Safety and Efficacy of TrenibotulinumtoxinE Following Repeat Treatments for Glabellar Lines: Findings From an Open-Label Phase 3 Study

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OBJECTIVE

To evaluate the safety and efficacy of up to 3 open-label treatment cycles of trenibotE 700 U for glabellar lines

CONCLUSIONS

TrenibotE was well-tolerated over 3 open-label treatments, showing a consistent safety profile, no new safety concerns, and no neutralizing antibody development

Treatment rapidly reduced glabellar line severity, with consistent efficacy over 3 open-label treatments based on investigator and participant assessments

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INTRODUCTION

- Facial lines that develop from repeated facial expression, such as glabellar lines (GL), are typically treated by selectively weakening specific muscles with botulinum neurotoxin type A (BoNT/A)[1]
- Individuals seeking to improve the appearance of wrinkles may be hesitant to try currently marketed BoNT/A products due to uncertainty around outcomes, including unnatural looking results
- TrenibotulinumtoxinE (trenibotE), a botulinum neurotoxin type E, is being developed as a trial toxin for the treatment of GL
- TrenibotE has a distinct pharmacological profile from BoNT/A, with rapid clinical results and shorter duration, and addresses treatment barriers for toxin-hesitant individuals[2,3]
- A single trenibotE 700 units (U) treatment has been shown to be well-tolerated and effective for reducing GL severity, producing high patient satisfaction and improved appearance-related psychological impact from GL[2,3]
- Here, we report findings from an 18-week, open-label, Phase 3 study evaluating the safety and efficacy of repeat trenibotE treatment (up to 3 open-label treatments) for GL

METHODS

Study Design

- **Participants:** Adults (≥18 years) with *Moderate* or *Severe* GL at maximum frown on the Facial Wrinkle Scale (FWS) at screening and baseline based on investigator and participant assessments
- **Key Retreatment Criterion:** Return to *Moderate* or *Severe* GL on the FWS

Treatment Administration

- Participants treated with trenibotE 700 U at baseline could receive up to 2 additional open-label treatments if retreatment criteria were met
- Treatment was administered as 5 intramuscular injections to the glabellar line area

Safety Assessments

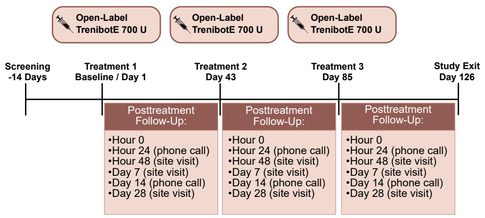
- Adverse Events (AEs) – Incidence, type, and severity
- Vital Signs – Measurements change from baseline
- Immunogenicity – Presence of binding and neutralizing anti-drug antibodies
- Electrocardiogram (ECG) – Parameter change from baseline

Efficacy

- Allergan Facial Wrinkle Scale (FWS) – GL severity change from baseline

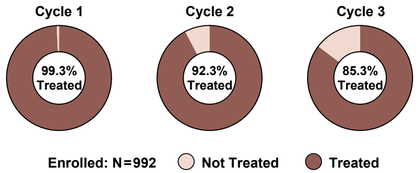
Blood sample collection for immunogenicity assays: Screening, prior to retreatment (Days 43, 85), and Study Exit (Day 126).

Study Design

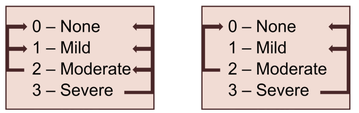


RESULTS

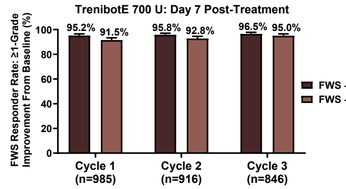
Most Participants Received 3 TrenibotE 700 U Treatments (Open-Label)



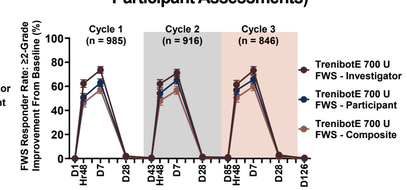
GL Severity (FWS): ≥1- or ≥2-Grade Improvement From Baseline



Trenibot 700 U: Consistent Efficacy Across 3 Treatment Cycles



GL Severity: ≥2-Grade Improvement Over 3 Treatments (Investigator and Participant Assessments)



Hr 48, D7, and D28 are relative to the start of each treatment cycle. Error bars indicate the 95% CI. Cycle 1, 2, 3 indicate treatment with at least 1, 2, and 3 doses, respectively. FWS – Composite, Facial Wrinkle Scale, Composite Score (Investigator- and Participant-Rated); FWS – Investigator, Facial Wrinkle Scale, Investigator-Rated; FWS – Participant, Facial Wrinkle Scale, Participant-Rated; CI, confidence interval; D, day; Hr, hour; TrenibotE, trenibotulinumtoxinE.

