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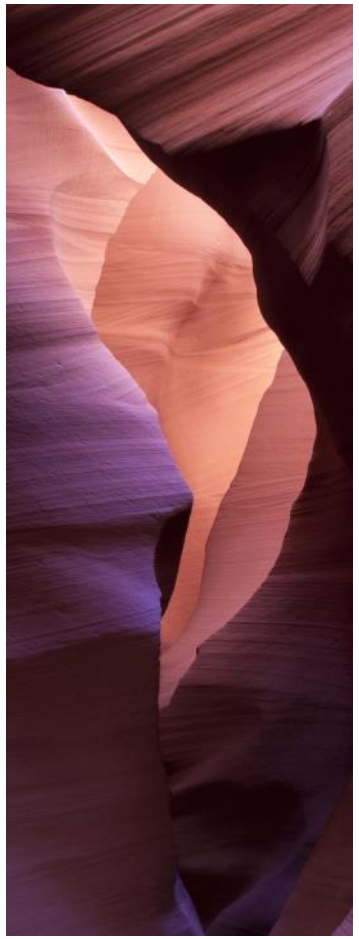

Abstract #1180:

A PHASE 2, OPEN-LABEL, DOSE-ESCALATING STUDY TO EVALUATE THE SAFETY AND PRELIMINARY EFFICACY OF DAXIBOTULINUMTOXINA FOR INJECTION (RT002) IN ISOLATED CERVICAL DYSTONIA

Cynthia L. Comella, Joseph Jankovic, Daniel D. Truong, Allison Brashear, Atul T. Patel, Marian Evatt, Carol Y. Chung, Roman G. Rubio

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Introduction

- Isolated cervical dystonia (CD) is a chronic neurologic disorder characterized by involuntary patterned contractions of cervical musculature resulting in abnormal movements or postural changes of the head, neck, and shoulders.
- Currently available treatments for CD call for injection of botulinum toxin (BoNT) about every 3-4 months, or 3-4 times per year.
- DaxibotulinumtoxinA for Injection (RT002), a neuromodulator currently in clinical development, is comprised of a 150 kDa BoNT-A molecule and a proprietary peptide, with no animal-derived components or human serum albumin (HSA).
- Study Objectives:
  - To assess the safety and preliminary efficacy of RT002 for Injection in subjects with isolated CD
  - To evaluate the duration of effect of RT002 for Injection in the treatment of isolated CD

