Jeuveau Extra-Strength Phase II, Randomized, Double Blind, Active-Controlled, Increasing Dose Trial to Study: Final Top Line Results

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ASDS® 2023 Annual Meeting
November 2-5
Chicago, IL

Jeuveau Extra-Strength Phase II Duration Study Glabellar Lines

Study the safety and duration of effect of prabotulinum at an increased dose for the treatment of moderate to severe glabellar lines

- Dose Doubled
- Hyper-concentrated

Primary Objective

- Duration of effect, time back to baseline by investigator assessment

Clinical Investigators

- Dr Sue Ellen Cox
- Dr Steve Fagien
- Dr John Joseph
- Dr Joely Kaufman-Janette
- Dr Keith Marcus

ASDS® 2023 Annual Meeting | November 2-5 Chicago, IL

Jeuveau Extra-Strength Phase II Duration Study

Study Design

- Multi-center, double blind, randomized, active controlled
  - 5 sites
  - N=150
- Three arms, randomization 1:1:1
  - 40U Prabotulinum
  - 20U Prabotulinum
  - 20U Onabotulinum
- Duration
  - 1 yr, or until return to baseline
- Study Population
  - Stable healthy adults, min 18 years of age
  - Moderate (GLS=2) to Severe (GLS=3) glabellar lines at max frown

Jeuveau Extra-Strength Phase II Duration Study Baseline Characteristics

	PraB E-S 40U N=51	OnaB 20U N=50	PraB 20U N=53
Age in years, mean (range)	46.8 (20,69)	47 (25, 72)	46.8 (22, 72)
Gender			
Female n (%)	48 (94.1%)	47 (94.0%)	50 (94.3%)
Male n (%)	3 (5.9%)	3 (6.0%)	3 (5.7%)
Race			
Asian	0 (0%)	1 (2%)	1 (1.9%)
Black or African American	3 (5.9%)	2 (4%)	3 (5.7%)
White	48 (94.1%)	47 (94.0%)	49 (92.5%)

Jeuveau Extra-Strength Phase II Duration Study Baseline Characteristics

	PraB E-S 40U N=51	OnaB 20U N=50	PraB 20U N=53
GLS Score at Max Frown by Investigator, n (%)			
Moderate	15 (29.4%)	14 (28.0%)	18 (34.0%)
Severe	36 (70.6%)	36 (72.0%)	35 (66.0%)
GLS Score at Max Frown by Subject, n (%)			
Moderate	11 (21.6%)	7 (14.0%)	13 (24.5%)
Severe	40 (78.4%)	43 (86.0%)	40 (75.5%)

Jeuveau Extra-Strength Phase II Duration Study Safety – Adverse Events

Adverse Event Summary	PraB ES 40U N=51	OnaB 20U N=50	PraB 20U N=53
# Events (N=36)			
All Adverse Events	8 (22.2%)	12 (33.3%)	16 (44.4%)
Drug Related Adverse Events	3	2	3
# Subjects with AE's (N=26)			
All Adverse Events	7 (13.7%)	11 (22.0%)	8 (15.1%)
Drug Related Adverse Events	2	2	3

Drug Related Adverse Events:

PraB ES 40U – headache, forehead discomfort, eyelid ptosis
OnaB 20 U – headache, headache
Prabot 20U – headache, headache, vasovagal

