Improvement of platysma prominence with onabotulinumtoxinA: Safety and efficacy results from a randomized, double-blinded, placebo-controlled phase 3 trial

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Background: Platysma prominence (PP) refers to the undesirable effects that may occur with platysma muscle contraction.

Objective: Evaluate safety and efficacy of onabotulinumtoxinA for improving Moderate (Grade 3) to Severe (Grade 4) PP in adults.

Methods: Participants were randomized 1:1 to receive a total dose of onabotulinumtoxinA 26, 31, or 36 U or placebo on Day 1 and monitored for 120 days. Dosage was administered via superficial intramuscular injections into the platysma muscle based on baseline PP severity.

Results: At Day 14, 32.3% of onabotulinumtoxinA-treated participants in the intent-to-treat population versus 1.9% who received placebo achieved investigator- and participant-rated Grade 1 or 2 (Minimal or Mild) and ≥2-grade improvement from baseline in PP severity, while 56.9% and 51.7% achieved Grade 1

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Data sharing statement: AbbVie is committed to responsible data sharing regarding the clinical trials we sponsor. This includes access to anonymized, individual, and trial-level data (analysis data sets), as well as other information (eg, protocols, clinical study reports, or analysis plans), as long as the trials are not part of an ongoing or planned regulatory submission. This includes requests for clinical trial data for unlicensed products and indications. These clinical trial data can be requested by any qualified researchers who engage in rigorous, independent, scientific research and will be provided following review and approval of a research proposal, statistical analysis plan (SAP), and execution of a data sharing agreement (DSA). Data requests can be submitted at any time after approval in the US and Europe and after acceptance of this manuscript for publication. The data will be accessible for 12 months, with possible extensions considered. For more information on the process or to submit a request, visit the following link: https://vivli.org/ourmember/abbvie then select "Home."

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or 2 on investigator's and participant's assessments, respectively (all $P < .0001$). OnabotulinumtoxinA-treated participants reported higher satisfaction, less bother from jawline and vertical neck band appearance, and reduced psychosocial impact versus placebo (all $P < .0001$). Adverse event incidence was similar between onabotulinumtoxinA and placebo. No events of dysphagia or muscular weakness were reported.

Limitations: A single onabotulinumtoxinA treatment was evaluated.

Conclusion: OnabotulinumtoxinA showed favorable tolerability and significantly improved PP severity and patient-reported outcomes in participants with moderate-to-severe PP. (J Am Acad Dermatol 2025;92:285-91.)

Key words: botulinum toxins, type A; intramuscular injection; jawline; lower face; neck; patient satisfaction; platysma muscle; platysma prominence; randomized controlled trial; rejuvenation; vertical neck bands.

INTRODUCTION

The platysma muscle plays a significant role in the esthetic appearance of neck and lower face.[1-3] This broad and thin muscle originates in the fascia of the upper thoracic region and extends upward to insert into the mandibular periosteum, the superficial musculoaponeurotic system and parotid fascia, the mandibulocutaneus ligament or zygoma, and the skin and muscles of the lower face.[1-4] Its contraction results in visible tightening of its fibers along the neck, leading to the development of distinct vertical neck bands.[1,4] Additionally, contraction of the upper portion of the platysma muscle applies a downward force on the lower face, resulting in a blunting effect of the jawline contour.[1,5]

Esthetically, the unattractive disruption to the contour of the lower face and neck that occurs with platysma muscle contraction is referred to as platysma prominence (PP). This change is commonly associated with aging but also manifests in younger individuals.[6] Their appearance may exacerbate over time, becoming bothersome during normal activities like speaking or smiling.[7,8] Moreover, since contraction of the platysma muscle is involved in expressing negative emotions, PP can misrepresent a patient's emotional state.[9] This negatively impacts self-esteem and quality of life,[9] besides causing an appearance of aging. In contrast, relaxed draping of the platysma muscle over jawline and neck contributes to a desired smooth, contoured appearance of lower face and neck.