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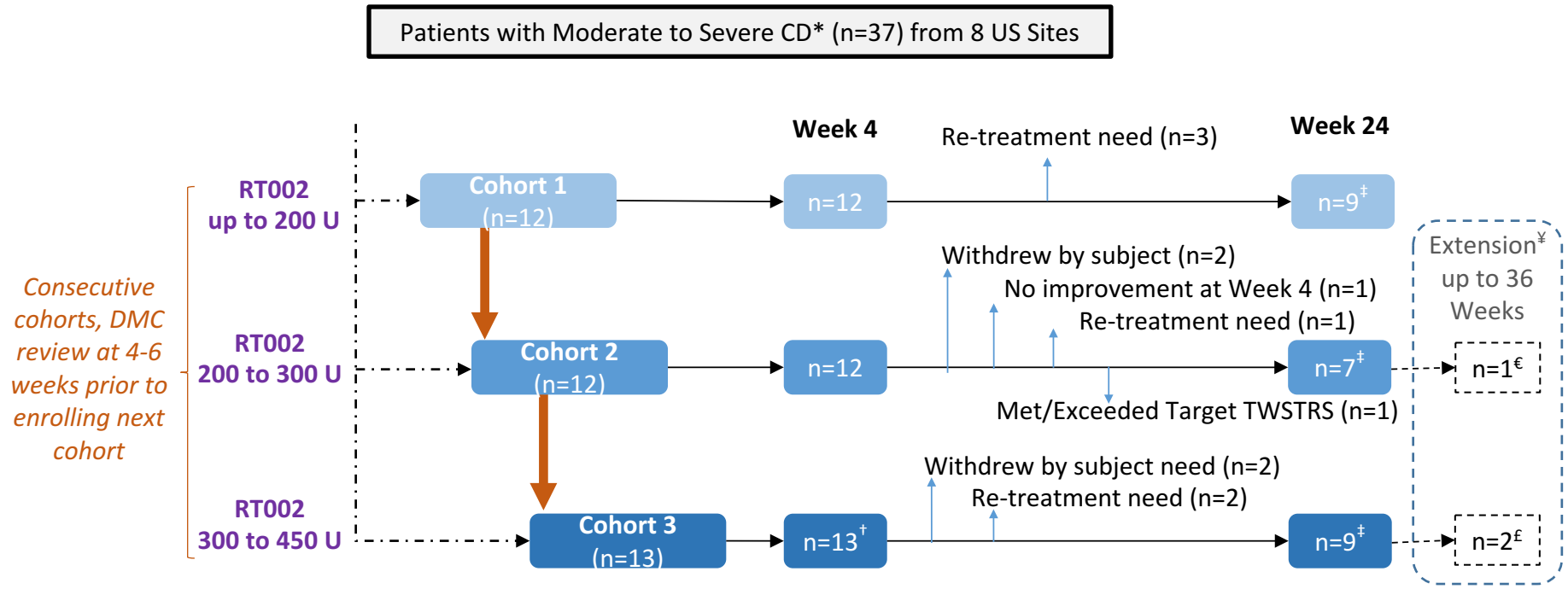
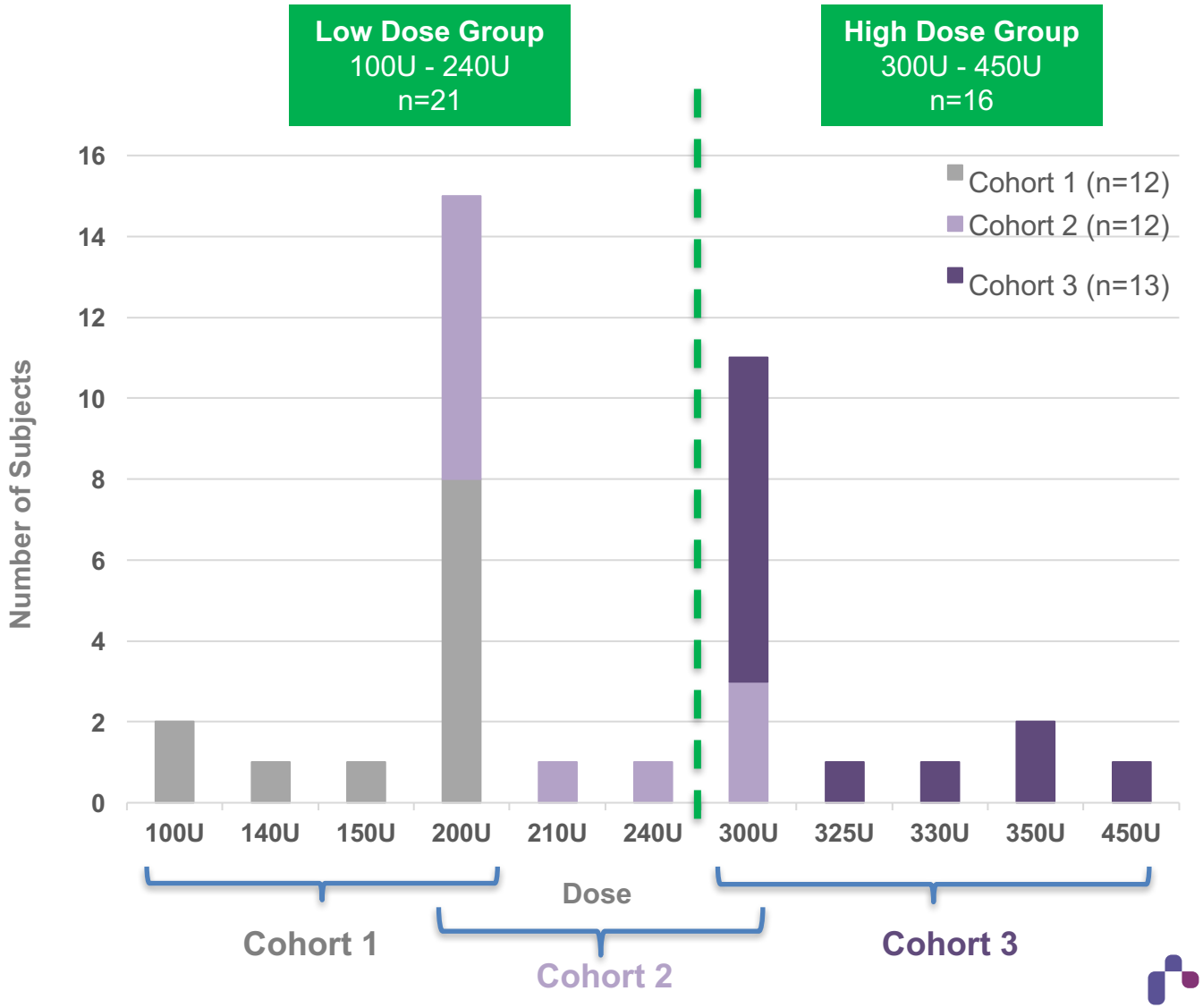
Dose-Escalating Study Design and Subject Disposition



Subjects were evaluated at 2-4 week intervals for 24-36 weeks or until loss of benefit.

*TWSTRS-Total ≥ 20, TWSTRS-Severity ≥ 15, and treatment-naïve or no BoNT within last 6 months.
†Two subjects missed the Week 4 visit. ‡Met/exceeded Target-TWSTRS at Week 24 for n=1 in Cohort 1 and n=2 in Cohort 2; at Week 20 for n=2 in Cohort 2; at Week 6 for n=1 in Cohort 3. ¥Added in the protocol as of January 2017.
€Completed Week 36. £Ongoing.

Subject Distribution by Dose



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Demographics and Baseline Characteristics
By Dose Group

	Group A 100-240 U (n=21)	Group B 300-450 U (n=16)	All (n=37)
Mean age [range]	54 [32–74]	58 [30–70)	56 [30–74]
Females, n (%)	18 (86%)	10 (63%)	28 (76%)
Caucasians, n (%)	18 (86%)	14 (88%)	32 (86%)
Mean/Median CD duration (yrs) [range]	7.3/4.8 [0.02–24.1]	7.9/7.2 [0.02–23.3]	7.6/4.9 [0.0–24.1]
Prior treatment with BoNT	9 (43%)	8 (50%)*	17 (46%)
Mean RT002 dose, U	188	319	244
Mean TWSTRS Score:			
Total Score	44.4	43.8	44.1
Severity Score	20.5	21.9	21.1
Disability Score	12.6	11.6	12.2
Pain Score	11.3	10.3	10.8

*Three subjects received RT002 in Cohort 1 or 2, and re-enrolled to Cohort 3.