Jeuveau Extra-Strength Phase II Duration Study
Safety – Adverse Events

Adverse Event Severity

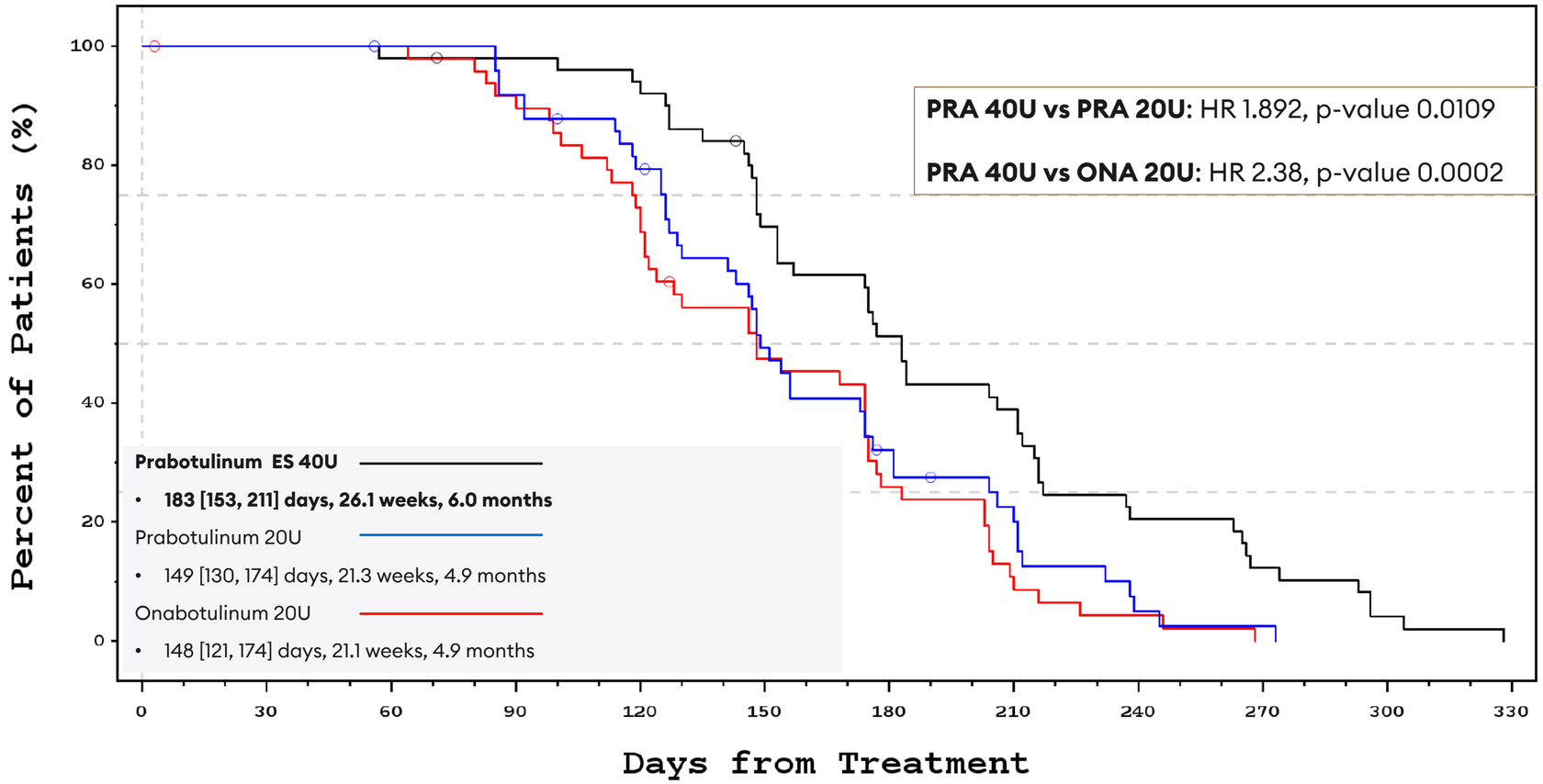
- Number of AE's, 36 events
  - Mild: 88.9%
  - Moderate: 11.1%
  - Severe: 0%

- Serious AE: None

Adverse Event Summary	PraB ES 40U N=51	OnaB 20U N=50	PraB 20U N=53
Severity of AE's			
Mild	7 (87.5%)	9 (75.0%)	16 (100)%
Moderate	1 (12.5%)	3 (25.0%)	0 (0%)
Severe	0	0	0
Serious AE	0	0	0

