

## Results of a Clinical Study on EXCEPTIONHYAL® STAR

### ► INTRODUCTION

EXCEPTIONHYAL® STAR is a new generation hyaluronic acid (HA) based on a full spectrum of hyaluronic acids from biotechnology. It is composed of hyaluronic acids of different molecular weights, ranging from 50 kDa to 3,000 kDa, as found in the skin, which allows to perfectly meet the physiological needs for hyaluronic acid, in particular thanks to its high level of absorption.

### ► I. CLINICALLY PROVEN EFFECTS OF EXCEPTIONHYAL® STAR

#### I.1 CHARACTERISTICS OF THE STUDY

- Study Type : Double-blind randomized placebo-controlled clinical study
- On 15\* healthy female subjects aged over 18 years old
  - 10 subjects took the active formulation and 5 took the placebo
  - the blood concentration of the hyaluronic acid (HA) administrated by the food supplement is preliminary evaluated by means of blood samplings taken at baseline (T0) and after 7 (T7), 14 (T14), 21 (T21) and 28 (T28) days of treatment.
- On 60\* healthy female subjects aged over 18 years old
  - 30 subject took the active formulation and 30 took the placebo
  - The assessment of product efficacy is carried out after 4 weeks of product intake, by means of non-invasive bioengineering

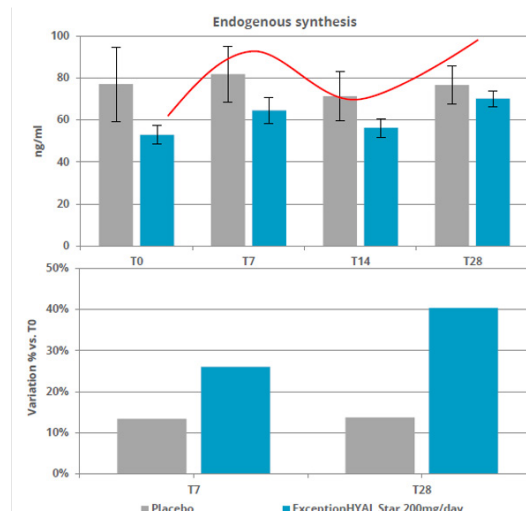
techniques able to quantify skin moisturizing, skin elasticity/firmness, trans epidermal water loss (TEWL) and skin profilometry. Moreover, the instrumental analysis is integrated with the self-assessment of the enrolled subjects.

- Dosage : 200 mg/day of EXCEPTIONHYAL® STAR

\*data of first 15 subjects (10 active and 5 placebo) that performed both the evaluation of the HA blood concentration and HA anti-aging efficacy refers to a preliminary study performed in our facility under the same experimental conditions (our internal reference code: E.HU.016-0015.19.004L\_2016/2557). Further 45 enrolled subjects underwent only the evaluation of HA anti-aging efficacy (present study).

### I.2 STUDY RESULTS

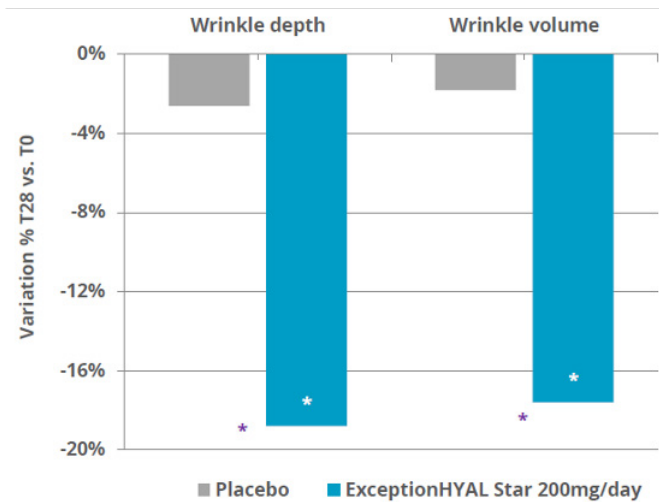
#### I.2.1. Bioavailability – Human model



EXCEPTIONHYAL® STAR demonstrates a relevant increase of Hyaluronic Acid in the blood, already starting from T7, reaching **+40.3%** at the end of the treatment (T28).

