Subject and investigator treatment experience with ready-to-use AbobotulinumtoxinA solution versus powder botulinumtoxinA for treatment of glabellar lines

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• Botulinum toxin type A (BoNT-A) is widely used to treat glabellar lines (GLs).

• Alluzience¹ (AbobotulinumtoxinA solution, AboBoNT-A solution) is a recently approved ready-to-use (RTU) formulation, with a unique manufacturing process and no human- or animal-derived excipients, which is expected to simplify injection practices and prevent reconstitution error.

• The clinical development program of AboBoNT-A solution for GLs has shown²:
  – Rapid onset of effect, starting on day 1
  – A long duration, up to 6 months
  – Improved psychological well-being after GL treatment

PURPOSE

Overall Study Objectives

• To assess subject and investigator experience during GL treatment sessions, using RTU AboBoNT-A solution and powder onabotulinumtoxinA (OnaBoNT-A)

• To evaluate aesthetic improvement, satisfaction, and safety after a single treatment of moderate-to-severe GLs with AboBoNT-A solution during a 6-month follow-up period

Primary objective

• To evaluate the time needed to prepare AboBoNT-A solution and a powder BoNT-A (OnaBoNT-A)
STUDY DESIGN

- Phase IV, open-label, randomized study (NCT05277337), conducted at 8 sites in Germany and the UK

- **Planned population:** 150 females, 18 to <65 years of age with moderate-to-severe GLs at maximum frown, with prior experience of facial BoNT-A treatment

- Single treatment of GLs with RTU AboBoNT-A solution 50U, or powder OnaBoNT-A 20U

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**Assessments:**

- Investigator treatment experience, including preparation time and usability
- Subject treatment experience
- Aesthetic improvement of GLs after treatment with AboBoNT-A solution
- Subject satisfaction after treatment with AboBoNT-A solution
- Collection of adverse events
RESULTS

**Subjects and Demographics**

- **99 subjects** were treated with AboBoNT-A solution and **51 subjects** with powder OnaBoNT-A

<table>
<thead>
<tr>
<th></th>
<th>AboBoNT-A solution (RTU)</th>
<th>OnaBoNT-A (Powder)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of treated subjects</strong></td>
<td>N=99</td>
<td>N=51</td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (Min, Max)</td>
<td>45.9 (23, 64)</td>
<td>44.6 (24, 64)</td>
</tr>
<tr>
<td><strong>Sex (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Females</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Race (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>95%</td>
<td>96%</td>
</tr>
<tr>
<td>Black or African American</td>
<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>Asian</td>
<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>Other*</td>
<td>3%</td>
<td>0</td>
</tr>
<tr>
<td><strong>Toxin naïve</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

*Other races included: Indian, Kazakhstan, Arab*
RESULTS

Primary objective: Preparation time

- **On average 1 minute less** was required to prepare RTU AboBoNT-A solution (0:33 min:sec) than to reconstitute powder OnaBoNT-A (1:34 min:sec)
- The difference was statistically significant $p<0.0001$

Mean time (minutes:seconds)

- **Powder OnaBoNT-A, N=51**: 1:34
- **RTU AboBoNT-A solution, N=99**: 0:33

**Error bars show standard deviation. p-value is from a T-test**

Presented at the Aesthetic & Anti-Aging Medicine World Congress (AMWC), Monte Carlo, Monaco, Mar 30 to Apr 1, 2023
RESULTS

Investigators’ usability experience with RTU AboBoNT-A solution

- **100%** of investigators (N=10) responded that the RTU AboBoNT-A solution
  - Fulfilled their expectations
  - Was easy to use
  - Was easy to learn
  - Required the fewest possible steps for its purpose
RESULTS

Investigators’ treatment session experience with RTU AboBoNT-A solution

At each treatment session (N=99) investigators were asked if they

- Preferred to use an RTU solution over the powder product (81% agreed/strongly agreed) and felt more precise in their injection with an RTU (76% agreed/strongly agreed)

TIME

- Could dedicate more time to explain the treatment procedure (97% agreed/strongly agreed)
- Could save time on the reconstitution and injection procedure (93% agreed/strongly agreed)

MATERIALS

- 99% agreed or strongly agreed that less materials for injection were required and 97% that substantially less waste was produced while preparing the RTU product than a reconstituted product
- 100% agreed/strongly agreed that use of RTU product is better for the environment

"Compared to a product that needs to be reconstituted...”