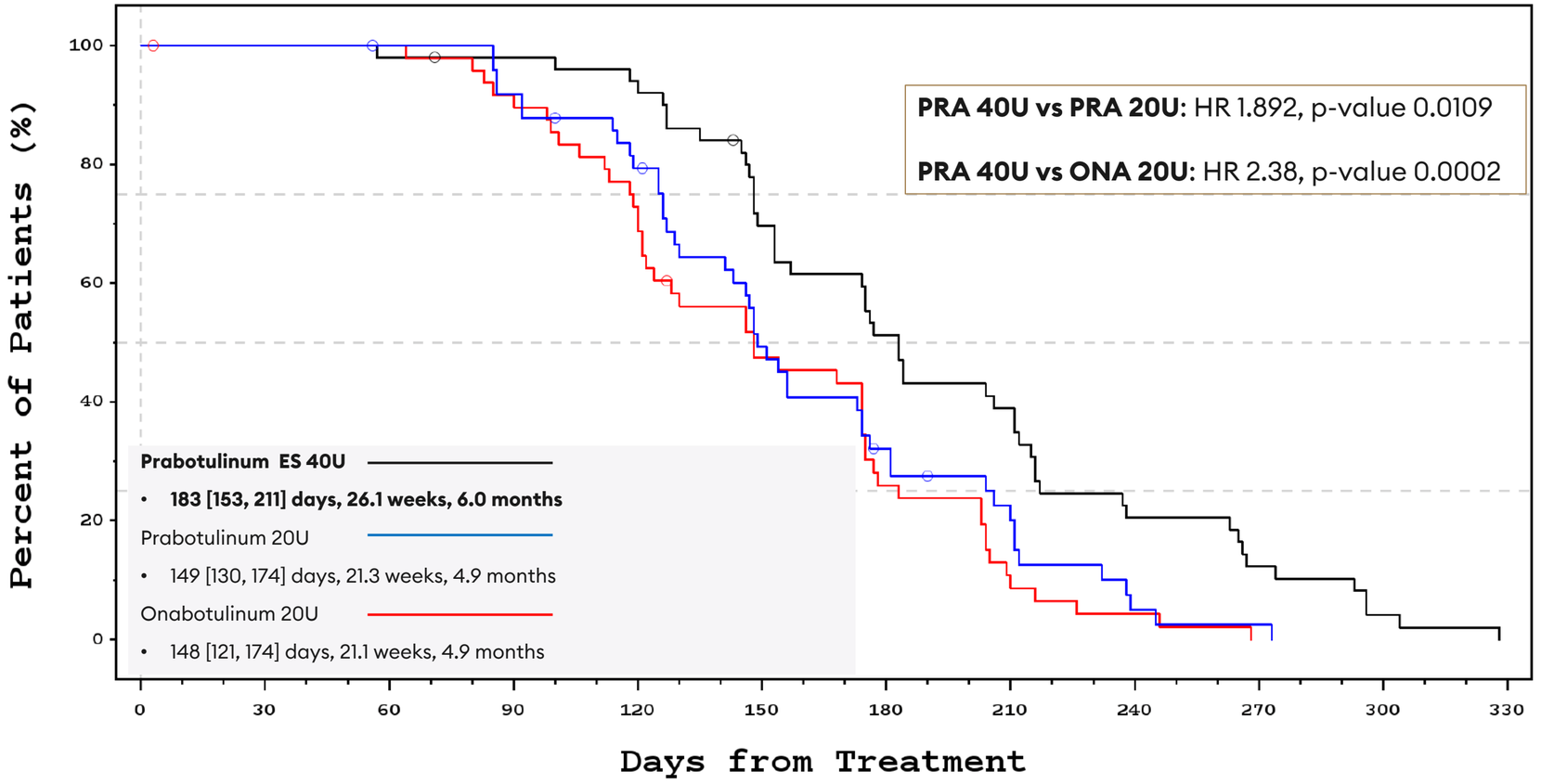
Jeuveau Extra-Strength Phase II Duration Study Duration

Kaplan-Meier: Return to Baseline Glabellar Lines Scale at Maximum Frown Investigator Assessment