OnabotulinumtoxinA (onabotA; BOTOX Cosmetic; Allergan Aesthetics, an AbbVie company) may alleviate the visible effects of an overactive platysma by reducing muscle contraction.[2,10-12] This Phase 3 study evaluated the safety and efficacy of a single onabotA treatment for improvement in the appearance of Moderate to Severe PP.

CAPSULE SUMMARY

- Nonsurgical treatments for platysma prominence are lacking, despite its potential negative impact on psychosocial well-being.
- OnabotulinumtoxinA was well tolerated and resulted in statistically significant and clinically meaningful improvements in platysma prominence severity, high satisfaction with treatment effect, less bother from jawline and vertical neck band appearance, and reduced psychosocial impact.

METHODS

Study design

A Phase 3 multicenter, double-blind, randomized, placebo-controlled study (NCT04949399) was conducted at 30 sites in the United States and Canada from July 2021 to December 2022, adhering to the Declaration of Helsinki and all International Council for Harmonization Good Clinical Practice guidelines. Before study initiation, an independent ethics committee and an institutional review board reviewed and approved the study protocol at each study site, and all participants provided informed consent.

Randomization and blinding

On Day 1, eligible participants with Moderate to Severe PP were randomized (1:1) with interactive response technology to onabotA or placebo. Randomization was stratified by investigational site and baseline severity on Day 1. A fixed dose of onabotA 16 U (2 U/injection) or placebo was administered along the jawline to the upper segment of the platysma muscle, 1 to 2 cm below the mandibular border, with 4 injections/side. An additional onabotA dose of 10, 15, or 20 U (1 U/injection) or placebo was injected into 2, 3, or 4 neck bands, respectively, with 5 injections/band (Supplementary

Abbreviations used:

ANLFQ:	Appearance of Neck and Lower Face Questionnaire
BAS-PP:	Bother Assessment Scale—Platysma Prominence
C-APPS:	Clinician Allergan Platysma Prominence Scale
ITT:	intent-to-treat
mITT:	modified intent-to-treat
OnabotA:	onabotulinumtoxinA
P-APPS:	Participant Allergan Platysma Prominence Scale
PP:	platysma prominence
TEAE:	treatment-emergent adverse event

Fig 1, available via Mendeley at https://data.mendeley.com/datasets/kdh5p39vsc/1). The number of injected bands varied based on the participant's baseline PP severity, treating 1 to 2 bands per side (Supplementary Table I, available via Mendeley at https://data.mendeley.com/datasets/kdh5p39vsc/1). More details on the injection pattern have been previously published.[12]

To ensure blinding, an independent individual reconstituted onabotA in preservative-free saline (4 U/0.1 mL) or placebo and prepared the syringes with the required volume. Investigators, study site personnel, and participants were blinded to treatment allocation. Investigators administered the treatment superficially through intramuscular injections into the platysma muscle by pinching the skin and underlying platysma away from the surrounding neck structures.

The study included a screening period (Day −14 to Day −7), a randomization/baseline/treatment visit (Day 1), follow-up visits (Days 14, 30, 60, and 90), and an exit visit (Day 120).

Participants

Adults at least 18 years old with a body mass index between 18 kg/m^2 and 30 kg/m^2, able to correctly and consistently maximally contract their platysma muscle, were included if they had Moderate (Grade 3) or Severe (Grade 4) PP at maximum contraction on both the left and right sides. Before treatment administration, PP severity was assessed independently by the investigator at screening and Day 1 using the Clinician Allergan Platysma Prominence Scale (C-APPS) and the participant at Day 1 using the Participant Allergan Platysma Prominence Scale (P-APPS). Participants could have a different PP severity on each side. Eligible participants had responses of at least *Somewhat bothered* on both items (Item 2 [jawline] and Item 1 [vertical neck bands]) of the Bother Assessment Scale—Platysma Prominence (BAS-PP) before treatment administration at Day 1. Key exclusion criteria included excess skin, submental fat, jowls, increased medical risk after exposure to onabotA, or medical conditions that could interfere with study assessments.

