Patient Satisfaction With OnabotulinumtoxinA Treatment of Glabellar and Lateral Canthal Lines Evaluated Using the FLSQ®: A New Patient-Reported Outcome Measure

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Disclosures

- J.K. Rivers has served as an advisory board member and on a speakers' bureau for Allergan, Inc., and has received honoraria and research grants from that company.
- V. Bertucci has received honoraria, served as a remunerated consultant and speaker, and served on an advisory board for Allergan, Inc.
- C. Muhn has served as a remunerated consultant and speaker, served on advisory boards and received research funding from Allergan, Inc.
- N. Rosen has served as an advisory board member and a remunerated speaker for Allergan, Inc.
- K. Smith has served as a remunerated consultant and speaker, served on advisory boards and received research funding from Allergan, Inc.
- N. Solish has served on an advisory board for Allergan, Inc.
- S. Wheeler, S.R. Daniels, and C.J. Gallagher are employees of Allergan, Inc.

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Introduction

- Clinicians historically have focused on optimizing physical outcomes of aesthetic treatments and minimizing associated side effects[1]
- However, additional factors, including subject satisfaction, are increasingly recognized as important in assessing treatment success[2]
- Subject satisfaction is a multidimensional evaluation of various components, including subject expectations and the quality and duration of treatment effects[3,4]
- The Facial Line Satisfaction Questionnaire (FLSQ®) is a new patient-reported outcome measure, designed to assess subject satisfaction with an aesthetic treatment for correcting facial lines
- The FLSQ® was developed and validated using rigorous qualitative and quantitative methods that comply with the current US FDA PRO Guidance
- The objective of this study was to determine subject satisfaction with onabotulinumtoxinA for treatment of GL and CFL

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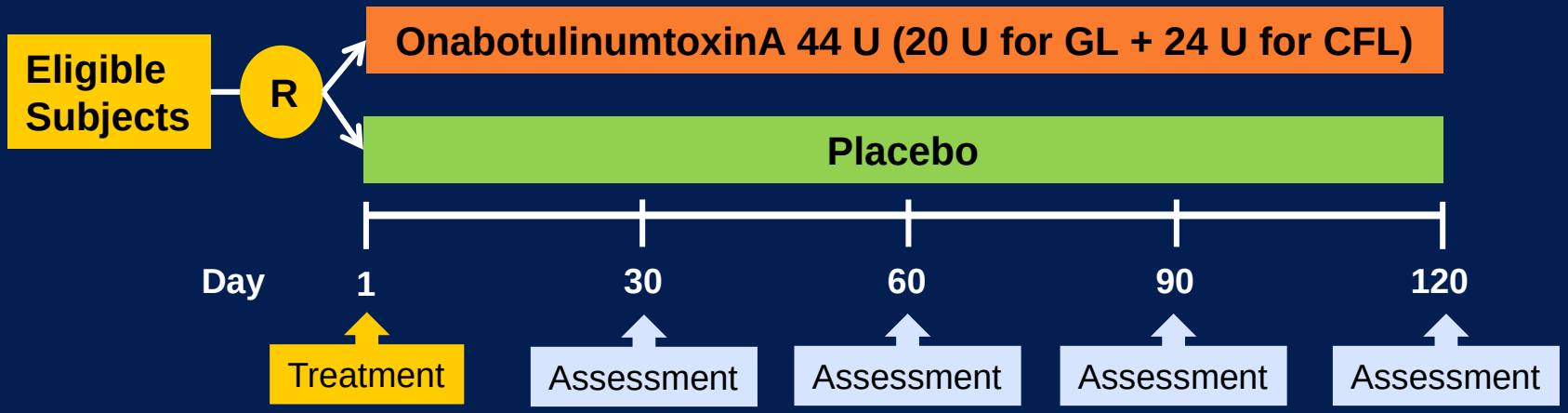
CFL, crow's feet lines; FDA, Food and Drug Administration; GL, glabellar lines; PRO, patient-reported outcomes.