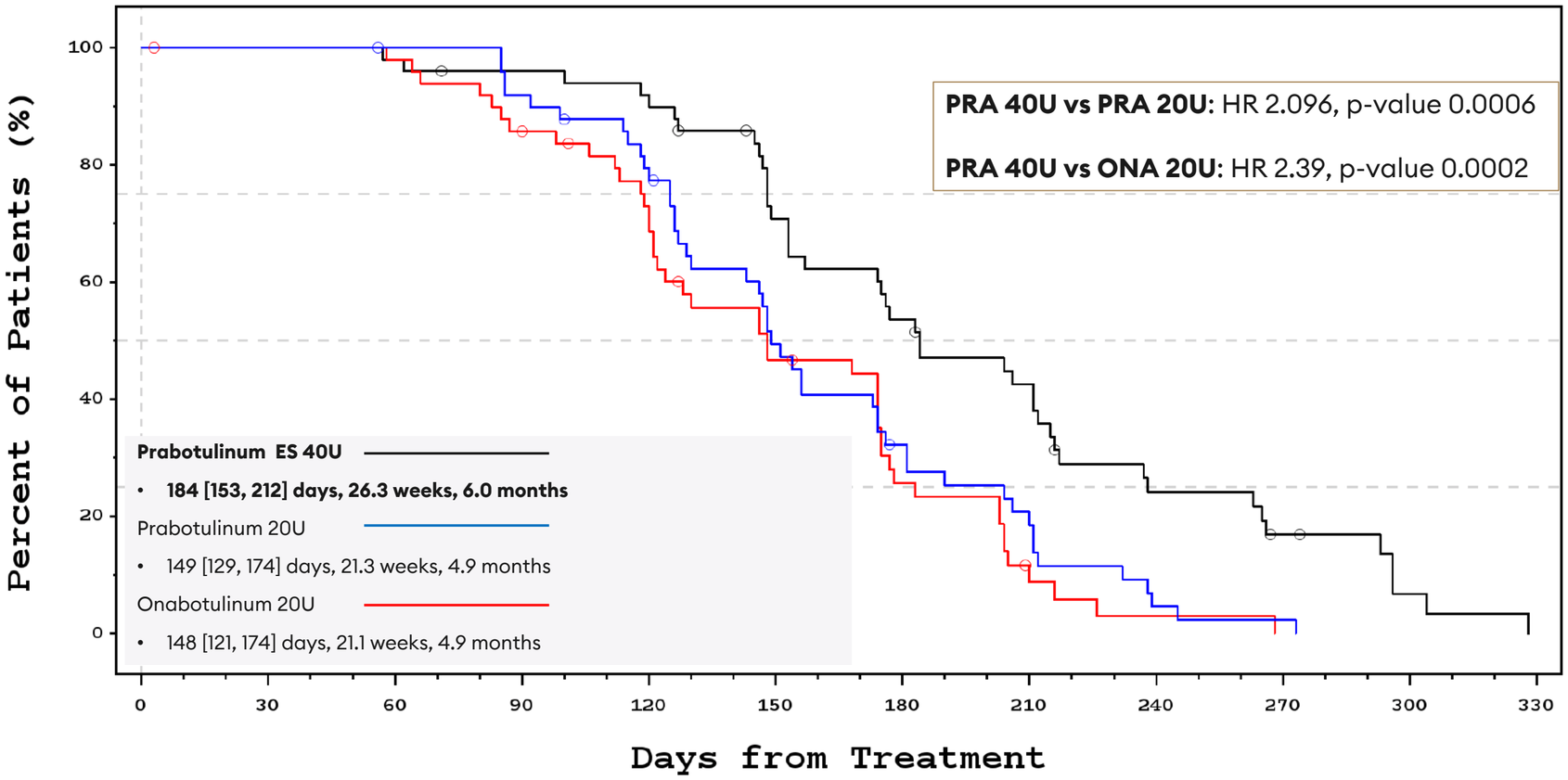
Jeuveau Extra-Strength Phase II Duration Study Duration

Kaplan-Meier: ≥1 Pt Improvement Glabellar Line Scale at Maximum Frown Investigator Assessment