Outcomes

Efficacy analyses were performed in the intent-to-treat (ITT) population (all randomized participants) and the modified ITT (mITT) population (participants psychosocially impacted by PP appearance, determined by a summary score ≥19 on the Appearance of Neck and Lower Face Questionnaire [ANLFQ]: Impacts at baseline).

The composite primary efficacy endpoint and coprimary efficacy endpoints were selected following consultations with the US Food and Drug Administration and the European Medicines Agency, respectively. The composite primary efficacy endpoint was assessed in the ITT population and defined as the achievement of Grade 1 or 2 (Minimal or Mild) and ≥2-grade improvement from baseline based on both investigator's assessment using the C-APPS and participants' self-assessment using the P-APPS at maximum contraction at Day 14. The coprimary efficacy endpoints were assessed in the mITT population and defined as the achievement of ≥2-grade improvement from baseline based on: (1) investigator's assessment using the C-APPS at maximum contraction at Day 14, and (2) participant's self-assessment using the P-APPS at maximum contraction at Day 14. The C-APPS and P-APPS are validated 5-point photonumeric scales (1 = Minimal; 2 = Mild; 3 = Moderate; 4 = Severe; 5 = Extreme) to assess PP severity.[12,13] A 1-grade change in these scales was suggested as meaningful by clinicians and participants.

Secondary efficacy endpoints included: (1) achievement of Grade 1 or 2 at maximum contraction over time according to investigator's and participant's assessment using the C-APPS or P-APPS, respectively (ITT); (2) achievement of Grade 1 or 2 according to participant's self-assessment using the P-APPS at maximum contraction at Day 14 (mITT); (3) responses of *Satisfied* or *Very satisfied* on the ANLFQ: Satisfaction (Follow-up) Item 5 (effect of treatment) at Day 14 (ITT and mITT); (4) responses of *Not at all bothered* or *A little bothered* on the BAS-PP Item 2 at Day 14 (ITT and mITT); (5) responses of *Not at all bothered* or *A little bothered* on the BAS-PP Item 1 at Day 14 (ITT and mITT); (6) change from baseline on the ANLFQ: Impacts summary score at Day 14 (ITT and mITT), and Days 30, 60, and 90 (mITT). Details about the ANLFQ: Satisfaction, BAS-PP, and ANLFQ: Impacts scales have been previously published.[13]

The safety population included all participants who received the study drug. Treatment-emergent adverse events (TEAEs) and vital signs were monitored throughout.

Statistical analysis

Sample sizes of 360 (ITT) and 180 (mITT) participants were estimated to have >99% power to detect a difference in responder rates between onabotA and placebo for the composite primary and coprimary endpoints, respectively, using a 2-sided significance level of 0.05.

A hierarchical testing strategy was used to control the family-wise Type 1 error rate at 5% across primary and secondary endpoints. Secondary endpoints assessed over time were excluded from the hierarchical testing.

Prior to analysis, missing data were imputed using multiple imputation. Between-group comparisons for responder rates were analyzed using the Cochran–Mantel–Haenszel test stratified by C-APPS severity at Day 1 and by investigator site. For treatment differences, 95% CIs were estimated. Tests were 2-sided and conducted at the 0.05 significance level.

RESULTS

Participants

A total of 408 participants were randomized and included in the ITT and safety populations (Supplementary Fig 2, available via Mendeley at https://data.mendeley.com/datasets/kdh5p39vsc/1). Overall, 94.6% of participants completed the study. The primary reason for discontinuation was loss to follow-up. No participant discontinued due to adverse events.