Study Design

- Randomized, double-blind, parallel-group study conducted at 8 sites in Canada from February through July 2013 (clinicaltrials.gov: NCT01777620)



- Subjects used the 11-item FLSQ® Baseline Version to measure treatment expectations and the impact of facial lines at baseline
- Subjects used the 13-item FLSQ® Follow-up Version to assess treatment satisfaction, impact of facial lines, continuance of treatment, achievement of treatment expectations, and treatment recommendations at post-baseline visits
- Investigators used the 4-grade Facial Wrinkle Scale with photonumeric guide (FWS)* to assess severity of GL and CFL

*FWS 4-grade scale: none, mild, moderate, or severe.

CFL, crow's feet lines; GL, glabellar lines; R, randomized.

Key Eligibility Criteria

Inclusion Criteria

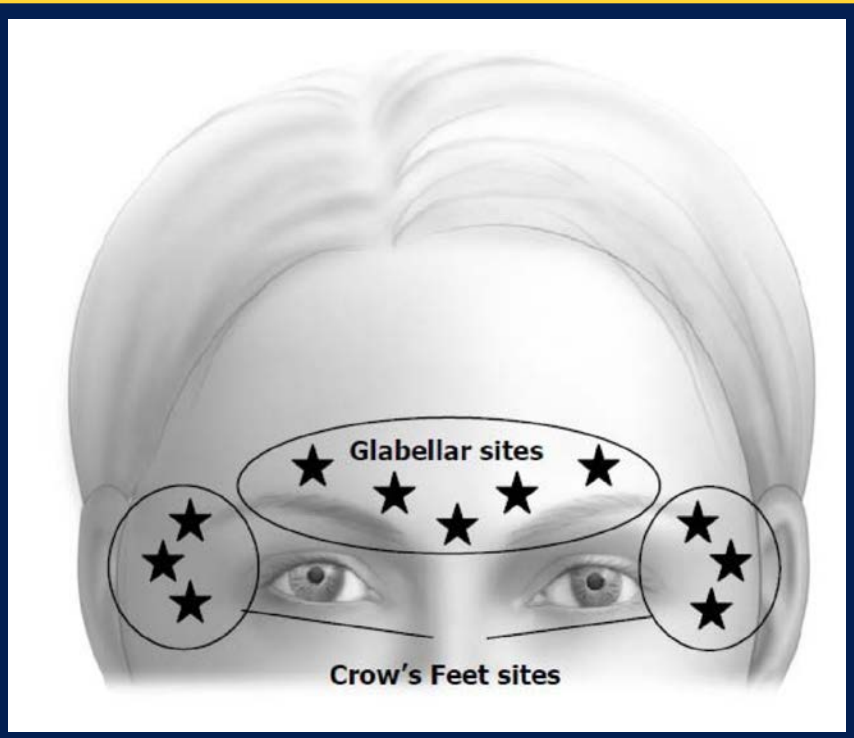
- Aged 18–65 years
- Moderate or severe GL during maximum attempted muscle contraction (based on FWS)
- Bilaterally symmetrical CFL at maximum smile requiring treatment, as determined by investigator
- No prior botulinum toxin therapy
- Women of childbearing potential: negative pregnancy test at baseline and use of reliable form of contraception throughout study