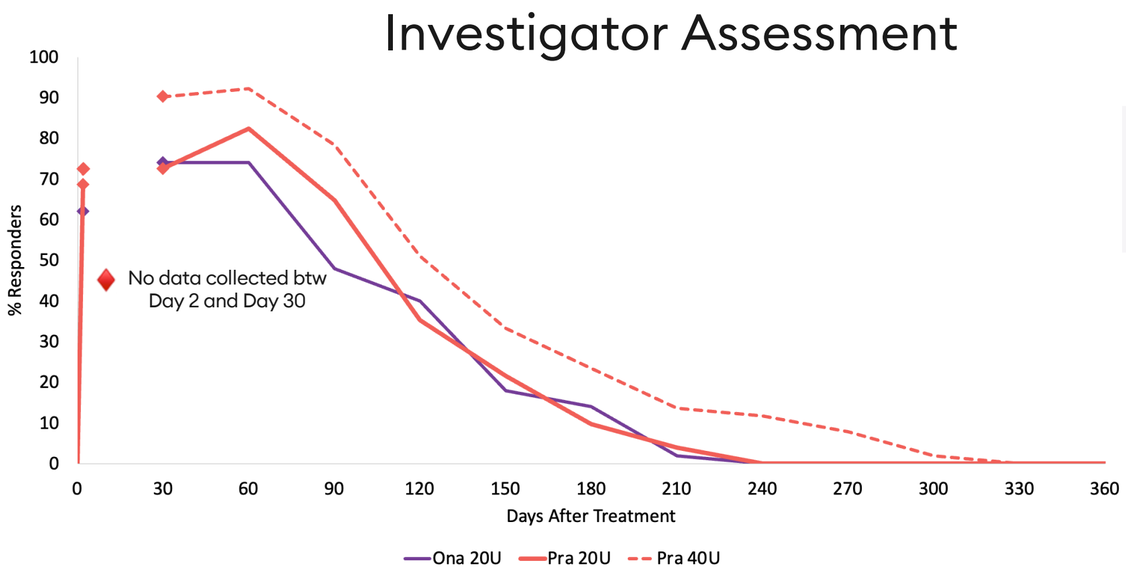
Jeuveau Extra-Strength Phase II Duration Study Duration

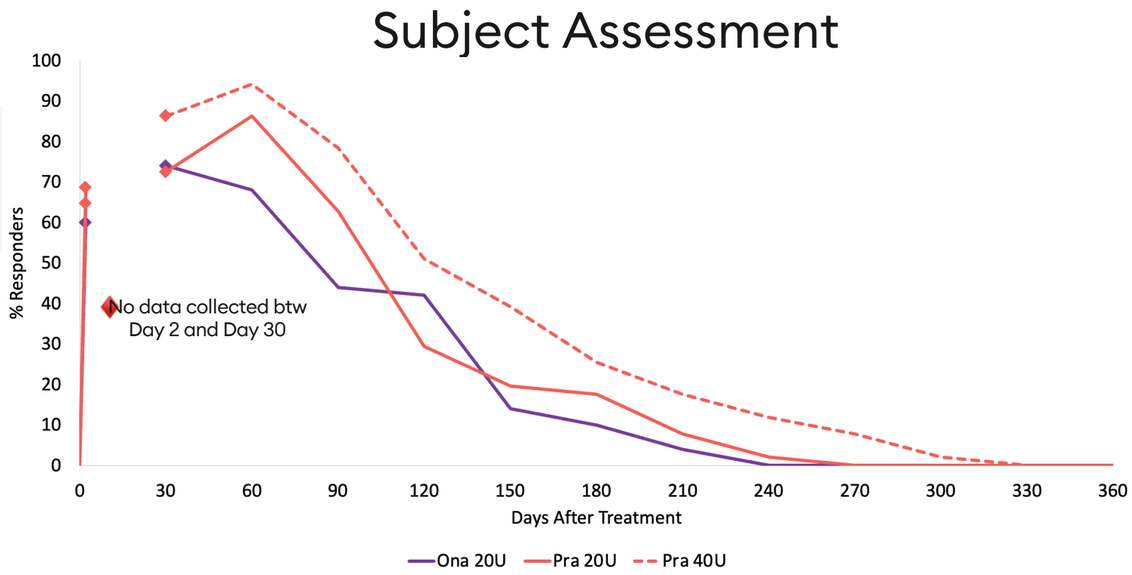
Kaplan-Meier: Global Aesthetic Improvement Return to Baseline (Improved, Much Improved) Investigator Assessment



Jeuveau Extra-Strength Phase II Duration Study Efficacy: None or Mild Glabellar Line

None or Mild Glabellar Line Scale at Maximum Frown





Study Compliance

Subjects Completing Study: 94.7% (144/152)

- Prabot 40U 96.1% (49/51)
- Prab 20U 92.2% (47/51)
- Ona 20U 96.0% (48/50)

Glabellar Line Scale Score at Maximum Frown
None or Mild Glabellar Lines as a Responder Definition