Demographic and baseline characteristics of ITT and mITT populations were comparable (Supplementary Tables II and III, available via Mendeley at https://data.mendeley.com/datasets/kdh5p39vsc/1). Participants self-reported sex, race, and ethnicity, with a majority self-identifying as female (94.1%) and White (89.7%) in the ITT population. The mean age was 49.7 years (range 19 to 82 years). All Fitzpatrick skin types were represented, with type II (36.8%) and III (37.3%) as the most prevalent. At baseline, a higher percentage of participants in the onabotA and placebo groups had PP severity of Grade 4 on both sides (48.8%), compared to Grade 3 on both sides (23.8%) or Grade 3 on one side and Grade 4 on the other side (27.5%). Participants were *Somewhat bothered, A lot bothered, or Extremely bothered* by their jawline definition (BAS-PP Item 2) and vertical neck bands (BAS-PP Item 1), with a higher percentage being *A lot bothered* (44.4% and 52.0%, respectively).

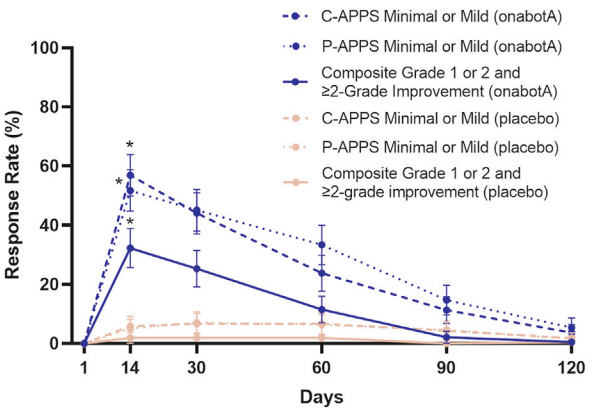

Fig 1. Achievement of Grade 1 or 2 (Minimal or Mild) and ≥2-grade improvement from baseline based on both investigator's assessment using the Clinician Allergan Platysma Prominence Scale (C-APPS) and participant's assessment using the Participant Allergan Platysma Prominence Scale (P-APPS) at maximum contraction (intent-to-treat population). *$P < .0001$ versus placebo; error bars indicate the 95% CIs. Missing data were imputed with multiple imputation. *OnabotA*, onabotulinumtoxinA.

Efficacy outcomes

The primary composite endpoint showed a significantly greater response rate for onabotA (32.3%; 95% CI [25.7% to 38.9%]) versus placebo (1.9%; 95% CI [0.1% to 3.8%]; $P < .0001$) at Day 14 (Fig 1). Similar results were obtained for the mITT population (Supplementary Table IV, available via Mendeley at https://data.mendeley.com/datasets/kdh5p39vsc/1). Representative photographs of a participant before treatment and after treatment on Day 14 are shown in Fig 2.

OnabotA achieved statistical significance versus placebo for all secondary endpoints at Day 14 (all $P < .0001$). The proportion of participants achieving Grade 1 or 2 (Minimal or Mild) at maximum contraction was greater for the onabotA group versus placebo at all follow-up visits (Fig 1). At Day 14, onabotA responder rates were significantly higher compared to placebo for both C-APPS (onabotA: 56.9%; 95% CI [49.9% to 63.9%]; placebo: 5.8%; 95% CI [2.5% to 9.2%]; $P < .0001$) and P-APPS (onabotA: 51.7%; 95% CI [44.7% to 58.8%]; placebo: 5.1%; 95% CI [2.1% to 8.2%]; $P < .0001$), and the effect gradually declined through Day 120 (final visit). The onabotA group also had a higher proportion of participants achieving ≥1-grade improvement throughout the study compared to placebo, with 80.1% (95% CI [74.5% to 85.7%]) (C-APPS) and 80.5%