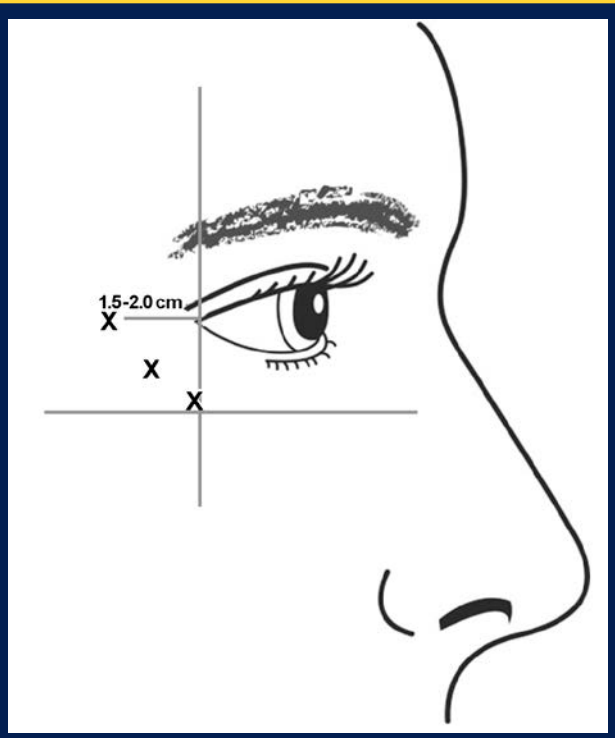
Exclusion Criteria

- Prior facial cosmetic surgery or tissue grafting/augmentation
- Brow or eyelid ptosis, excessive dermatochalasis, deep dermal scarring, or thick sebaceous skin
- Inability to substantially reduce resting facial lines by physically spreading them apart
- Oral retinoid therapy within prior year
- Not on stable topical retinoid or hormone cream applied to the face for ≥6 months prior to study treatment

CFL, crow's feet lines; FWS, Facial Wrinkle Scale with photonumeric guide; GL, glabellar lines.

Injection Paradigm for Glabellar and Crow's Feet Sites





- Separate 1.0–mL syringes with 30-guage needle used for treatment of glabellar and crow's feet sites
- Glabellar sites: onabotulinumtoxinA 20 U or placebo divided into 5 injections
- Crow's feet sites: onabotulinumtoxinA 24 U or placebo divided into 6 injections, given bilaterally at 3 sites
- If the lines in the crow's feet region were primarily below the lateral canthus, the injector had the option to inject below the lateral canthus

Key Endpoints

Primary endpoint

- **Subject satisfaction:** Proportion of subjects who were “very satisfied” or “mostly satisfied” with study treatment on FLSQ® Item 5 (satisfaction) on day 60 for GL

Secondary endpoints

- **Treatment expectations:** Proportion of subjects who indicated study treatment “met” or “exceeded” their expectations on FLSQ® Item 11 (treatment met expectations) on day 60 for GL and CFL combined
- **Subject satisfaction:** Proportion of subjects who were “very satisfied” or “mostly satisfied” with study treatment on FLSQ® Item 5 (satisfaction) on day 60 for GL and CFL combined
- **Responder rate for glabellar lines:** Proportion of subjects with scores of none or mild on FWS for GL at maximum frown on Day 30
- **Responder rate for crow’s feet lines:** Proportion of subjects with ≥1-grade improvement from baseline on FWS for CFL at maximum smile on Day 30

- Data are presented for the per-protocol population, which included all randomized subjects who received treatment, had a post-baseline efficacy assessment, and had no major protocol violations

CFL, crow’s feet lines; FLSQ, Facial Line Satisfaction Questionnaire; FWS, Facial Wrinkle Scale with photonumeric guide; GL, glabellar lines.

Demographic and Baseline Characteristics (per-protocol population)