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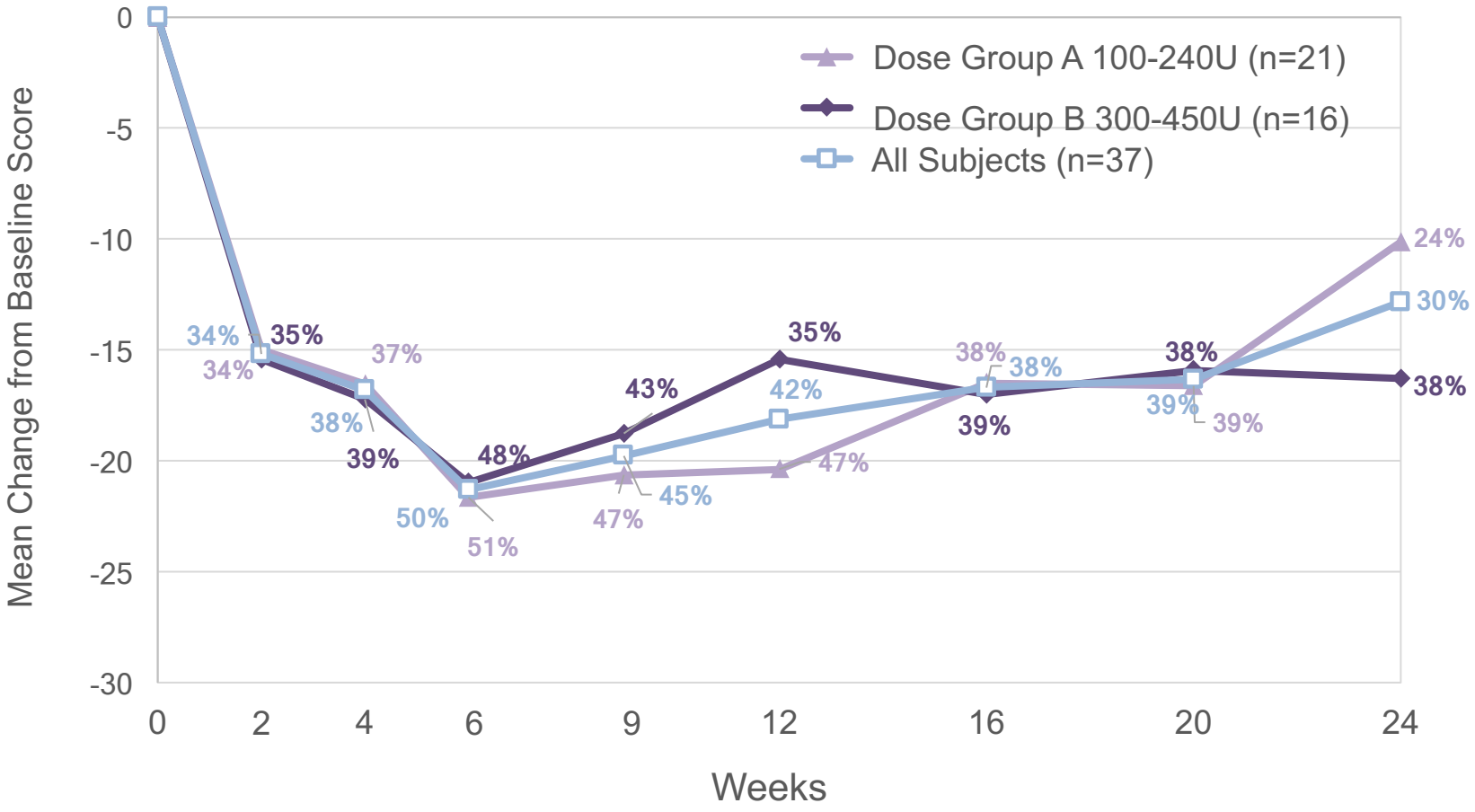
Reduction in TWSTRS-Total Score Over Time
By Dose Group

Clinically meaningful reduction in TWSTRS-Total Score of 34% for all subjects beginning at Week 2, with the majority of this benefit maintained through Week 24 in both dose groups