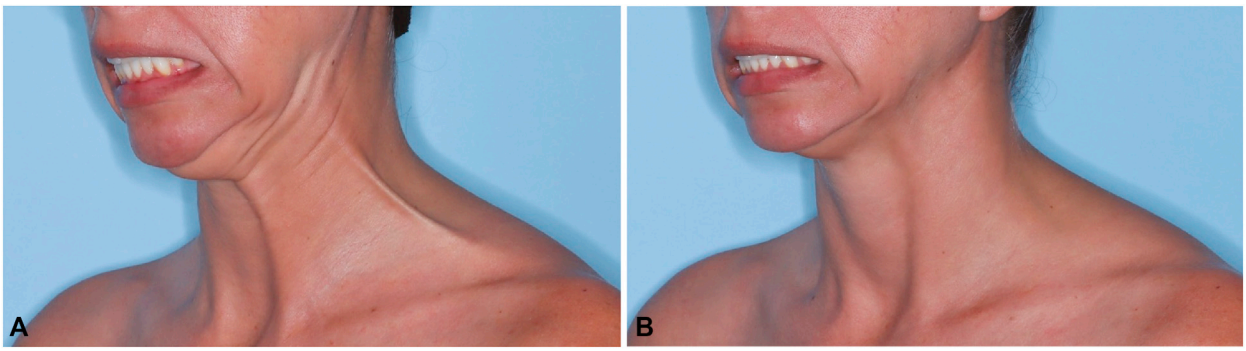

Fig 2. Clinically meaningful improvement in platysma prominence after treatment with 31 U of onabotulinumtoxinA. This participant was rated by the clinician as Grade 4 (Severe) on the left side at Day 1 (**A**) and achieved a Grade 1 (Minimal) at Day 14 (**B**). According to the participant, the platysma prominence severity on the right side improved from Grade 4 at Day 1 to Grade 2 at Day 14. Additionally, this participant responded *Very satisfied* in the Appearance of Neck and Lower Face Questionnaire: Satisfaction (Follow-up) Item 5 (effect of treatment) at Day 14 and improved from being *A lot bothered* at Day 1 to *Not at all bothered* in the Bother Assessment Scale-Platysma Prominence Item 2 (jawline) and Item 1 (vertical neck bands) at Day 14.

(95% CI [74.9% to 86.1%]) (P-APPS) responders on onabotA versus 19.0% (95% CI [13.5% to 24.5%]) and 23.2% (95% CI [17.3% to 29.1%]), respectively, on placebo at Day 14.

Treatment satisfaction at Day 14 was significantly higher in the onabotA group (65.9%; 95% CI [59.2% to 72.6%]) versus placebo (11.1%; 95% CI [6.7% to 15.6%]; $P < .0001$) (Fig 3). Assessment of bother on the BAS-PP Item 2 at Day 14 showed 53.9% of onabotA participants were *Not at all bothered* or *A little bothered* by their jawline definition (95% CI [46.9% to 60.8%]; $P < .0001$) versus 14.7% in the placebo group (95% CI [9.6% to 19.8%]). On the BAS-PP Item 1, 52.1% of onabotA participants were *Not at all bothered* or *A little bothered* by their vertical neck bands (95% CI [45.1% to 59.1%]; $P < .0001$) versus 7.4% in the placebo group (95% CI [3.8% to 11.1%]). Additionally, onabotA-treated participants showed greater improvements in psychosocial impact versus placebo, with a mean change from baseline of −7.4 for onabotA and −1.7 for placebo ($P < .0001$) at Day 14.

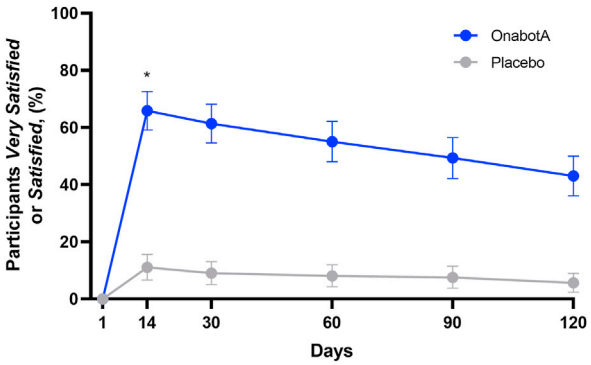

Fig 3. Percentage of participants in the intent-to-treat population reporting *Satisfied* or *Very satisfied* on the Appearance of Neck and Lower Face Questionnaire (ANLFQ): Satisfaction (Follow-up) Item 5 (effect of treatment) over time. *$P < .0001$ versus placebo; error bars indicate the 95% CIs. Missing data were imputed with multiple imputation. *OnabotA*, onabotulinumtoxinA.

