INTRODUCTION

- Two injection volumes (0.05 mL and 0.08 mL) of Dysport® (abobotulinumtoxinA [ABO]; manufactured by Biologics Ltd, Wrexham, UK), reconstituted in either 1.5 mL or 2.5 mL of sterile preservative-free 0.9% sodium chloride for injection USP respectively, were approved for the treatment of glabellar lines (GLs).
- Even though both injection volumes are approved for reconstitution in the US label, many injectors tend to believe that with the higher dilutions volumes of neurotoxin, the greater risk of toxin spread or other unwanted safety issues.
- This study aimed to show both injection volumes result in similar efficacy and safety profiles.

SUBJECTS AND METHODS

- **Subject Selection and Methods**
  - This 130 day, multi-center, randomized, subject- and evaluator-blinded, study enrolled subjects with moderate-to-severe glabellar line severity (GLSS) who were naïve to botulinum toxin treatment in the basal area.
  - Subjects were randomized to 1 of 5 age, gender, blinded evaluator GLSS to receive either 0.05 mL/injection (Group A) or 0.08 mL/injection (Group B).
  - Subjects received 1 treatment which consisted of 5 injections in the glabellar area. Each subject received a total of 30 mL (15 mL/injection) of ABO.

PRIMARY ENDPOINT

- The proportion of composite responders (defined as subjects who achieved a 3-point reduction from baseline in GLSS at maximum frown) in each treatment group was assessed at each study visit, by evaluating the GLSS change from baseline (subject, blinded evaluator, and treating investigator assessments).

SECONDARY ENDPOINTS

- Subject satisfaction with appearance and naturalness of results using a subject questionnaire and 5-point Likert scale for evaluators.

RESULTS

- **Demographics**
  - A total of 13 treatment emergent adverse events (TEAEs) were reported in 6 subjects (71.4% from each treatment group). 4 TEAEs were related to treatment and were assessed as related to treatment (2 subjects in Group A, 1 subject in Group B; Table 1).
  - No SAEs were reported and both treatments were well-tolerated.

- **Safety**
  - A total of 13 treatment emergent adverse events (TEAEs) were reported in 6 subjects (71.4% from each treatment group). 4 TEAEs were related to treatment and were assessed as related to treatment (2 subjects in Group A, 1 subject in Group B; Table 1).
  - No SAEs were reported and both treatments were well-tolerated.

- **Proportion of composite responders with at least a 1-point reduction from baseline in GLSS, maximum frown (n = 60); mITT Population**

- **Proportion of composite responders with at least a 2-point reduction from baseline in GLSS, maximum frown (n = 60); mITT Population**

- **Primary Efficacy Endpoint**

- Subject and blinded evaluator assessment for Onset of Effect (IOE) at all time points.

- The proportion of ≥1-point and ≥2-point composite responders at each visit, by evaluating the GLSS change from baseline (subject, blinded evaluator, and treating investigator assessments).

- **Secondary Efficacy Endpoint**

- The proportion of composite responders (defined as subjects who achieved a 3-point reduction from baseline in GLSS at maximum frown) in each treatment group was assessed at each study visit, by evaluating the GLSS change from baseline (subject, blinded evaluator, and treating investigator assessments).

- **Safety Population** = 60 subjects. Group A (1.5 mL) – 0.05 mL/injection; Group B (2.5 mL) – 0.08 mL/injection. Counts reflect the number of subjects experiencing TEAEs, not the number of TEAEs.

- **Safety**

- Both treatments provided a natural looking aesthetic outcome and were found to be safe and well tolerated. The looking outcome were maintained through 120 days.

- **Dermatitis contact 1 (3.3)**

- **Migraine 1 (3.3)**

- **Vision blurred 1 (3.3)**

- **Nasopharyngitis 0 (0)**

- **Dermatitis contact 1 (3.3)**

REFERENCE

- Takeda (Barella) Inc, Itasca, IL. RebuildSkin was manufactured under cGMP. (May 2017). Takeda (Barella) Inc, Itasca, IL.

ACKNOWLEDGEMENTS

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Figure 1. Representative Photographs - Subject J02-003

Figure 2. Proportion of Composites Responders

Table 1. Summary of Treatment-Emergent Adverse Events (TEAEs)

<table>
<thead>
<tr>
<th>Group A (n = 30)</th>
<th>Group B (n = 30)</th>
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</thead>
<tbody>
<tr>
<td><strong>Number of Subjects with ≥1 TEAE (%)</strong></td>
<td>3 (10)</td>
</tr>
<tr>
<td><strong>Number of Subjects with Morbidity, ≥2 (%)</strong></td>
<td>2 (6.7)</td>
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Figure 3. Proportion of Subjects Who Achieved Onset of Effect (IOE), Based on Combined Subject and Blinded Evaluator Assessments (n = 60); mITT Population

Figure 4. Subject Satisfaction, Natural Looking Appearance

Figure 5. Time, post-treatment

REFERENCES

- Takeda (Barella) Inc, Itasca, IL. RebuildSkin was manufactured under cGMP. (May 2017). Takeda (Barella) Inc, Itasca, IL.

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