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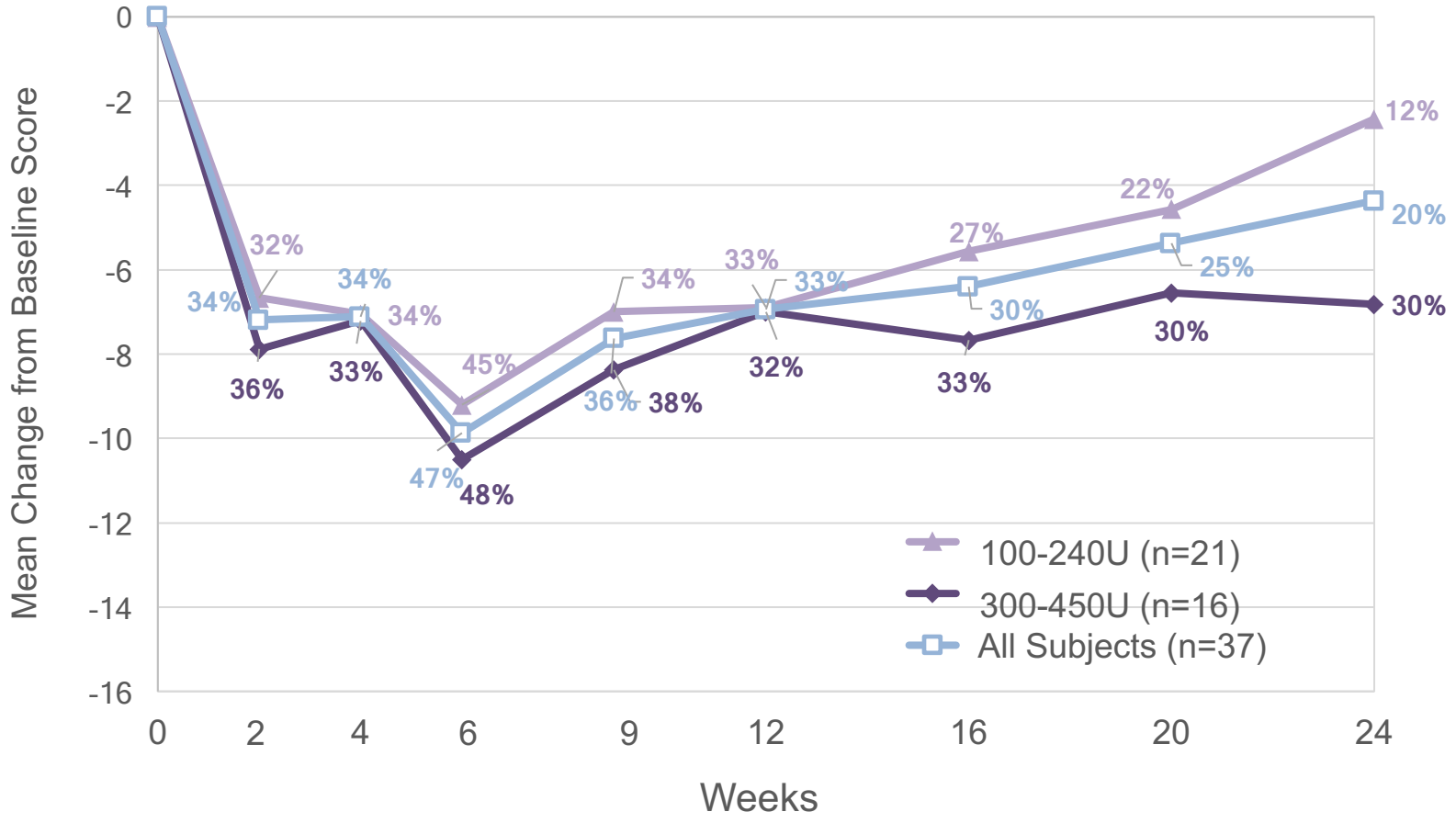
Reduction in TWSTRS-Severity Over Time
By Dose Group

Clinically meaningful reduction in TWSTRS-Severity Score of 34% for all subjects beginning at Week 2, with the majority of this benefit maintained through Week 24 in both dose groups



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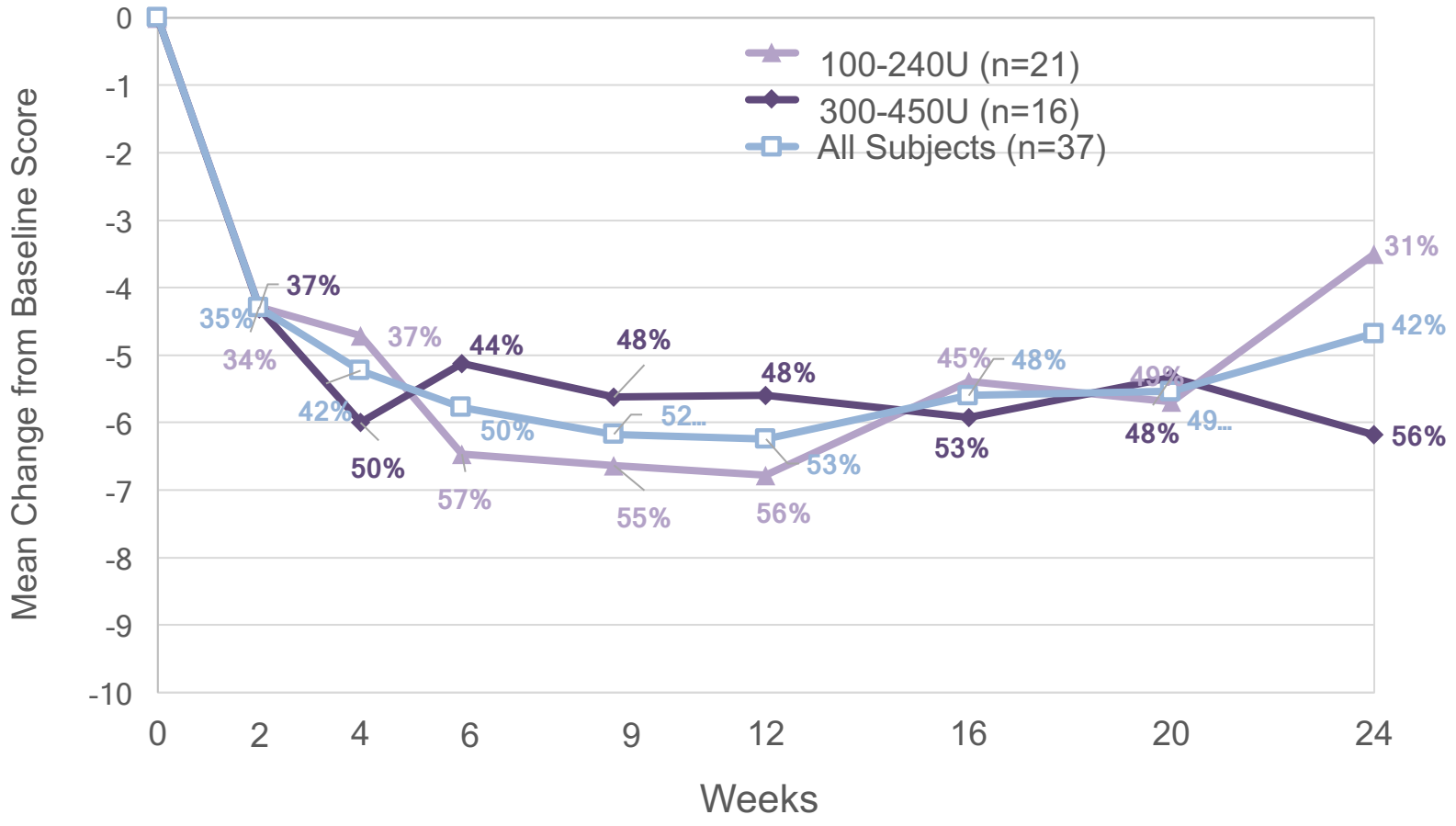
Reduction in TWSTRS-Disability Over Time
By Dose Group