Safety

At least 1 TEAE was reported by 23.6% of participants in the onabotA group and 21.5% in the placebo group (Table I). Most TEAEs were mild, with the most common ones being COVID-19 infection (3.7%), injection site bruising (1.7%), and injection site hemorrhage (1.5%).

Six (3.0%) participants in the onabotA group and 10 (4.8%) in the placebo group reported at least 1 treatment-related TEAE. The most frequently reported treatment-related TEAEs were injection site hemorrhage (onabotA: 1.5%; placebo: 1.4%) and injection site bruising (onabotA: 0.5%; placebo: 2.4%), which were considered related to the study procedure by the investigator (Supplementary Table V, available via Mendeley at https://data.mendeley.com/datasets/kdh5p39vsc/1). The majority of treatment-related TEAEs were mild, localized to the treatment area, temporary (median duration: 6 days), and resolved spontaneously. No events of dysphagia or neck muscle weakness were reported. No serious treatment-related TEAE occurred.

No evidence of distant spread of toxin events was observed, and no clinically meaningful changes in vital signs from baseline were detected.

Table I. Participants with adverse events in the safety population

	Placebo (*n* = 209) *n* (%)	OnabotA (*n* = 199) *n* (%)	Total (*N* = 408) *n* (%)
Treatment-emergent adverse events (TEAEs)	45 (21.5)	47 (23.6)	92 (22.5)
TEAE related to study treatment	10 (4.8)	6 (3.0)	16 (3.9)
TEAE related to study procedure	10 (4.8)	6 (3.0)	16 (3.9)
TEAE related to study drug	3 (1.4)	3 (1.5)	6 (1.5)
Mild	9 (4.3)	6 (3.0)	15 (3.7)
Moderate	1 (0.5)	0 (0.0)	1 (0.2)
Severe	0 (0.0)	0 (0.0)	0 (0.0)
Treatment-emergent serious adverse events (TESAE)	3 (1.4)	2 (1.0)	5 (1.2)*
Related to study treatment	0 (0.0)	0 (0.0)	0 (0.0)
TEAE leading to death	0 (0.0)	0 (0.0)	0 (0.0)
Treatment-emergent adverse events of special interest (AESI)†	0 (0.0)	0 (0.0)	0 (0.0)
Possible distant spread of toxin (PDSOT) TEAE	1 (0.5)	0 (0.0)	1 (0.2)‡
Deaths	0 (0.0)	0 (0.0)	0 (0.0)

AESI, Adverse events of special interest; *onabotA*, onabotulinumtoxinA; *TEAE*, treatment-emergent adverse event.

*TESAEs were appendicitis, cellulitis, ophthalmic vascular thrombosis, subarachnoid hemorrhage, and thyroid cancer. None were related to the study treatment.

†AESI included aspiration, aspiration pneumonia, dry mouth, dysphagia, dyspnea, facial paresis (lower facial muscle weakness), and muscular weakness (neck muscle weakness).

‡Dyspnea as a symptom of allergic reaction was identified as a PDSOT in the placebo group. No evidence of distant spread of the toxin was determined.

