AESTHETIC CORRECTION

OF MIDFACE

www.hyalual.com

A POST-MARKETING, OPEN-LABEL, NON-COMPARATIVE, MULTI-CENTER INVESTIGATION TO EVALUATE THE EFFECTIVENESS AND SAFETY OF A MEDICAL DEVICE “ALEXA VOLUME” (DIACO BIOFARMACEUTICI S.R.L., ITALY) BASED ON CROSS-LINKED HYALURONIC ACID FOR CORRECTION OF THE MIDFACE VOLUME LOSS.

PURPOSE OF THE CLINICAL INVESTIGATION

This analysis is intended to explore whether a medical device "Alexa Volume" (DIACO BIOFARMACEUTICI S.r.l., Italy) based on cross-linked hyaluronic acid is safe and effective for correction of **the middle face area (upper cheeks) volume loss and decreasing the severity of nasolabial folds.**

DESCRIPTION OF THE CLINICAL INVESTIGATION POPULATION

The clinical investigation was planned to involve 68 male and female subjects, twenty-five (25) years or older, with loss of volume of the midface area, nasolabial folds and willingness for correction or enhancement of their midface area.

CLINICAL INVESTIGATION METHOD USED

1) Effectiveness assessment:

a) Global Aesthetic Improvement Scale (GAIS)

The subjects were photographed for the GAIS evaluation at the Visit 1 (before Alexa Volume administration), the Visit 2 and the Visit 3.The 5-grade GAIS was used to assess the improvement of the midface volume by comparing the photographs taken for the front, 45° left side, and 45° right side of the face at the Visit 1 to photos made at Visit 2 and Visit 3.

b) Wrinkle Severity Rating Scale (WSRS)

The 5-grade wrinkle severity rating scale was used to evaluate the nasolabial folds. The WSRS scores range from absent to extreme. Using WSRS, the Investigator rated the depth of left and right nasolabial folds on photographs of the face before (Visit 1) and after administration of Alexa Volume (Visit 2 and Visit 3).The right and left nasolabial fold were evaluated separately, at Visit 1 (baseline) and during Visit 2 and Visit 3. WSRS changing for each subject was evaluated by comparing the results of this scale at photos made at Visit 2 and Visit 3 to Visit 1 results for each fold separately.

c) Medicis Midface Volume Scale (MMVS)

The 4-grade scale was used to bilateral assessment of none (1), mild loss (2), moderate loss (3), substantial loss (4) of fullness in the midface area. Using MMVS, the Investigator rated the three photographs (front side, 45° left, 45° right) of the face before (Visit 1) and after administration of Alexa Volume (Visit 2 and Visit 3). MMVS changing for each subject was evaluated by comparing the results of this scale at photos made at Visit 2 and Visit 3 to Visit 1 results.

SAFETY ASSESSMENT

- Information regarding adverse events, adverse device effects, device deficiencies was collected continuously during the investigation. The Investigator collected information about local tolerability, swelling, pain, itching, bruising and tenderness etc. at the injection site(s) at each visit. In an emergency, a subject may had contacted the Investigator at any time between visits, by phone or in person, to resolve the safety concerns.

RESULTS OF THE CLINICAL INVESTIGATION

Towards the **primary endpoint**, namely “Investigator-evaluated change in the GAIS from Visit 1 (baseline) to Visit 3” the mean improvement for mITT1, mITT2 population **was (-2.44) points** (95% CI (-2.62 – (-2.26)), for PP population – **(-2.43) points** (95% CI (-2.61 – (-2.25))

The difference with baseline was **statistically significant** ($p<0.001$) for both populations.

The higher positive effect on the correction of the volume loss in the midface area as evaluated in GAIS (both by Investigator and subject) and MMVS as well as the better effect on correction of the nasolabial folds’ depth as assessed in WSRS were obtained at Visit 3 (day 28) compared to Visit 2 (day 14) for both populations.

RESULTS OF THE CLINICAL INVESTIGATION

- **Percentage of subjects with a ≥ 1 point change on WSRS** as evaluated by Investigator at Visit 3 was **67.6%** for both left and right side in mITT1 (equals to mITT2) population and **67.2%** for both left and right side in PP population.
- **100% of subjects** both from mITT1 (equals to mITT2) and PP populations had a ≥ 1 point change on the MMVS as evaluated by Investigator at Visit 3.
- **57.4% and 56.7% of subjects** of mITT1 (equals to mITT2) and PP population respectively
- received injection of Alexa Volume at Visit 2.

CONCLUSION OF SAFETY

- Results obtained towards safety endpoints demonstrated that no device deficiencies were observed during investigation and only 2 mild adverse device effects were registered in 2 subjects.

CONCLUSION OF INVESTIGATION

- The investigation showed high effectiveness of the “Alexa Volume” (DIACO BIOFARMACEUTICI S.r.l., Italy) based on cross-linked hyaluronic acid towards the primary and all secondary effectiveness endpoints.

  Furthermore, the high safety of the IMD was demonstrated as 3 adverse events (severe, mild, and moderate) and 2 mild adverse device effects was registered during investigation.

GET IN TOUCH

www.hyalual.com