Clinically meaningful reduction in TWSTRS-Disability Score of 35% for all subjects beginning at Week 2, with the majority of this benefit maintained through Week 24 in both dose groups



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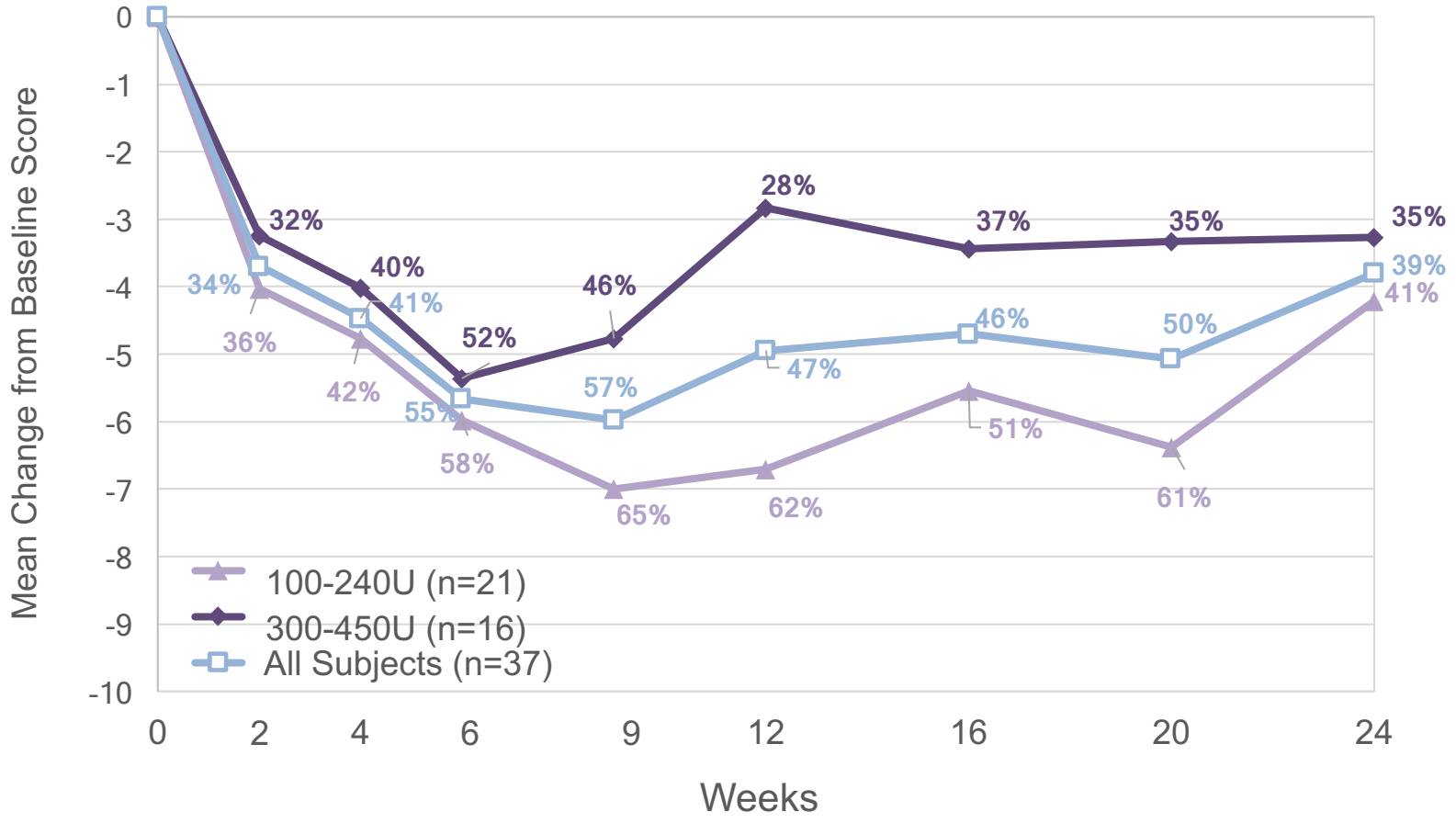
Reduction in TWSTRS-Pain Over Time

By Dose Group

Clinically meaningful reduction in TWSTRS-Pain Score of 34% for all subjects beginning at Week 2, with the majority of this benefit maintained through Week 24 in both dose groups