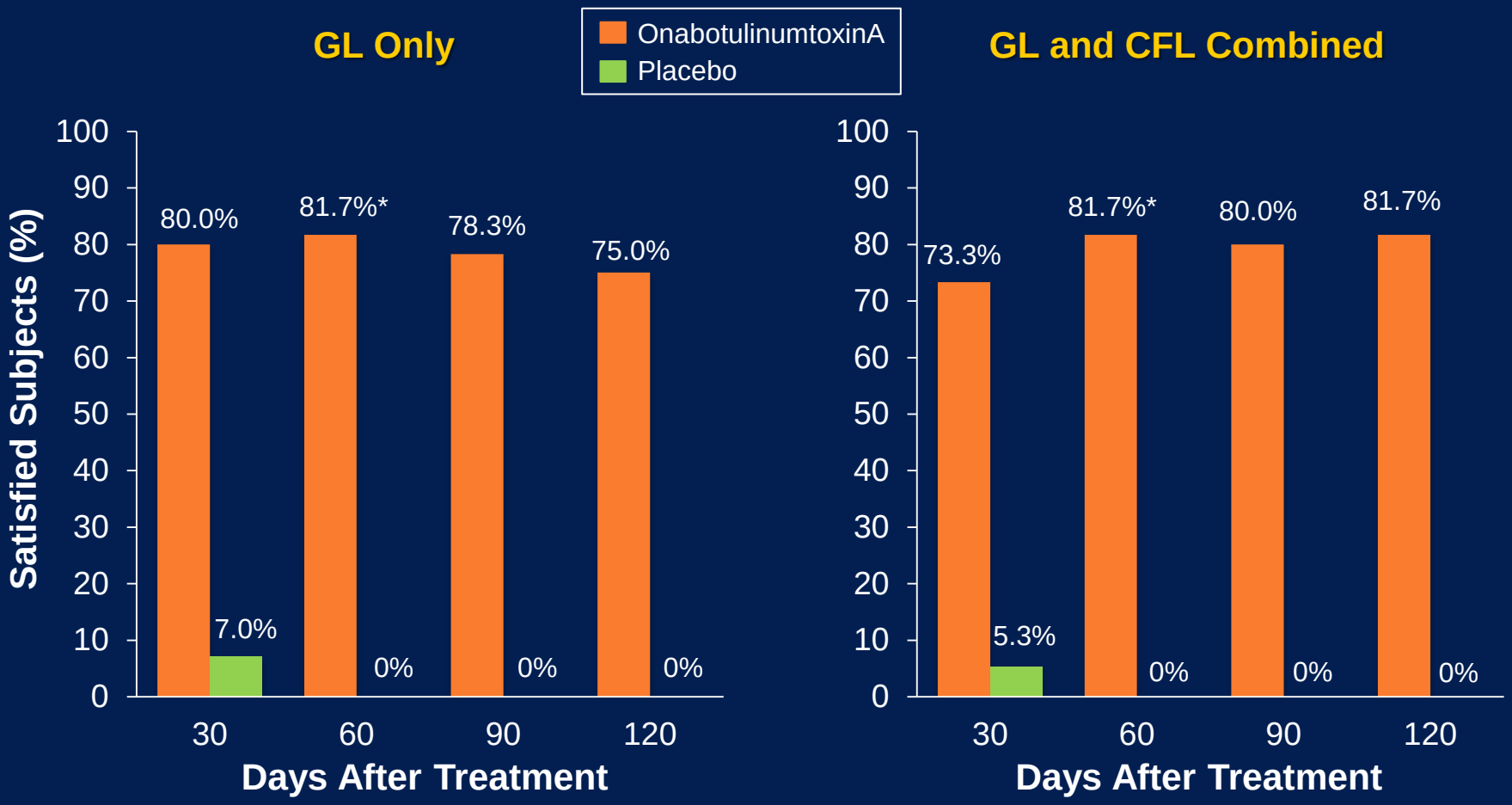
Characteristic	OnabotulinumtoxinA (n=60)	Placebo (n=57)
Mean age, years (SD)	45.9 (9.66)	47.1 (9.76)
Females, n (%)	48 (80.0)	50 (87.7)
White, n (%)	59 (98.3)	56 (98.2)
Fitzpatrick skin type, n (%)*		
II	15 (25.0)	17 (29.8)
III	29 (48.3)	27 (47.4)
IV	10 (16.7)	10 (17.5)
GL severity at maximum frown, n (%)		
Severe	24 (40.0)	30 (52.6)
Moderate	36 (60.0)	27 (47.4)
CFL severity at maximum smile, n (%)		
Severe	23 (38.3)	18 (31.6)
Moderate	34 (56.7)	38 (66.7)
Mild	3 (5.0)	1 (1.8)

*Other Fitzpatrick skin types in onabotulinumtoxinA and placebo groups: type I, n=3 (5.0%) and n=2 (3.5%), respectively; type V, n=3 (5.0%) and n=1 (1.8%), respectively.

CFL, crow's feet lines; GL, glabellar lines.

