trial center and submitted to the sponsor, is filled in by the subjects at the end of the study on D84 to subjectively evaluate the properties, the efficacy, the tolerance and the future use of the studied product.

3.3.2. Results

The subjects' answers to the subjective evaluation questionnaire are presented in the **Appendix 7.5**. To be easier to read, the percentages are rounded off. The sum of these percentages may be different from 100%. In this study (n=30), one subject represents 3.3% respectively.

A synthesis of the answers is presented below. In comparison with the theoretical proportion of 50% and population number (n=30), the results >68.3% are considered as significant according to the calculation of the bilateral confidence interval of a proportion.

GENERAL APPRECIATION OF THE PRODUCT AND ITS PROPERTIES

	% of subjects (very pleasant/ pleasant)	Very pleasant	Pleasant
General appreciation	80%	13%	67%
Aspect	87%	30%	57%
Texture	60%	20%	40%
Fragrance	47%	10%	37%
Colour	60%	10%	50%

PRODUCT'S EFFICACY AFTER 84 DAYS OF USE

	% of subjects (yes)
Any change in hair and scalp	57%
Product is easy to use	93%
Product is practical to use	87%
Product packaging is practical	90%

	% of subjects (agree / agree somewhat)	Agree	Agree somewhat
Product allows to realize scalp massage easily	94%	57%	37%
Product penetrates quickly into the hair and scalp	87%	40%	47%
Hair seems to be denser	80%	27%	53%
Hair seems to be softer	63%	23%	40%
Hair seems to be stronger	80%	37%	43%
Hair is silky	70%	23%	47%
Hair and scalp are nourished	80%	37%	43%

	% of subjects (yes)
Product stimulates hair growth	63%
Other people noticed hair growth	40%

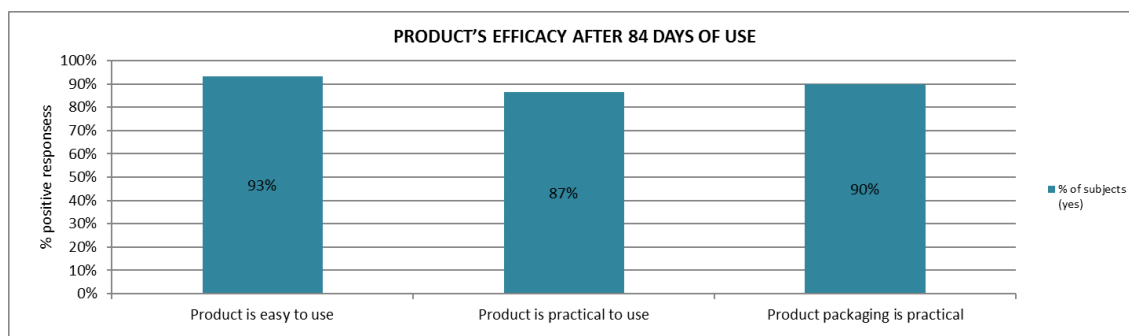
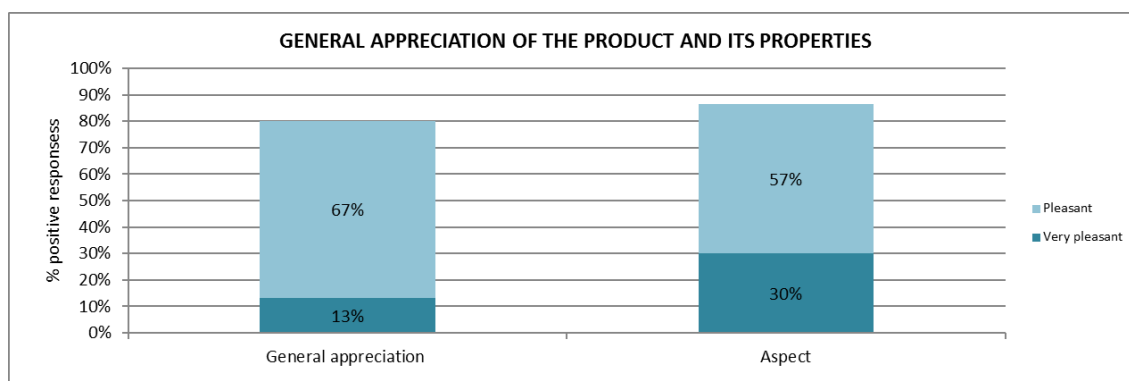
TOLERANCE