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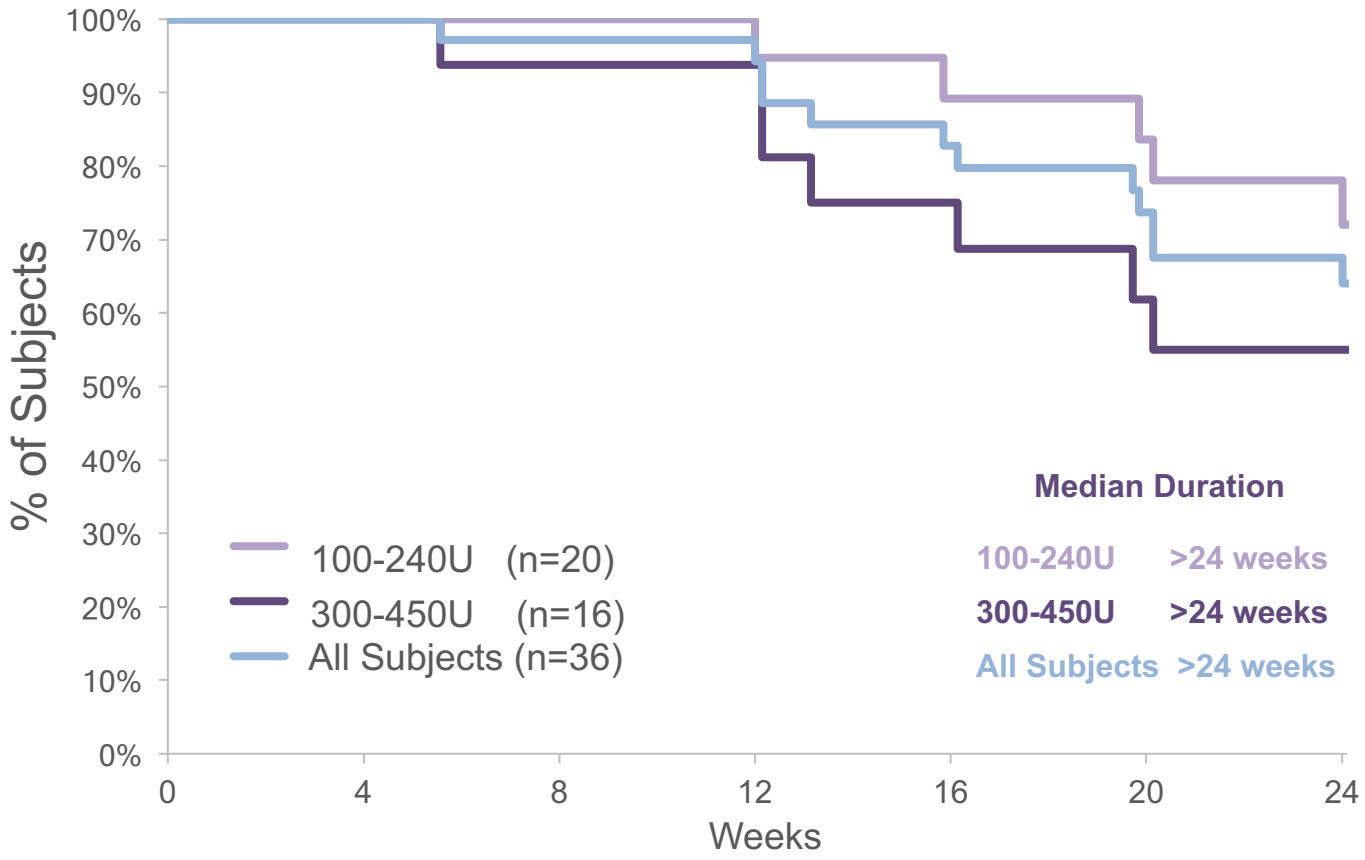
Duration of Effect

Defined by % Subjects Maintaining ≥ 20% of Treatment Benefit*

Median Duration of Response > 24 Weeks for Both Dose Groups



*Of subjects with Improvement at Week 4. Withdrawals due to need for retreatment are considered as events. Treatment benefit defined as the reduction in TWSTRS-Total score at Week 4.

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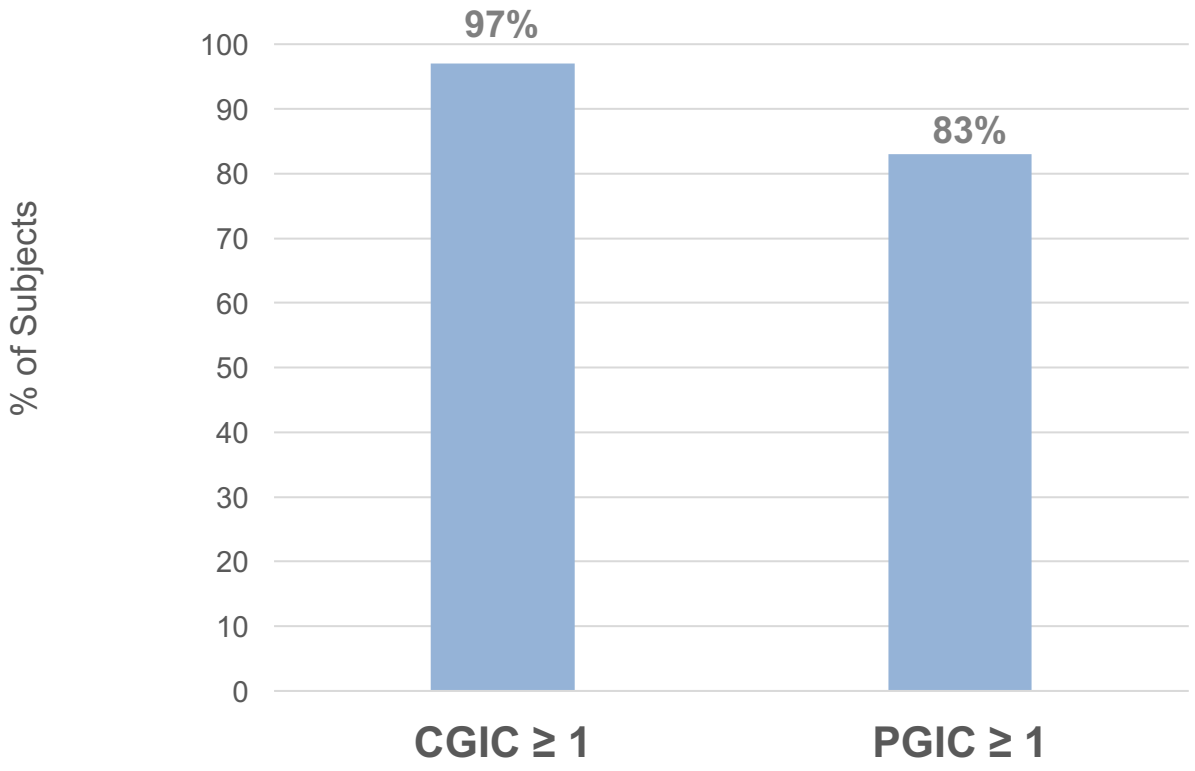
Response Rate by Global Impression of Change at Week 4
All Subjects (n=35*)

