Sequential Administration of TrenibotulinumtoxinE and OnabotulinumtoxinA for Glabellar Lines: A Phase 1 Evaluation

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OBJECTIVE

To assess the safety and efficacy of sequential administration of trenibotulinumtoxinE (trenibotE) and onabotulinumtoxinA (onabotA), when onabotA was administered 30 days after trenibotE

CONCLUSIONS

Sequential administration of trenibotE followed by onabotA was well tolerated, with no new safety signals identified for either product

The efficacy of onabotA for treating glabellar lines (GL) was similar whether the participant initially received trenibotE or placebo

Data from this study are intended to provide information to clinicians on sequential administration of trenibotE followed by onabotA, administered 30 days apart, for continued treatment of GL[1]

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[1]TrenibotE is not currently approved.

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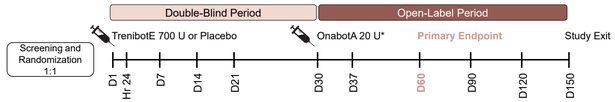
INTRODUCTION

- Individuals seeking to improve the appearance of wrinkles may be considering neurotoxin treatments but are hesitant to try currently marketed botulinum neurotoxin type A (BoNT/A) products due to uncertainty around outcomes, including unnatural results
- TrenibotE, a botulinum neurotoxin serotype E being developed for the treatment of GL, has a distinct pharmacological profile from BoNT/A, demonstrates rapid clinical results and shorter duration, and addresses treatment barriers for toxin-hesitant individuals
- Patients treated with trenibotE may transition to onabotA for continued treatment of GL; however, the effect of administering onabotA after trenibotE has been unknown
- This Phase 1 study is the first clinical evaluation of efficacy and safety of sequential administration of trenibotE and onabotA

METHODS

- **Participants**: Adults (≥18 years) with *Moderate* or *Severe* GL at maximum frown on the Allergan Facial Wrinkle Scale (FWS)
- **Primary Endpoint (Day 60)**: *None* or *Mild* on the FWS at maximum frown as assessed by Investigator 30 days after onabotA treatment; no formal hypothesis testing was conducted
- **Safety Assessments**: Treatment-emergent adverse events, physical exams, vital signs, electrocardiograms, lab assessments, immunogenicity

Study Design



*Participants who returned to *Moderate* or *Severe* at maximum frown on the FWS. D, day; Hr, hour; U, units.

RESULTS

Participants

- A total of 90 participants were enrolled and treated, and most completed the study
- Most participants were female and White, with no history of prior toxin use, and had severe GL on the FWS at baseline

Participant Disposition

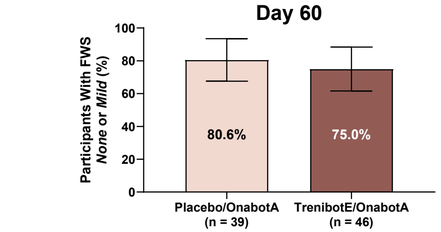
Participant Disposition	Period 1: Double-Blind		Period 2: Open-Label				Total
	Placebo	TrenibotE	Placebo / None	Placebo / OnabotA	TrenibotE / None	TrenibotE / OnabotA	
Treated, n	42	48	0	39	0	46	90
Completed Study, n (%)	40 (95.2)	47 (97.9)	0 (0.0)	38 (97.4)	1 (100.0)	44 (95.7)	83 (92.2)
Discontinued Study, n (%)	2 (4.8)	1 (2.1)	1 (100.0)	1 (2.6)	0 (0.0)	2 (4.3)	7 (7.8)
Discontinued Treatment, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)[a]	0 (0.0)	1 (1.1)

[a]Participant discontinued treatment due to adverse event which was considered unrelated to study treatment; participant remained in the study for safety follow-up.

Efficacy

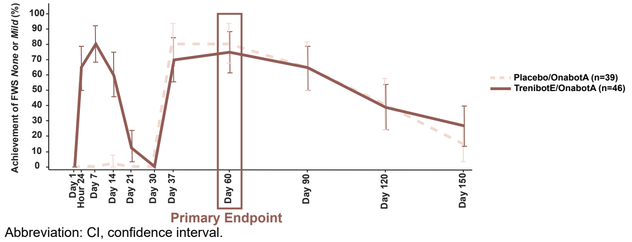
- FWS improvements were similar between participants treated initially with placebo or trenibotE who subsequently received onabotA

FWS at Maximum Frown: Investigator-Rated



Difference[a] (95% CI): -5.1% (-24.2%, 13.1%)

[a]Response rate difference for trenibotE/onabotA vs placebo/onabotA groups.



Abbreviation: CI, confidence interval.

Baseline Demographics

Baseline Demographics	Placebo (n = 42)	TrenibotE (n = 48)	Total (N = 90)
Mean age, years	48.0	50.1	49.1
Sex, n (%)			
Female	33 (78.6)	38 (79.2)	71 (78.9)
Male	9 (21.4)	10 (20.8)	19 (21.1)
Race, n (%)			
Asian	0 (0.0)	1 (2.1)	1 (1.1)
Black / African American	2 (4.8)	4 (8.3)	6 (6.7)
White	40 (95.2)	43 (89.6)	83 (92.2)
Baseline FWS at maximum frown,[a] n (%)			
Moderate	8 (19.0)	14 (29.2)	22 (24.4)
Severe	34 (81.0)	34 (70.8)	68 (75.6)
Prior aesthetic toxin use, n (%)	8 (19.0)	11 (22.9)	19 (21.1)

[a]Based on investigator rating.

Safety and Immunogenicity

- The incidence of treatment-emergent adverse events (TEAEs) was similar in placebo/onabotA and trenibotE/onabotA groups
- There were no deaths and no serious related TEAEs reported
- No possible distant spread of toxin TEAEs were reported
- No participants developed treatment-emergent binding or neutralizing antibodies to trenibotE or onabotA (timepoints for blood collection – screening, Day 30, Day 60, and Day 150 [Study Exit])

Safety

Safety Endpoint	Period 1: Double-Blind		Period 2: Open-Label	
	Placebo (n = 42)	TrenibotE (n = 48)	Placebo / OnabotA (n = 39)	TrenibotE / OnabotA (n = 46)
Treatment-emergent adverse event (TEAE), n (%)	4 (9.5)	8 (16.7)	13 (33.3)	15 (32.6)
Treatment-related TEAE, n (%)	0 (0.0)	1 (2.1)	1 (2.6)	0 (0.0)
Treatment-emergent serious adverse event (TESAE), n (%)	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)
Related to study treatment[a]	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Severe TEAE, n (%)	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)
Related to study treatment[a]	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TEAEs leading to study drug discontinuation, n (%)	0 (0.0)	1 (2.1)	-	-
Related to study treatment[a]	0 (0.0)	0 (0.0)	-	-

Most common TEAE in participants receiving trenibotE during Period 1 was headache. Most common TEAEs in any participant receiving onabotA during Period 2 were COVID-19, headache, and nasopharyngitis. Both treatment-related TEAEs were events of headache; both were assessed as related to drug and procedure. TESAE: ischemic skin ulcer. TEAE leading to study drug discontinuation: hemianesthesia in a participant with history of multiple sclerosis. [a]Based on assessments by the investigator.