# TrenibotulinumtoxinE Rapidly Improves Moderate to Severe Glabellar Lines: Pooled Phase 3 Efficacy and Safety Across East Asian and North American/European Trials

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## OBJECTIVE

This pooled analysis of 3 Phase 3 clinical studies of trenibotulinumtoxinE (trenibotE) 700U for glabellar lines (GL) evaluated the potential impact of regional differences between East Asian and North American/European Union (EU) populations on treatment outcomes

## CONCLUSIONS

Rapid clinical results are seen with trenibotE for GL treatment, with consistent effects in East Asian and North American/ European populations

TrenibotE's shorter efficacy duration seen across different regional populations may lower treatment barriers for toxin-hesitant individuals

TrenibotE 700U is well tolerated and demonstrates a favorable benefit-risk profile across different regional populations

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## INTRODUCTION

### Background

- Facial movements may result in unwanted wrinkles, such as GL, leading to dissatisfaction with facial appearance[1]
- 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[2]
- TrenibotE, a botulinum neurotoxin serotype E being developed as a trial toxin 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[3]

## METHODS

### Treatment

- Participants received either trenibotE 700U or placebo followed by 1 open-label treatment of trenibotE 700U

### Safety Assessments

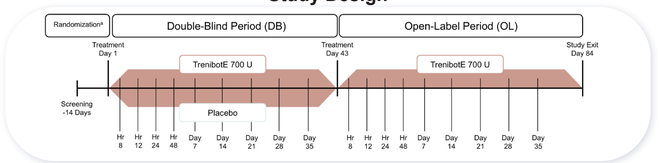
- Adverse events, vital signs, and immunogenicity assessments

### Statistical Analysis

- This pooled analysis used safety and efficacy data from 3 studies to compare 2 regional populations: 1 pivotal Phase 3 (Ph3), placebo-controlled (PC) study with East Asian participants to 2 pivotal Ph3, PC studies with North American (United States, Canada)/EU (Germany, Hungary, Poland) participants

## METHODS, CONT'D.

### Study Design




[a]East Asian study was randomized 2:1; North America/EU Studies were randomized 3:1

### Endpoints Analyzed

- ≥2-grade improvement at Day 7 in GL with the Facial Wrinkle Scale with Asian Photonumeric Guide (FWS-A) or Facial Wrinkle Scale with Photonumeric Guide (FWS) using participant-based assessments
- ≥2-grade improvement at Day 7 in GL with FWS-A or FWS using investigator-based assessments
- ≥2-grade improvement at Hour 24 in GL with the FWS-A or FWS using participant- and investigator-based assessments
- ≥1-grade improvement at Hour 24 in GL with the FWS-A or FWS using participant- and investigator-based assessments

## RESULTS

### Participant Demographics

| | East Asian Study (N = 161) | | North American/EU Studies (N = 947) | |
|---|---|---|---|---|
| | TrenibotE (n = 106) | Placebo (n = 55) | TrenibotE (n = 709) | Placebo (n = 238) |
| **Mean Age, years (SD)** | 42.1 (12.5) | 40.5 (12.4) | 45.9 (13.0) | 46.0 (12.9) |
| **Sex, n (%)** | | | | |
| *Female* | 75 (70.8) | 44 (80.0) | 610 (86.0) | 201 (84.5) |
| *Male* | 21 (29.2) | 11 (20.0) | 99 (14.0) | 37 (15.5) |
| **Region, n (%)** | | | | |
| *East Asia* | 106 (100.0) | 55 (100.0) | 0 | 0 |
| *North America/EU* | 0 | 0 | 709 (100.0) | 238 (100.0) |
| **Race and Ethnicity, n (%)** | | | | |
| *Asian* | 106 (100.0) | 55 (100.0) | 32 (4.5) | 7 (2.9) |
| *Black or African American* | 0 | 0 | 35 (4.9) | 9 (3.8) |
| *White* | 0 | 0 | 621 (87.6) | 210 (88.2) |
| **Fitzpatrick Skin Type, n (%)** | | | | |
| *I* | 1 (0.9) | 0 | 35 (4.9) | 6 (2.5) |
| *II* | 9 (8.5) | 8 (14.5) | 250 (35.3) | 97 (40.8) |
| *III* | 36 (34.0) | 16 (29.1) | 259 (36.5) | 86 (36.1) |
| *IV* | 54 (50.9) | 28 (50.9) | 114 (6.1) | 31 (13.0) |
| *V* | 6 (5.7) | 3 (5.5) | 38 (5.4) | 11 (4.6) |
| *VI* | 0 | 0 | 13 (1.8) | 7 (2.9) |

EU, European Union; SD, standard deviation; TrenibotE, trenibotulinumtoxinE.