DISCUSSION

In this study, participants with Moderate to Severe PP were treated with onabotA 26, 31, or 36 U based on baseline PP severity on each side of the neck, considering anatomical variabilities in PP presentation. OnabotA dosage selection was guided by the Phase 2 study, where onabotA ([26, 31, 36 U] and [52, 62, 72 U]) showed greater efficacy than placebo, with the 26, 31, and 36 U doses demonstrating a more favorable safety profile.[12] Dosing targeted the jawline, below the mandibular border, and the neck bands, with a maximum of 2 bands/side. Ensuring an appropriate dose in the neck via superficial injections was crucial to prevent unwanted local diffusion of toxin, which could lead to complications like neck weakness and dysphagia.[8,14]

Our study demonstrated clinically meaningful and statistically significant improvements at Day 14, as assessed by composite primary and coprimary efficacy endpoints ($P < .0001$ vs placebo) and secondary endpoints ($P < .0001$ vs placebo). OnabotA was more effective than placebo regardless of baseline severity. Over 50% of participants achieved Grade 1 or 2 (Minimal or Mild), and approximately 80% achieved ≥1-grade improvement after 14 days (both $P < .0001$ vs placebo). Improvements were observed until the final visit with gradual decline over time.

Patient-reported outcomes were included to comprehensively assess onabotA impact on treatment, given the potential esthetic displeasure and emotional distress associated with PP.[5,6] High satisfaction has been reported among participants who undergo botulinum toxin treatment for platysma bands.[15,16] In our study, onabotA-treated participants reported significantly higher treatment satisfaction after 14 days (65.9% vs 11.1% in the placebo group, $P < .0001$) and reduced bother with jawline definition and vertical neck bands (over 50% vs <15% in the placebo group, $P < .0001$). They also experienced a significant decrease in psychosocial impact related to PP compared to placebo ($P < .0001$). These findings highlight the efficacy of onabotA in addressing the esthetic and emotional challenges of PP.

Complications such as muscular weakness, dysphagia, or uneven smile can arise from improper injection or inadvertent diffusion of the toxin to neighboring muscles of the neck or lower face.[14,17] An increased incidence of unwanted effects has been reported with the use of high onabotA doses.[8,11,12,18] In this study, onabotA was well tolerated and showed a similar safety profile to its other esthetic indications,[19] with no new safety concerns identified. The incidence of TEAEs and treatment-related TEAEs were similar between onabotA and placebo, with most TEAEs considered mild and unrelated to study treatment by the investigator. No adverse events such as dysphagia or neck muscle weakness (ie, difficulty lifting head from recumbent position or during physical activity) were reported.

Although efforts were made to include diverse racial and ethnic backgrounds, these findings may not

be generalizable to all populations. This study focused on a single onabotA treatment. Safety and efficacy of repeat onabotA treatment for improving PP have been evaluated in an 8-month, open-label extension study (*manuscript in preparation*).

CONCLUSIONS

Treatment with onabotA 26, 31, or 36 U was well-tolerated and led to a statistically significant and clinically meaningful improvement in PP severity versus placebo. PP is one of the many changes the lower face and neck undergo over time.[1,18,20] OnabotA can be used as a noninvasive approach that, when combined with other treatment modalities such as soft tissue fillers and energy-based treatments, may address the various aspects impacting lower face and neck appearance.

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Conflicts of interest

Financial arrangements of the authors with companies whose products may be related to the present report are listed as declared by the authors. Dr Fabi is a consultant/speaker for AbbVie, Galderma, Merz Aesthetics, Revance, CROMA, and Ortho Dermatologics; has received research support from AbbVie, Galderma, Merz, Revance, CROMA, and Raziel; and holds stock in AbbVie and Revance Therapeutics. Drs Biesman and George are speakers, consultants, investigators, and advisory board members for Allergan Aesthetics, an AbbVie company. Dr Humphrey is a speaker, consultant, and/or investigator for Allergan Aesthetics, an AbbVie company, Galderma, Merz, and Revance. Drs LaTowsky and Weiss are speakers, consultants, investigators, and advisory board members for Allergan Aesthetics, an AbbVie company, and Galderma. Drs Park and Shimoga are employees of AbbVie and may own AbbVie stock. Ms Lee, Mr Jierjian, Mr Tong, and Ms Hopfinger are employees of Allergan Aesthetics, an AbbVie company, and may own AbbVie stock.

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