Reduction of Masseter Muscle Prominence After Treatment with OnabotulinumtoxinA: Results from a Phase 3 Double-Blind, Randomized, Placebo-Controlled Study Period in the United States

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OBJECTIVE

To compare the safety and efficacy of onabotulinumtoxinA (onabotA) with placebo in reducing masseter muscle prominence (MMP) in adults with 'Marked' (Grade 4) to 'Very marked' (Grade 5) MMP in the United States (US)

CONCLUSIONS

Adults in the US treated with onabotA 48 U achieved significant reduction in MMP as well as reductions in lower facial volume and width compared with placebo

Participants reported significantly greater satisfaction with the effect of onabotA treatment as compared with placebo

Treatment with onabotA was well tolerated with no new safety concerns identified, underscoring its utility as a treatment option for MMP reduction in adults in the US

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INTRODUCTION

Background

- Masseter muscle prominence (MMP), enlargement of the masseter muscle, can appear as a wide, square lower face[1]
- Minimally invasive aesthetic procedures that sculpt and enhance the contour of the lower face continue to grow in popularity, particularly non-surgical approaches for treating MMP[2,3]

Treatment Strategy and Present Study

- OnabotulinumtoxinA (onabotA) injections to the masseter muscles can reduce MMP severity, slim the lower face, and improve patient satisfaction with lower facial appearance[3]
- This ongoing randomized phase 3 study (NCT06387394) compared the safety and efficacy of onabotA with placebo in adults with 'Marked' (Grade 4) to 'Very marked' (Grade 5) MMP in the United States (US)

METHODS

Enrollment and Study Design

- The study enrolled adults in the US (N=202) with bilateral Grade 4/5 MMP at baseline, assessed using the validated 5-grade investigator-assessed Masseter Muscle Prominence Scale (MMPS) and validated participant-assessed MMPS-Participant (MMPS-P), who had no history of temporomandibular joint dysfunction
- In the double-blind, randomized, placebo-controlled period, participants were randomized to receive onabotA 48 units (U) (n=150) or placebo (n=52) at baseline
- A total of six intramuscular injections were administered bilaterally into the area of maximal bulge (8 U per injection site, 24 U per masseter muscle), and participants were followed for 180 days

METHODS (CONT'D.)

Study Endpoints

- Primary multi-component endpoint: achievement of Grade ≤3 and ≥2-grade improvement from baseline on the MMPS and MMPS-P at day 90
- Secondary endpoint: responses of 'Very satisfied' or 'Satisfied' with effect of treatment on the validated Lower Facial Shape Questionnaire-Treatment Satisfaction Assessment (LFSQ-TXSAT [Follow-up version]) at day 90
- Additional endpoints:
  - Individual components of MMPS and MMPS-P Grade ≤3 and ≥2-grade improvement
  - Reduction in lower facial volume (cm^3) and width (mm)

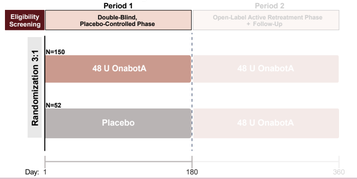
Safety

- Treatment-emergent adverse events (TEAEs) were monitored throughout the study

Statistical Analyses

- Missing values up to day 180 were imputed using multiple imputation, and statistical significance was evaluated at a two-sided α level of 0.05

Study Schematic



Measure	Description
Masseter Muscle Prominence Scale (MMPS)	Investigator assessment of MMP severity on a 5-point scale ranging from 1 ("Minimal") to 5 ("Very marked")
MMPS-Participant (MMPS-P)	Participant assessment of MMP severity on a 5-point scale from 1 ("Not at all noticeable") to 5 ("Extremely noticeable")
LFSQ-Treatment Satisfaction Assessment (LFSQ-TXSAT): Follow-up Version	Single-item measure assessing satisfaction with the effect of treatment on the appearance of the lower face on a 5-point scale ranging from −2 ("Very dissatisfied") to +2 ("Very satisfied")

Measures developed and validated in accordance with international regulatory and professional society standards.
Abbreviations: MMP, Masseter Muscle Prominence; onabotA, onabotulinumtoxinA.

RESULTS

Participants

- Participants were mostly White (69.8%) or Asian (20.8%) and female (90.1%), with a mean age of 36.7 years and mean body mass index of 24.6 kg/m²
- Participant demographics were similar between treatment arms