Satisfaction With Study Treatment

- The majority of subjects were “very satisfied” or “mostly satisfied” with onabotulinumtoxinA treatment based on FLSQ® Item 5

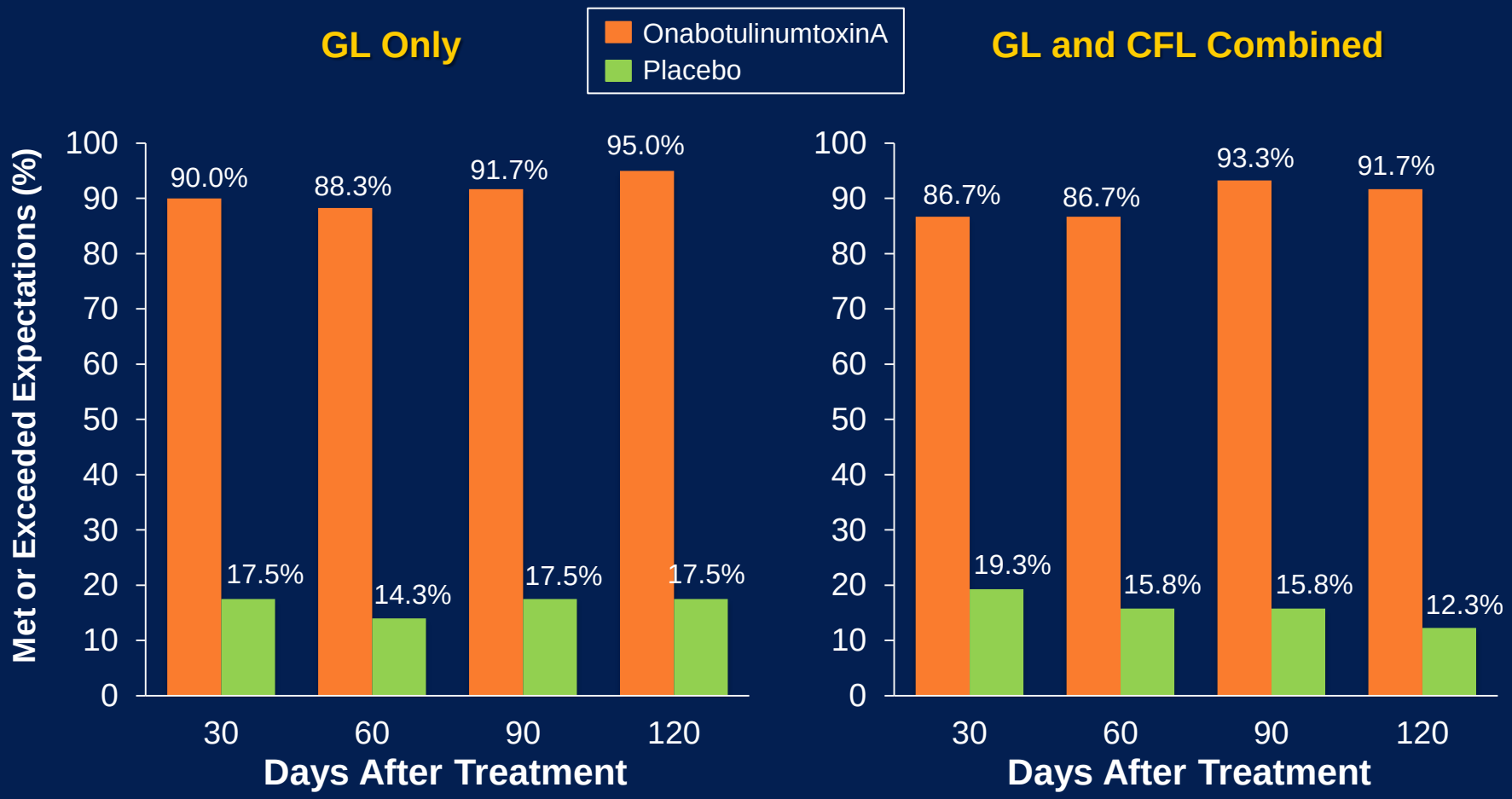


P<.001 vs placebo at primary time point.