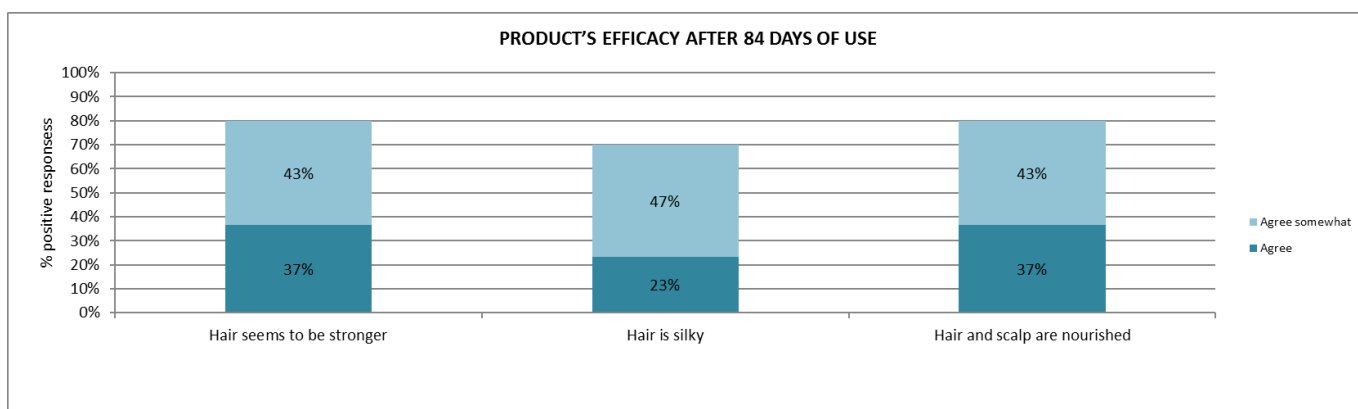
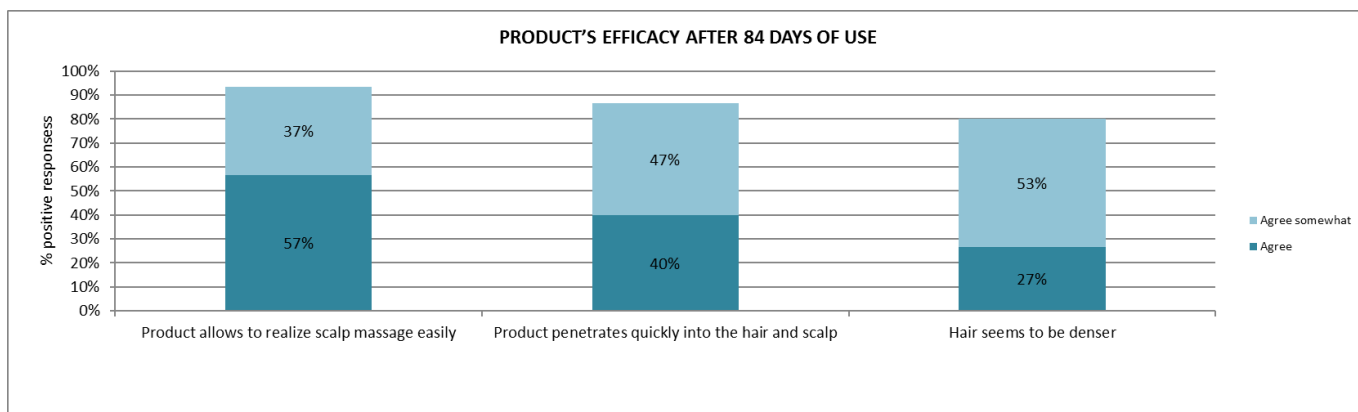
	% of subjects (yes)
Cutaneous irritation sensations	0%

FUTURE USE OF THE PRODUCT

	% of subjects (yes)
Would like to continue to use the product	67%
Would like to buy this product at the end of the study	47%

A synthesis of the answers considered as significant is presented in the graphs below:





See details about the subjects' answers (in percentage) to the subjective evaluation questionnaire in **Appendix 7.5**.

4. CONCLUSION

Under these study conditions, we observed that:



After 84 days of twice daily use, the product "Welcome Hair – Hair Serum":

- was very well tolerated on the cutaneous level,
- presented a hair growth efficacy, characterized by a statistically significant increase in Total clinical score on D84 ($p = <0.001$). This effect was observed for 90% of the subjects.
- was appreciated by the majority of the subjects for its efficacy.

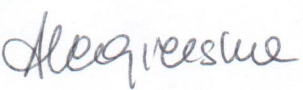
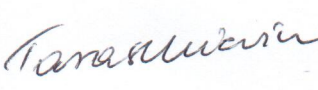
The product "Welcome Hair – Hair Serum" induced a significant increase in hair growth.

5. CERTIFICATION

The study is conducted according to Helsinki Declaration (1964) and its successive updates. Data are obtained using the study protocol, current internal procedures and as closely as possible to the guidance on Good Clinical Practice CPMP / ICH / 135 / 95.

This study is totally performed under the responsibility of DERMSCAN.

All the observations and numerical data collected throughout the study are reported in this document and are in accordance with the obtained results.

	INVESTIGATOR - DERMATOLOGIST	PROJECT MANAGER
Name	Agnieszka CEGIELSKA	Aleksandra TARASZKIEWICZ
Date	21/06/2017	21/06/2017
Signature		

Any modifications are the sole responsibility of the author of the modification, whether he/she is acting for the Sponsor or independently.