- I prefer to utilize an RTU solution: 81%
- I feel I am more precise in my injection with an RTU solution: 76%
- I could dedicate more time to explain the treatment procedure with the RTU solution: 97%
- I could save time on the reconstitution and injection procedure to do something else: 93%
- I produced substantially less waste of non-toxin material using the RTU product: 97%
- I spend less materials for injection: 99%
- Use of RTU toxin is better for the environment as I produce less waste: 100%

Strongly agree/Agree
RESULTS

Subjects’ treatment session experience with RTU AboBoNT-A solution

TIME
- 100% of subjects felt that the treating investigator could focus on them and their treatment at all times

COMFORT & EXPECTATIONS
- 91% felt comfortable with the injection procedure
- 94% found that the treatment session was good and exceeded their expectations

ANIMAL-FREE & ENVIRONMENT
- 90% felt good about being injected with an animal- and human-origin free neuromodulator
- 98% appreciated the environmentally friendly manufacturing of AboBoNT-A solution

I felt comfortable with the injection procedure: 91%

The treatment session was good and exceeded my expectations: 94%

I felt that the Treating Investigator could focus on me and my treatment at all times during the treatment session: 100%

I feel good when being injected with an animal and human origin free toxin: 90%

I appreciate that the product is manufactured in an environmentally friendly manufacturing facility: 98%
RESULTS

Subject satisfaction with appearance 6 months after treatment with RTU AboBoNT-A solution

- High rates of subjects were satisfied with their appearance (88%) and aesthetic outcome (85%) after RTU AboBoNT-A solution treatment

- Most subjects felt that they looked refreshed (85%) and natural (95%) after treatment with RTU AboBoNT-A solution

![Bar charts showing subject satisfaction with appearance and aesthetic outcome.](chart.png)
RESULTS

Aesthetic improvement in GLs at maximum frown after RTU AboBoNT-A solution treatment

- At Month 1, 99% of subjects had aesthetic improvement in GLs at maximum frown, which persisted in ~76% up to Month 6
- Similar aesthetic improvement rates were reported by investigators

Responders were defined as subjects assessed “improved”, “much improved” or “very much improved” on the Global Aesthetic Improvement Scale (GAIS).
RESULTS

Safety

- No SAEs and no ptosis occurred
- Treatment with both products was well tolerated with mostly mild and transient adverse events
- The most common treatment-related adverse events were headache and injection site pain

DISCUSSION

- The high subject satisfaction and aesthetic improvement shown in the present study supports the established clinical effect of the RTU AboBoNT-A solution, including a long duration of up to 6 months, accompanied by improved subject satisfaction and well-being after treatment.²

CONCLUSIONS

- **Less time** was required to prepare the RTU AboBoNT-A solution than powder OnaBoNT-A

- Most investigators preferred the AboBoNT-A RTU solution and considered it **user and environmentally friendly**.

- Both investigators and subjects reported **aesthetic improvement in GLs throughout 6 months**

- Subject **satisfaction was high and consistent** throughout 6 months

- Animal- and human-origin free product and **sustainable manufacturing was appreciated** by the subjects.

- Both treatments were **well tolerated**
DISCLOSURES

• Dr Chadha is a consultant and investigator for Galderma.
• Medical writing assistance was provided by Deepika, on behalf of Galderma Aesthetics.

Funding: This study was funded by Galderma.