CFL, crow’s feet lines; FLSQ, Facial Line Satisfaction Questionnaire; GL, glabellar lines.

Expectations Met With Study Treatment

- The majority of subjects reported that onabotulinumtoxinA “met” or “exceeded” their treatment expectations, based on FLSQ® Item 11

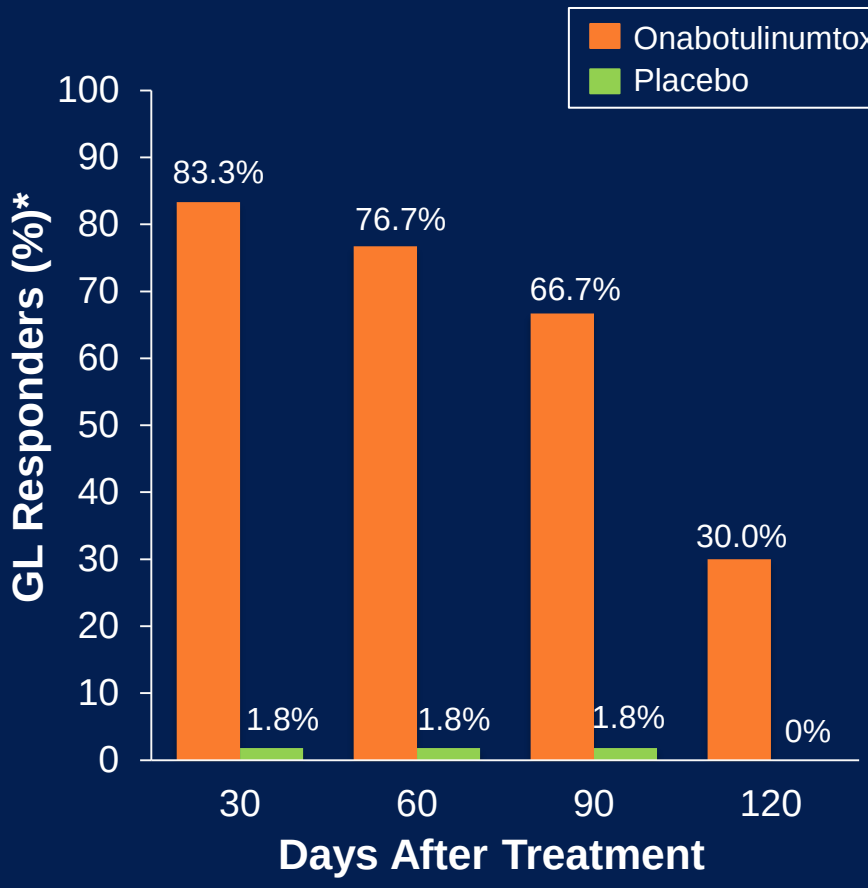


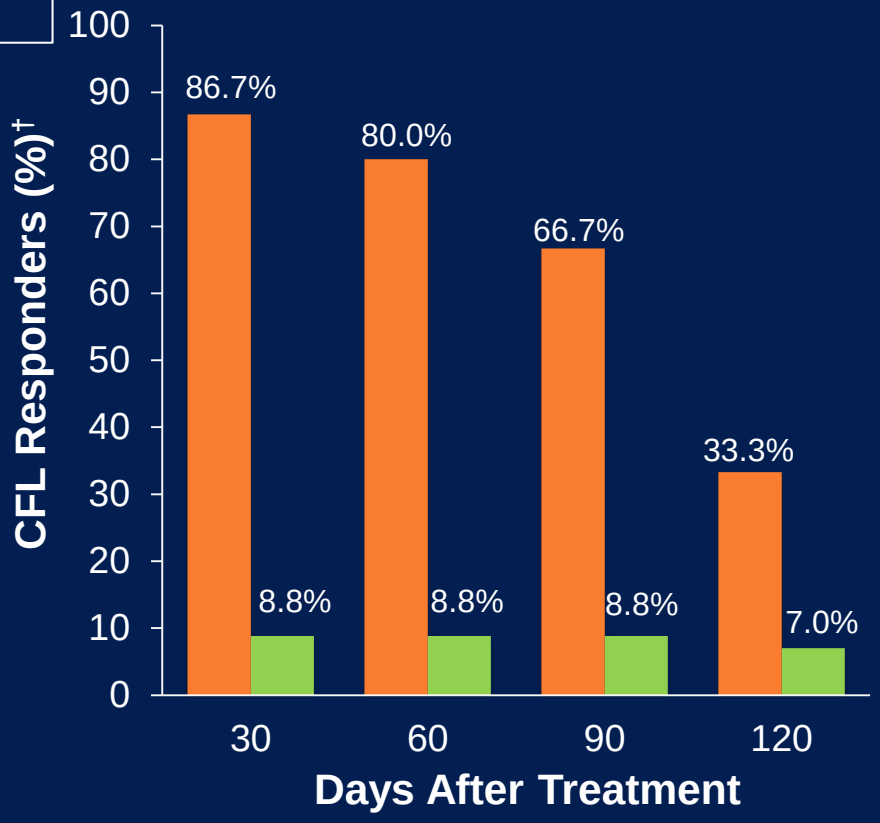
P<.001 vs placebo at primary time point.

CFL, crow’s feet lines; FLSQ, Facial Line Satisfaction Questionnaire; GL, glabellar lines.

Responses on Investigator-Assessed Facial Wrinkle Scale

- Most subjects demonstrated clinical efficacy of onabotulinumtoxinA based on FWS assessment of GL and CFL