Participant Demographics

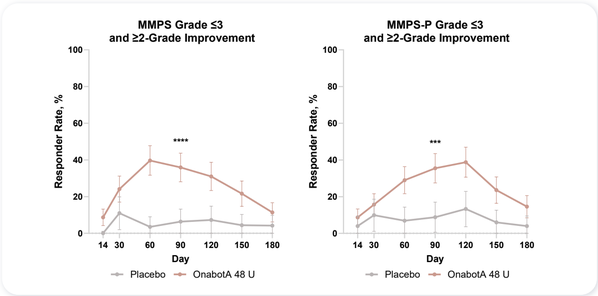
Demographics	Placebo N = 52	OnabotA 48 U N = 150
Age (years)		
Mean (SD)	35.2 (11.7)	37.3 (12.2)
Min, Max	19, 62	18, 78
Sex, n (%)		
Male	1 (1.9)	19 (12.7)
Female	51 (98.1)	131 (87.3)
Race, n (%)		
American Indian or Alaska Native	0 (0.0)	1 (0.7)
Asian	9 (17.3)	33 (22.0)
Black or African American	6 (11.5)	8 (5.3)
White	36 (69.2)	105 (70.0)
Multiple	1 (1.9)	3 (2.0)
Body mass index (kg/m²)		
Mean (SD)	24.3 (3.4)	24.7 (3.2)
Min, Max	16.3, 31.3	18.1, 37.6
Baseline Characteristics		
MMPS, n (%)		
Marked (Grade 4)	41 (78.8)	114 (76.0)
Very marked (Grade 5)	11 (21.2)	36 (24.0)
MMPS-P, n (%)		
Quite a bit noticeable (Grade 4)	40 (76.9)	113 (75.3)
Extremely noticeable (Grade 5)	12 (23.1)	37 (24.7)

Abbreviations: MMPS, Masseter Muscle Prominence Scale; MMPS-P, Masseter Muscle Prominence Scale-Participant; onabotA, onabotulinumtoxinA; SD, standard deviation.

Efficacy

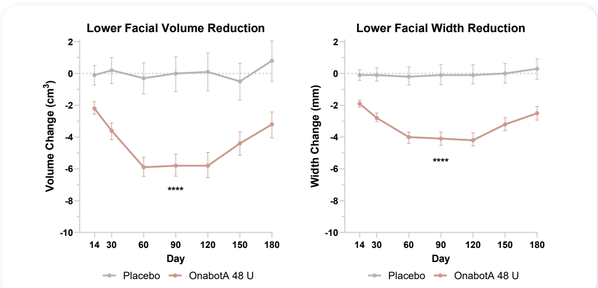
- Achievement of multi-component Grade ≤3 and ≥2-grade improvement in baseline MMP severity based on the MMPS and MMPS-P at day 90 was significantly greater in onabotA-treated participants than placebo (p=0.0046)
- A greater proportion of onabotA-treated participants achieved MMP severity Grade ≤3 and ≥2-grade improvement from baseline based on the MMPS (35.9% vs. 6.4%, nominal p<0.0001) and MMPS-P (35.5% vs. 8.8%, nominal p=0.0005) compared to placebo
- A significantly greater proportion of onabotA-treated participants reported feeling 'Very satisfied'/'Satisfied' with effect of treatment on the LFSQ-TXSAT compared to placebo (57.2% vs. 26.0%, p=0.0002) at day 90; satisfaction was maintained through day 180
- Treatment with onabotA reduced lower facial volume and width compared to placebo (both nominal p<0.0001), and this trend was maintained through day 180

Improvement in MMP Severity Following OnabotA or Placebo as Assessed by Investigators (MMPS) and Participants (MMPS-P)



Achievement of Grade ≤3 and ≥2-grade improvement in MMP severity based on (left) investigator-assessed MMPS and (right) participant-assessed MMPS-P plotted with 95% confidence interval bands. P-values were calculated based on the stratified Cochran-Mantel-Haenszel test using a two-sided α level of 0.05. Abbreviations: MMPS, Masseter Muscle Prominence Scale; MMPS-P, Masseter Muscle Prominence Scale-Participant; onabotA, onabotulinumtoxinA. ***nominal p<0.001, ****nominal p<0.0001 versus placebo.

Reduction of Lower Facial Volume and Width Following OnabotA or Placebo



Reductions in MMP-associated (left) lower facial volume and (right) width over time plotted with 95% confidence interval bands. P-values were calculated based on analysis of covariance (ANCOVA) using a two-sided α level of 0.05. Abbreviations: MMP, masseter muscle prominence; onabotA, onabotulinumtoxinA. ****nominal p<0.0001 versus placebo.

Safety

- Treatment of MMP with onabotA in adults in the US was well tolerated as assessed by the frequency, seriousness, and severity of TEAEs, with no serious or severe treatment-related TEAEs, and no evidence of distant spread of toxin
- The severity of most TEAEs was mild, with nasopharyngitis, upper respiratory tract infection, and pharyngitis streptococcal among the most commonly reported

Treatment-Emergent Adverse Events

Safety population as of iDBL cutoff, n (%)	Placebo N = 52	OnabotA 48 U N = 149[a]
TEAEs reported in >2.5% of any group and ≥2 participants		
Nasopharyngitis	3 (5.8)	4 (2.7)
Upper respiratory tract infection	1 (1.9)	4 (2.7)
Pharyngitis streptococcal	2 (3.8)	1 (0.7)
Treatment-related TEAEs		
Treatment-related serious adverse event	0	0
Severity of treatment-related TEAEs		
Mild	3 (5.8)	8 (5.4)
Moderate	0	1 (0.7)
Severe	0	0
Treatment-related TEAEs reported in ≥2 participants		
Paradoxical masseter muscle bulging	0	3 (2.0)

[a]Note: One participant was enrolled and randomized to the onabotA group but did not receive treatment and was excluded from the safety population. iDBL cutoff date for primary analysis: June 18, 2025. Abbreviations: iDBL, interim database lock; onabotA, onabotulinumtoxinA; TEAE, treatment-emergent adverse event.