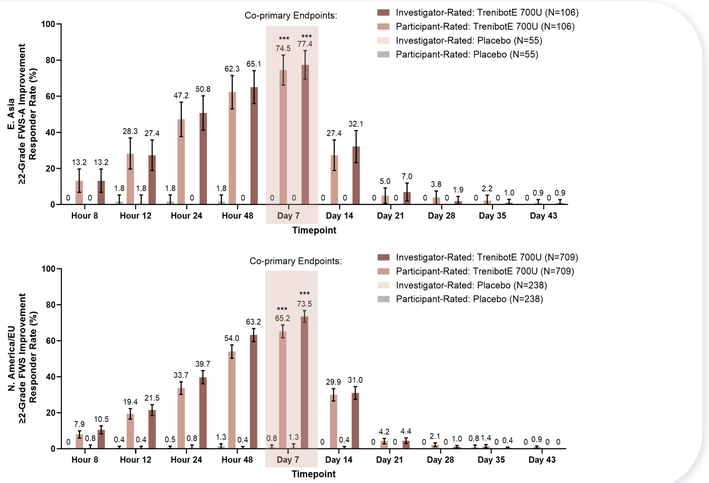
### Safety

| | East Asian Study (N = 161) | | North American/EU Studies (N = 947) | |
|---|---|---|---|---|
| | TrenibotE (n = 106) | Placebo (n = 55) | TrenibotE (n = 709) | Placebo (n = 238) |
| **Treatment-Emergent Adverse Events (TEAEs), n (%)** | 18 (17.0) | 11 (20.0) | 166 (23.4) | 63 (26.5) |
| **TEAEs Related to Study Treatment[a], n (%)** | 1 (0.9) | 0 | 54 (7.6) | 22 (9.2) |
| **Severe TEAEs, n (%)** | 0 | 0 | 4 (0.6) | 2 (0.8) |
| Related to Study Treatment[a] | 0 | 0 | 0 | 0 |
| **Serious TEAEs, n (%)** | 1 (0.9) | 0 | 4 (0.6) | 1 (0.4) |
| Related to Study Treatment[a] | 0 | 0 | 0 | 0 |
| **Possible Distant Spread of Toxin (PDSOT) TEAEs, n (%)** | 1 (0.9) | 0 | 1 (0.1) | 0 |
| **TEAEs Leading to Study Drug Discontinuation, n (%)** | 0 | 0 | 8 (1.1) | 0 |
| **All Deaths, n (%)** | 0 | 0 | 0 | 0 |

[a]Determined by investigator. EU, European Union; TrenibotE, trenibotulinumtoxinE.

- Overall, the incidence rate of treatment-related treatment-emergent adverse events (TEAEs) was lower in the East Asian population compared with the North American/EU participants
- The most frequently reported treatment-related TEAEs (≥ 1% participants) among trenibotE-treated participants were headache and injection site pain in the North American/EU participants. The only treatment-related TEAE in the East Asian population was dysphonia (2 events reported in 1 participant)
- No events were consistent with distant spread of toxin
- No clinically meaningful changes from baseline were observed for vital signs

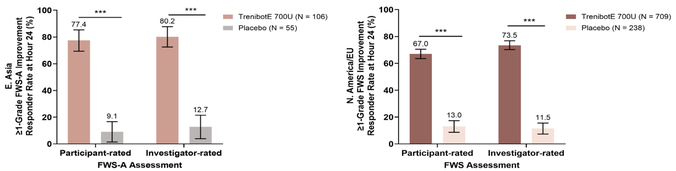
### TrenibotE Rapid Results and Duration of FWS Improvements Were Similar in Both East Asian and North America/EU Populations




Co-primary endpoints were statistically significant (***P < 0.0001); Responder rate of achievement of at least 2-grade improvement at maximum frown using the participant-rated and investigator-rated assessment on either the FWS or FWS-A. Error bars indicated 95% CI. For the E. Asian population, p-value was derived from Cochran-Mantel-Haenszel (CMH) test stratified by country/region and baseline FWS-A at maximum frown. For the N. American population, p-value was derived from CMH test stratified by study, investigator site, prior aesthetic use, and baseline FWS-A at maximum frown. CI, confidence interval; E Asian, East Asian; EU, European Union; FWS, Allergan Facial Wrinkle Scale; FWS-A, Allergan Facial Wrinkle Scale with Asian Photonumeric Guide; N. America, North America; TrenibotE, trenibotulinumtoxinE.

- Secondary endpoints were achieved: TrenibotE treatment led to significant FWS ≥2-grade improvements compared with placebo at Hour 24 ($P < 0.0001$) according to both participant and investigator ratings in both populations

### TrenibotE Treatment Led to Significant Improvements at Hour 24 in Both the East Asian and North America/EU Populations




Additional endpoints were statistically significant (***P < 0.0001); Responder rate of achievement of at least 1-grade improvement at maximum frown using the participant-rated and investigator-rated assessment on either the FWS or FWS-A at Hour 24. Error bars indicated 95% CI. For the E. Asian population, p-value was derived from Cochran-Mantel-Haenszel (CMH) test stratified by country/region and baseline FWS-A at maximum frown. For the N. American population, p-value was derived from CMH test stratified by study, investigator site, prior aesthetic use, and baseline FWS-A at maximum frown. CI, confidence interval; E Asian, East Asian; EU, European Union; FWS, Allergan Facial Wrinkle Scale; FWS-A, Allergan Facial Wrinkle Scale with Asian Photonumeric Guide; N. America, North America; TrenibotE, trenibotulinumtoxinE.