The Importance of Baseline Characteristics

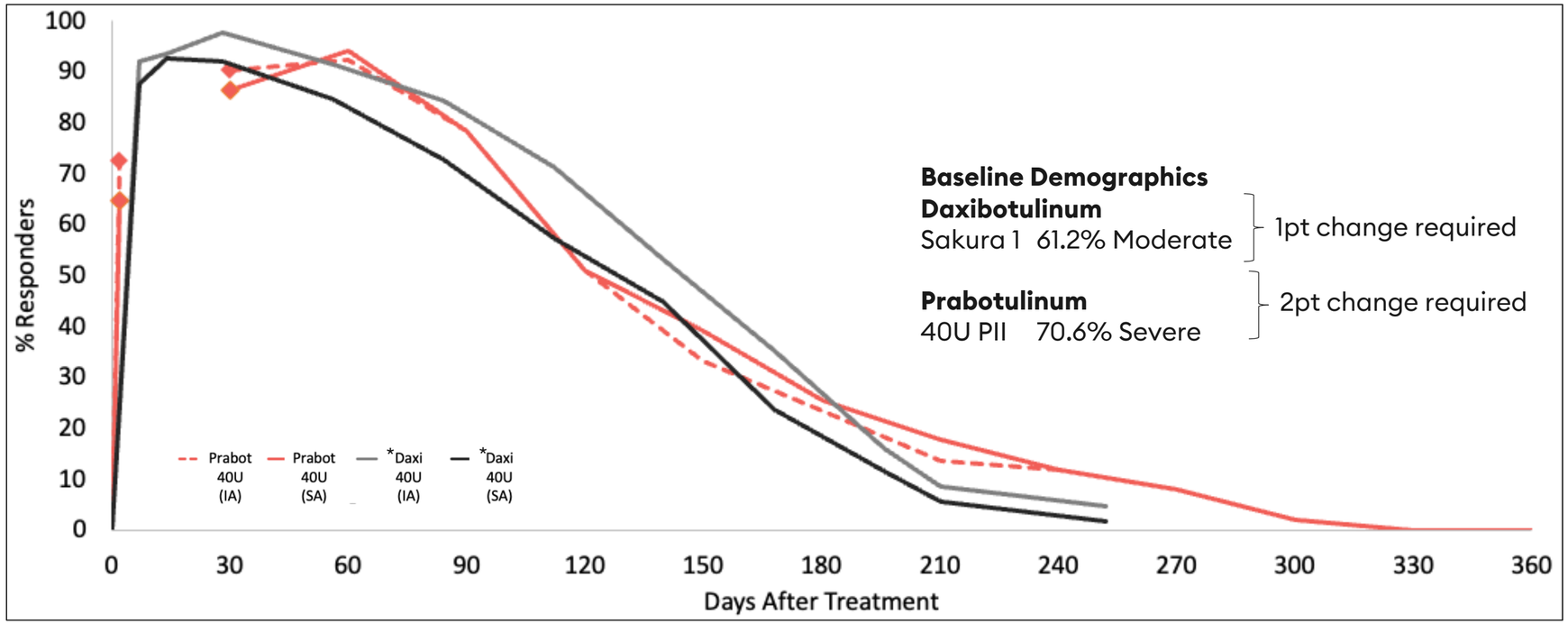
Glabellar Line Scale At Maximum Frown

	Score	Severity Description
Responder	**0**	No Lines
	1	Mild Lines
Non-Responder (1 Pt)	**2**	Moderate Lines
Non-Responder (2 Pt)	**3**	Severe Lines

Jeuveau Extra-Strength Phase II Duration Study Efficacy: None or Mild Glabellar Line Responders