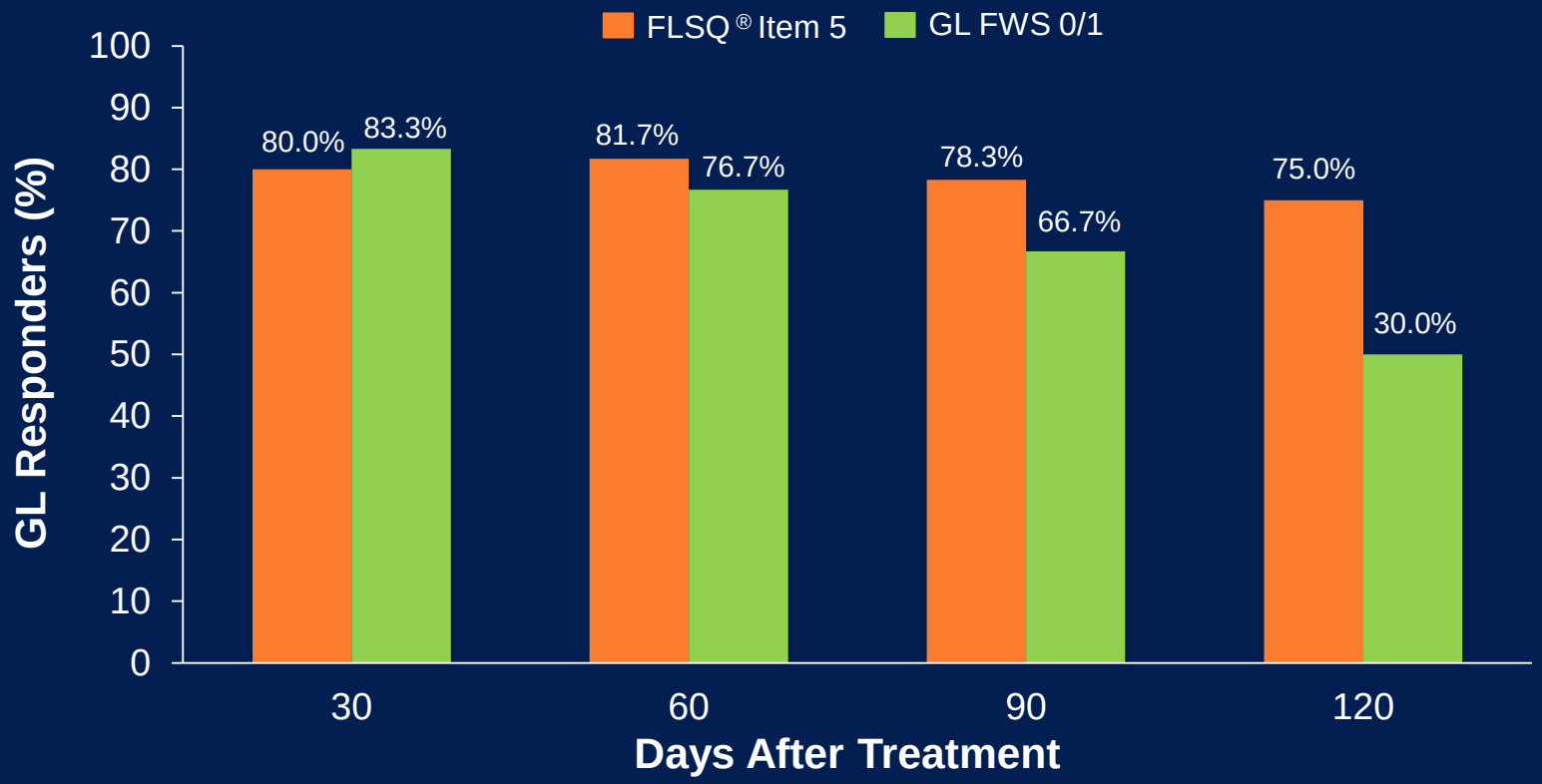




P<.001 vs placebo at primary time point.
*Responders defined by a rating of “none” or “mild”; †Responders defined by ≥ 1-grade improvement from baseline; CFL, crow’s feet lines; FWS, Facial Wrinkle Scale; GL, glabellar lines.

Comparison of Subject Satisfaction and Investigator-Assessed Treatment Responses for Glabellar Lines

- Satisfaction was aligned with treatment response through Day 90
- Satisfaction remained high up to Day 120, even though clinical efficacy declined



Satisfaction determined by the proportion of subjects who reported being ""very satisfied" or "mostly satisfied" with study treatment on FLSQ® Item 5 for glabellar lines. Responders defined by a rating of "none" or "mild" on the FWS.

FLSQ, Facial Line Satisfaction Questionnaire; FWS, Facial Wrinkle Scale with photonumeric guide; GL, glabellar lines.

Adverse Events

Adverse Event, n (%)	OnabotulinumtoxinA (N=63)	Placebo (N=62)
Subjects with ≥1 AE	13 (20.6)	11 (17.7)
Most common AEs*		
Headache	6 (9.5)	4 (6.5)
Injection site hematoma	1 (1.6)	2 (3.2)
Blepharospasm	1 (1.6)	1 (1.6)
Nasopharyngitis	1 (1.6)	1 (1.6)
Viral URTI	1 (1.6)	1 (1.6)

*AEs occurring in ≥2 subjects overall.

AE, adverse event; URTI, upper respiratory tract infection.

Conclusions

- The majority of subjects treated with onabotulinumtoxinA for GL and CFL had high and sustained rates of clinical efficacy and treatment satisfaction
- Subject satisfaction on FLSQ® Item 5 (satisfaction) was aligned with investigator-assessed treatment efficacy on the FWS through day 90 after treatment
- Despite the expected waning of clinical efficacy after day 90, the high rate of subject satisfaction persisted through day 120
- A large majority of subjects reported that onabotulinumtoxinA met or exceeded their treatment expectations—consistent with the high rate of subject satisfaction
- Although clinical efficacy remains an important outcome, subject satisfaction and meeting treatment expectations may be a driving motivation in facial aesthetic therapy

CFL, crow's feet lines; FLSQ, Facial Line Satisfaction Questionnaire; FWS, Facial Wrinkle Scale with photonumeric guide; GL, glabellar lines.