- ✓ Quick action
- ✓ Prolonged effect

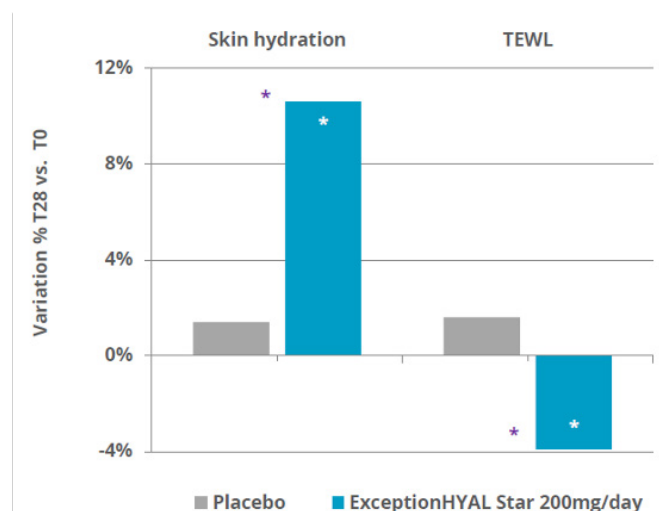
## I.2.2. Skin profilometry



EXCEPTIONHYAL® STAR demonstrates a significant improvement of skin profilometry in terms of both wrinkles depth and volume.

- ✓ Less marked wrinkles (**-17.6%**)
- ✓ Les deeped wrinkles (**-18,6%**)

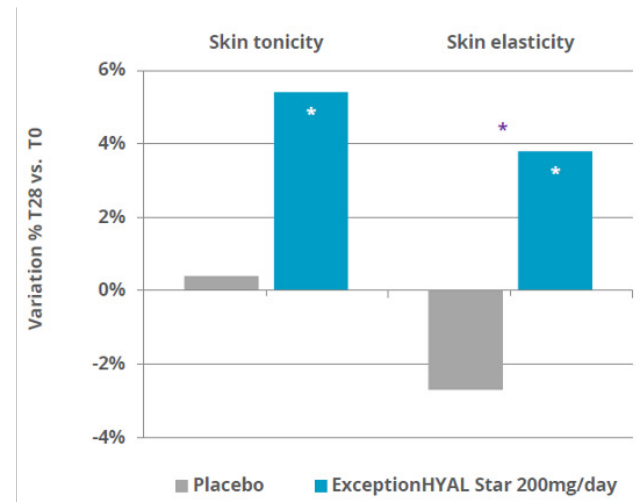
## I.2.3. Skin health



EXCEPTIONHYAL® STAR shows a significant effect on skin moisturization (hydration & TEWL)

- ✓ Skin is more hydrated (**+10.6%**)
- ✓ Skin is more protected from deshydration (**-3.9%** transepidermal water loss)

## I.2.4. Skin appearance



EXCEPTIONHYAL® STAR provides important benefits to skin beauty in terms of:

- ✓ Skin tonicity (**5.1%** in skin firmness vs T0)
- ✓ Skin elasticity (**+3.8%**)

## ▶ II.MATERIEL AND METHOD

### II.1. EVALUATION OF THE BLOOD CONCENTRATION OF HYALURONIC ACID – 15 SUBJECTS

The blood test are performed at an external accredited laboratory and the samples are analyzed by CLIA method. The evaluation is preliminary carried out on 15 out 60 enrolled subjects (10 active and 5 placebo treated).

### II.2. SKIN MOISTURIZING – 60 SUBJECTS

The measurement of the skin moisturizing is based on the internationally recognized CORNEOMETER®.

### II.3. TRANS EPIDERMAL WATER LOSS (TEWL) – 60 SUBJECTS

The measurement of the trans epidermal water loss is based on internationally recognized TEWAMETER® method.

### II.4. SKIN ELASTICITY/FIRMNESS – 60 SUBJECTS

Skin elasticity/firmness measurement is based on the suction/elongation method and the subsequent release of the skin inside the

opening of the instrument (Cutometer® MPA 580, Courage+Khazaka, electronic GmbH).

II.5 Skin profilometry evaluation – 60 subjects  
Skin surface is quantitatively assessed by Primos 3D (GFMesstechnik GmbH). Primos 3D is a non-contact in vivo skin measurement device based on structured light projection.

### ► III. CONCLUSION

EXCEPTIONHYAL® STAR determined:

- An improvement of the hyaluronic acid blood concentration (not statistically significant both compared to baseline and placebo treated group). This parameter has been evaluated only on 15 out 60 subjects; the low group numerosness and the great standard deviations do not allow to point out any statistical significance.
- An improvement of skin moisturizing (statistically significant both compared to baseline and placebo treated group) by +10.6%.
- A decrease of Trans Epidermal Water Loss (statistically significant both compared to baseline and placebo treated group) by -3.9%.
- An improvement of R2 parameter related to skin elasticity (statistically significant both compared to baseline and placebo treated panel) by +3.8%.
- A improvement of RO parameter related to an improvement of skin firmness (statistically significant compared to baseline) by 5.1%.
- A decrease of the monitored profilometric parameters (wrinkles appear less marked and less depth) both compared to baseline and placebo treated panel, respectively by -18.8% (wrinkles depth) and by -17.6% (wrinkles volume).

No statistically significant variations were noticed in subjects treated with the placebo formulation.

Furthermore, the active product was well tolerated by all the subjects participating

in the study and it was positively judged by the majority of them; the treatment efficacy perception was clearly better in subjects who took the active product respect to the ones treated with the placebo.