None or Mild Glabellar Lines at Maximum Frown

Investigator and Subject Assessment
Pra 40U vs Daxi 40U Sakura 1



♦ No prabot data collected between Day 2 and Day 30

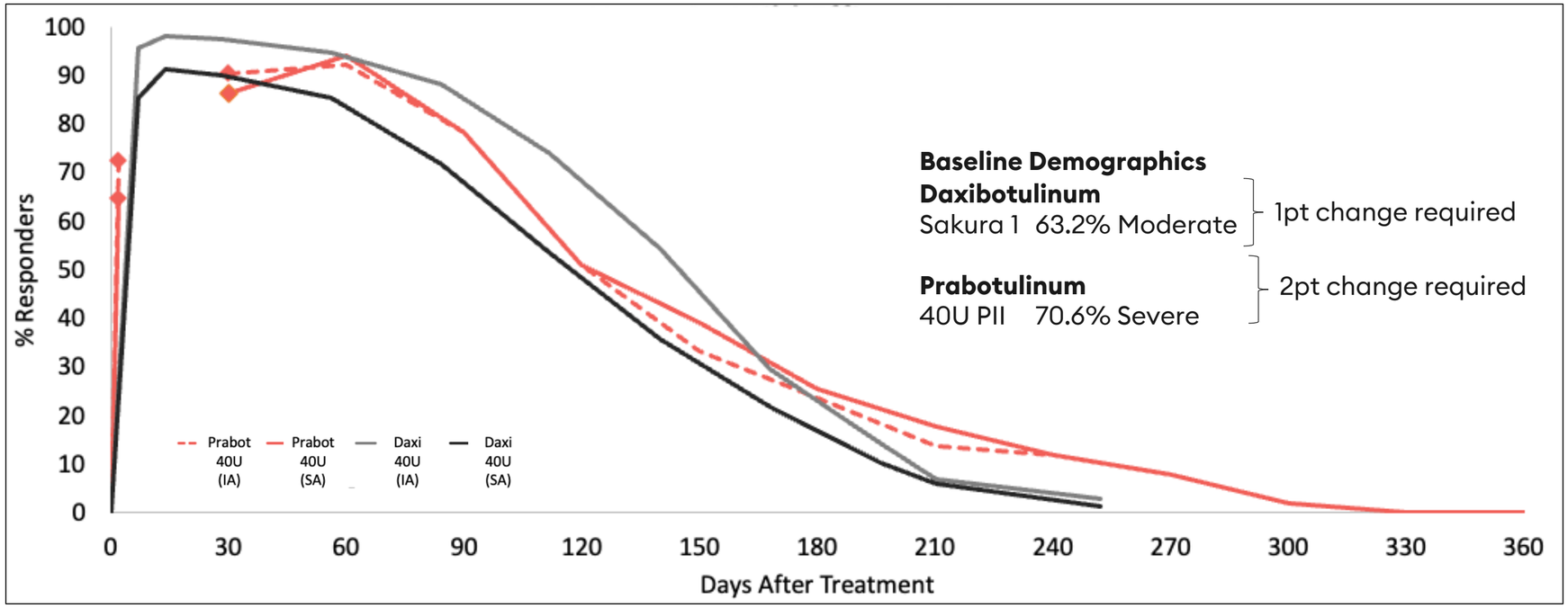
*Daxxify® FDA Prescribing Information (Graph GL1)
Carruthers, Plastic Reconstructive Surgery 2020 Jan; 145 (1):45-58

Note:
Results drawn from multiple studies.
Caution should be used when interpreting cross-study comparisons

Jeuveau Extra-Strength Phase II Duration Study Efficacy: None or Mild Glabellar Line Responders

None or Mild Glabellar Lines at Maximum Frown

Investigator and Subject Assessment
Pra 40U vs Daxi 40U Sakura 2



♦ No prabot data collected between Day 2 and Day 30

*Daxxify® FDA Prescribing Information (Graph GL2)
Carruthers, Plastic Reconstructive Surgery 2020 Jan; 145 (1):45-58

Note:
Results drawn from multiple studies.
Caution should be used when interpreting cross-study comparisons