Baseline Demographics and Characteristics

ITT population	TrenibotE (N = 992)
Mean age, years	49.3
Sex, n (%)	
Female	852 (85.9)
Male	140 (14.1)
Prior aesthetic toxin use, n (%)	
No	782 (78.8)
Yes	210 (21.2)
Fitzpatrick skin type, n (%)	
I / II	372 (37.5)
III / IV	517 (52.2)
V / VI	96 (9.7)
Missing	7 (0.7)
FWS at maximum frown – investigator, n (%)	
*Grade 0 – None**	1 (0.1)
*Grade 1 – Mild**	0 (0.0)
Grade 2 – Moderate	340 (34.3)
Grade 3 – Severe	640 (64.5)
*Missing**	11 (1.1)
FWS at maximum frown – participant, n (%)	
*Grade 0 – None**	0 (0.0)
*Grade 1 – Mild**	1 (0.1)
Grade 2 – Moderate	265 (26.7)
Grade 3 – Severe	718 (72.4)
*Missing**	8 (0.8)

**Missing, None* or *Mild* FWS at maximum frown was considered a protocol deviation; ITT, intent-to-treat; TrenibotE, trenibotulinumtoxinE.

Safety: Incidence of Treatment-Emergent Adverse Events

	Cycle 1 (n = 985)	Cycle 2 (n = 916)	Cycle 3 (n = 846)
Treatment-emergent adverse events (TEAEs), n (%)	217 (22.0)	175 (19.1)	124 (14.7)
TEAE related to study treatment, n (%)	94 (9.5)	54 (5.9)	42 (5.0)
TEAE related to study drug	77 (7.8)	45 (4.9)	32 (3.8)
TEAE related to study procedure	83 (8.4)	47 (5.1)	37 (4.4)
Severe TEAE, n (%)	4 (0.4)	1 (0.1)	3 (0.4)
Related to study treatment	0 (0.0)	0 (0.0)	0 (0.0)
Treatment-emergent serious AE (TESAE), n (%)	3 (0.3)	0 (0.0)	4 (0.5)
Related to study treatment	0 (0.0)	0 (0.0)	0 (0.0)
TEAE leading to study drug discontinuation, n (%)	6 (0.6)	4 (0.4)	N/A
Possible distant spread of toxin TEAE, n (%)	3 (0.3)	5 (0.5)	1 (0.1)
Neurological assessment-associated TEAE, n (%)	6 (0.6)	5 (0.5)	1 (0.1)
Deaths, n (%)	0 (0.0)	0 (0.0)	0 (0.0)

- Incidence of TEAEs and treatment-related TEAEs did not increase with subsequent treatment cycles
- The most frequently (≥ 1.0% of participants overall) reported treatment-related TEAEs were headache, injection site pain, and injection site bruising
- Types of treatment-related TEAEs were similar across treatment cycles
- Most treatment-related TEAEs were mild in severity
- No TESAEs and no TEAEs leading to study drug discontinuation were considered related to study treatment
- No events were consistent with distant spread of toxin

Safety: Vital Signs and Electrocardiograms

- No clinically meaningful changes from baseline were observed for vital sign measurements and electrocardiogram parameters

Immunogenicity

- Treatment-emergent binding antibodies to trenibotE were detected in 1/985 participants at study exit; there was no evidence of neutralizing antibody development posttreatment.
- The participant with binding antibodies received 3 trenibotE treatments and did not demonstrate cross-reactivity to BoNT/A; there was no impact on the safety or efficacy of trenibotE

KEY TAKEAWAYS

- TrenibotE demonstrated a favorable safety profile over 3 open-label treatments, with no significant safety concerns or evidence of neutralizing antibodies identified
- Treatment with trenibotE 700 U rapidly improved GL severity, demonstrating consistent efficacy over 3 open-label treatments
- TrenibotE may help lower barriers for toxin-hesitant individuals seeking GL improvement, offering a flexible entry point to neurotoxin treatment