97% of all subjects on CGIC† and 83% of all subjects on PGIC †† experienced an improvement in CD signs and symptoms (Score ≥ 1) at Week 4



*Two subjects missed Week 4 visit. †Clinician Global Impression of Change; ††Patient Global Impression of Change

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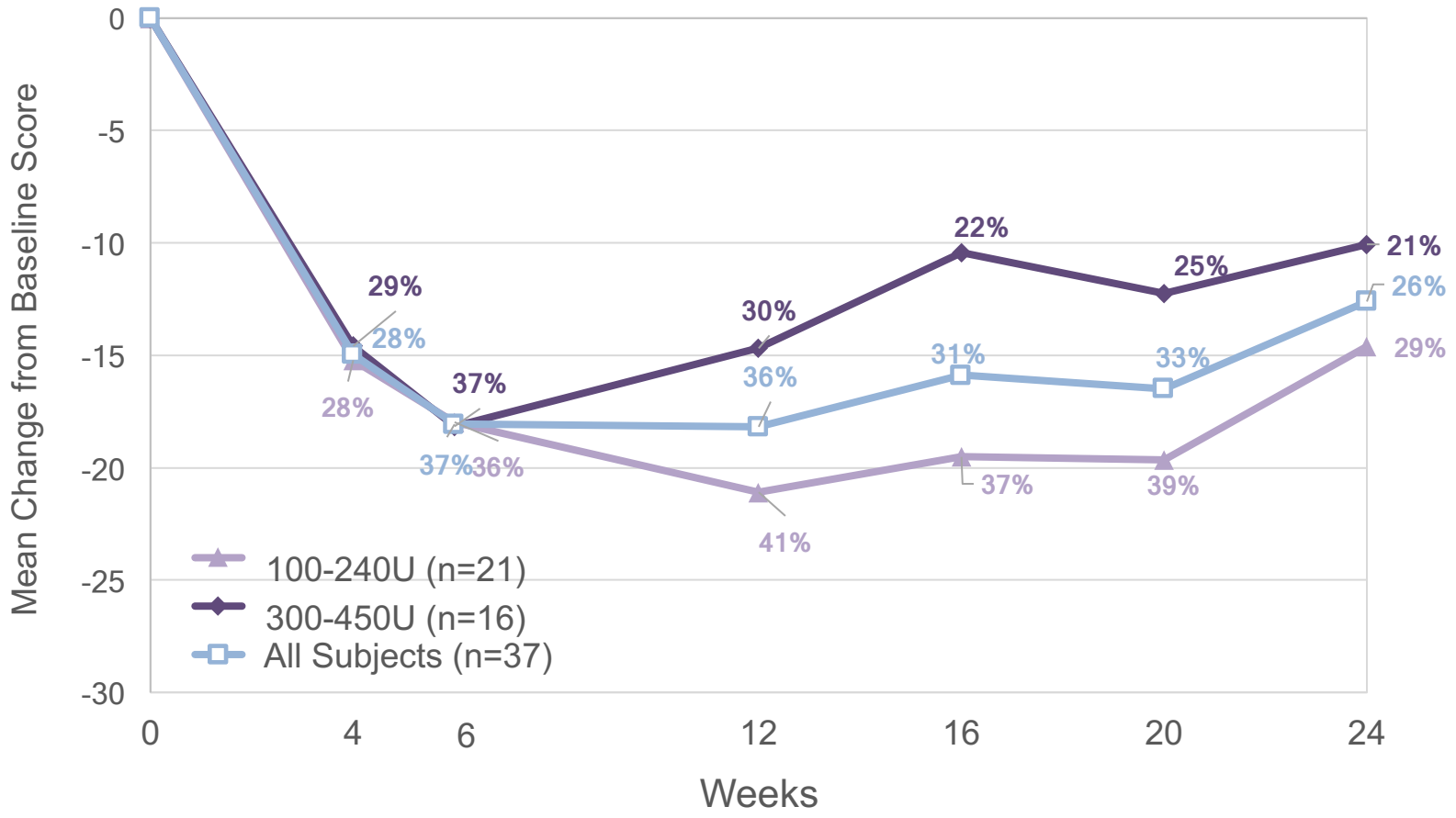
Quality of Life: Reduction in CDIP-58* Score Over Time
By Dose Group

Clinically meaningful reduction of 37% in CDIP-58 Score observed at Week 6 for all subjects, with the majority of this benefit maintained through Week 24