Guidance for Industry

Upper Facial Lines: Developing Botulinum Toxin Drug Products

August 2014

Efficacy Endpoints

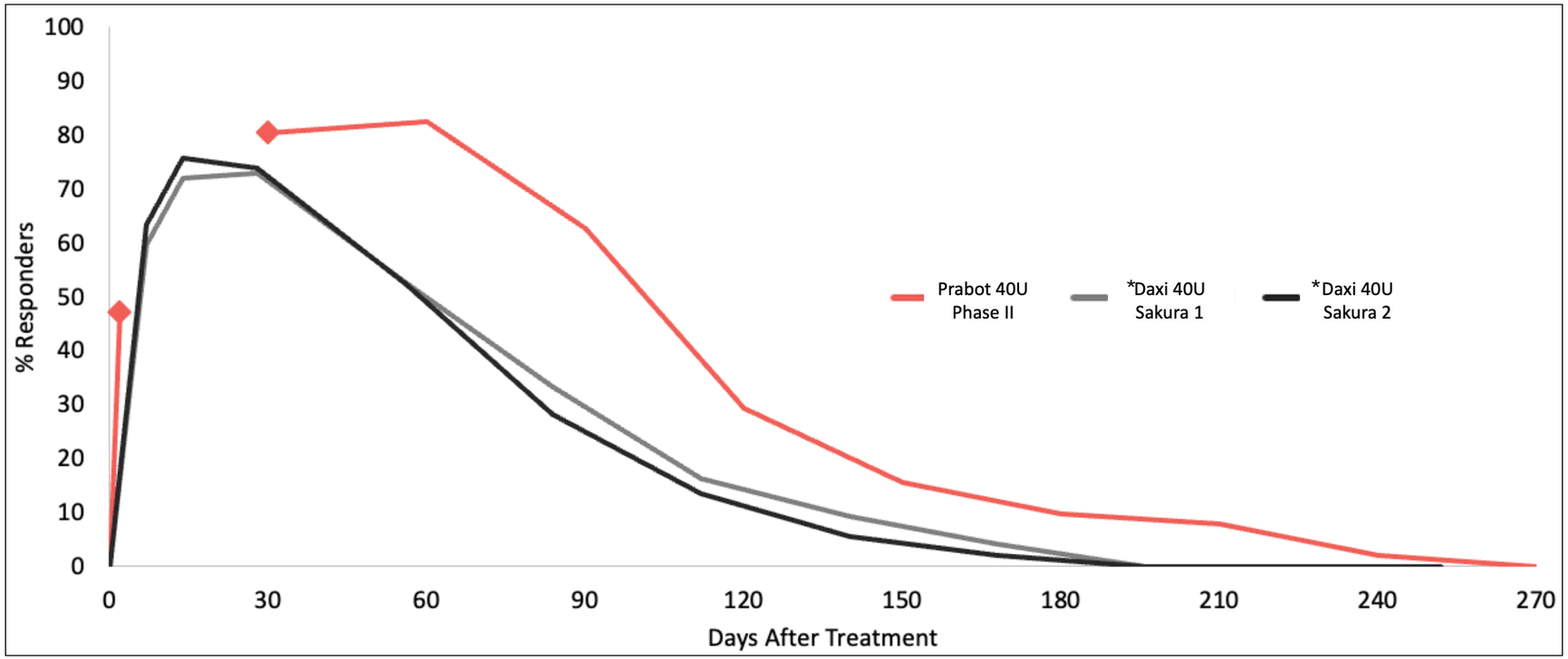
Success should be defined as achievement of a score of 0 or 1 *and* a two-grade improvement from the baseline, on both the IA and the SSA scales concurrently, to ensure clinical significance. Because it may be possible to move to an adjacent category on the assessment scale with only a small level of improvement, a one-grade change may not represent a clinically meaningful intrasubject change.

Sponsors should evaluate duration of effect with a clinically and statistically meaningful approach. Assessment measures for duration of effect should be the same as for the primary efficacy endpoint. Assessment of the duration of effect should reflect the time period for which a clinically meaningful proportion of subjects maintain response.

Jeuveau Extra-Strength Phase II Duration Study Efficacy: Glabellar Line Scale Composite Score

None or Mild at Maximum Frown and ≥ 2-Point Improvement

Investigator + Subject Assessment
(FDA Composite Score)



♦ No prabot data collected between Day 2 and Day 30

*Daxxify® FDA Prescribing Information (Graph GL1 and GL2)
Carruthers, Plastic Reconstructive Surgery 2020 Jan; 145 (1):45-58

Note:
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Jeuveau Extra-Strength Phase II Duration Study Summary

Safety

- Profile similar across the groups
  - 88.9% of AE's mild, 11.1% moderate
- No Serious adverse events

Duration

- Time to return to baseline among multiple parameters was 26 weeks or 6 months



Thank you!