* Cervical Dystonia Impact Profile-58 Quality of Life Measure

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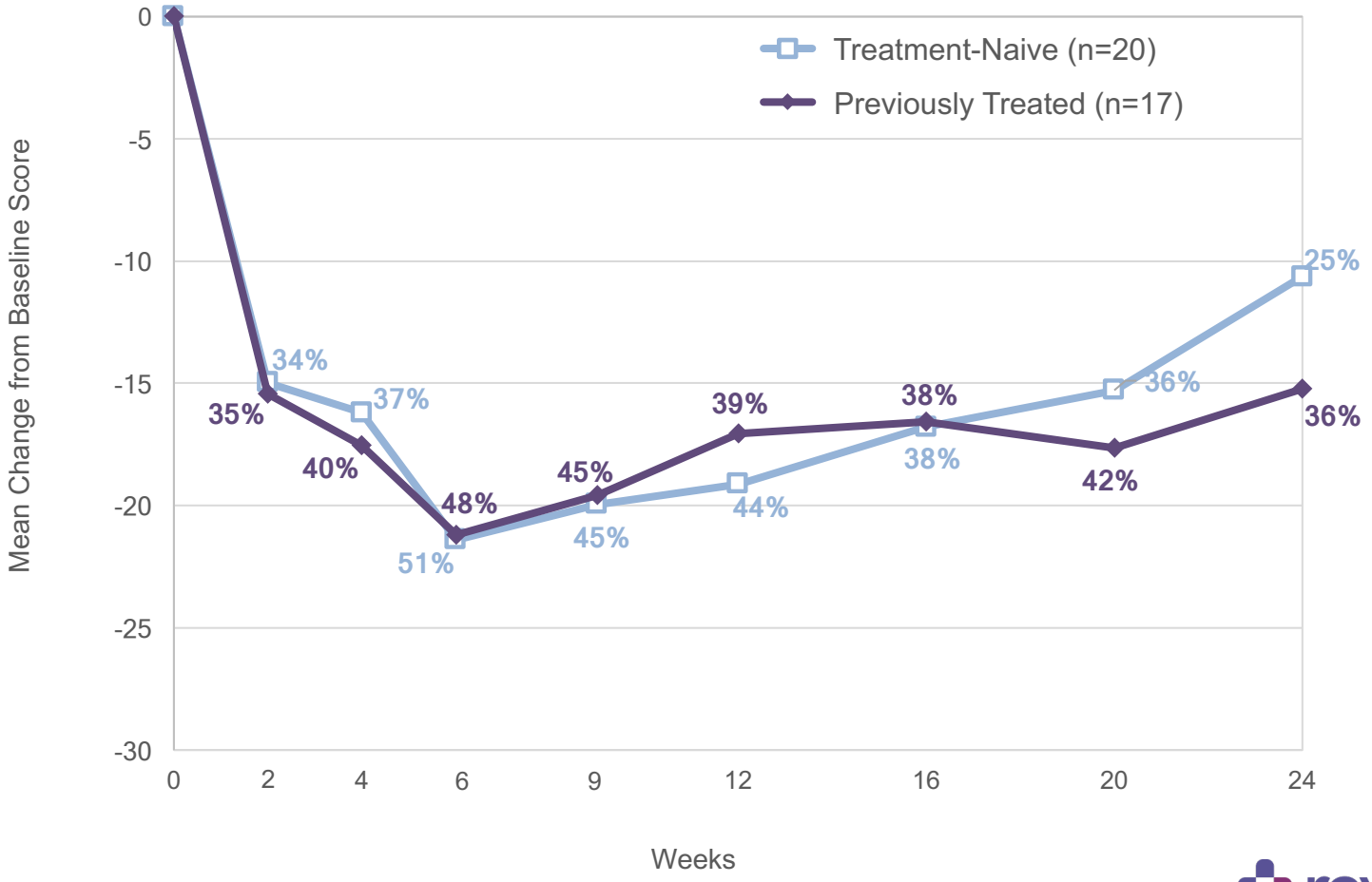
Reduction in TWSTRS-Total Score Over Time
By Prior BoNT Treatment

A clinically meaningful reduction in TWSTRS-Total Score of 37-41% was observed at Week 4, with the majority of this benefit maintained through Week 24 regardless of prior BoNT treatment



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Efficacy Summary

- **Duration of Effect of > 24 Weeks:** Median duration of effect, defined as subjects maintaining ≥ 20% of the Week 4 treatment benefit (Target TWSTRS Score), was > 24 Weeks for both dose groups (Group A: 100-240U and Group B: 300-450U).

- **Improvement in Cervical Dystonia Signs and Symptoms:** A clinically significant mean reduction from baseline in the TWSTRS-Total Score of 16.8 (or 38%) was observed at Week 4 across all subjects.

  - Therapeutic benefit peaked at Week 6 with 50% mean reduction from baseline, and was maintained at ≥ 30% through Week 24.
  - Clinically meaningful reductions in TWSTRS-Severity, -Disability and -Pain Subscales were consistent and also observed at all time points.

- **Quality of Life:** Meaningful reduction in CDIP-58 score of 37% (mean reduction of 18.1) was observed at Week 6, the majority of which was maintained (26%, mean reduction of 12.6) through Week 24 across all subjects.

- A clinically meaningful improvement in TWSTRS-Total Score of ≥ 37% was observed at Week 4 regardless of whether subjects had previously received BoNT treatment.

Safety Summary

- RT002 appeared to be safe and generally well tolerated in both dose groups through Week 24, with no increase in treatment-emergent adverse events (TEAEs) upon dose escalation. All except one TEAE were mild or moderate in severity and no serious AEs were reported.
- Total of 22 treatment-related AEs in 13 of 37 subjects (35%) were reported and all resolved.
  - Reported in ≥2 cases included: dysphagia (14%), injection site erythema (8%), injection site bruising (5%), injection site pain (5%), muscle tightness (5%), and muscle weakness (5%).
- Treatment-related AEs of special interest had similar or lower incidence rates vs. prior BoNT-A studies.
  - Dysphagia: 14% (5/37; all mild); average duration 35 days.
  - Muscular weakness: 5% (2/37, 1 mild, 1 moderate), both local.
  - Neck pain: 3% (1/37; only severe TEAE reported), duration of 2 days.