were detected in 35 (1.3%) subjects. No subjects had treatment-boosted anti–RTP004-binding antibodies. In the majority of subjects, the binding antibodies were transient and not present in the final sample. No subject had binding antibodies to both daxibotulinumtoxinA and RTP004. All subjects with treatment-induced binding antibodies to daxibotulinumtoxinA or RTP004 achieved a response of none or mild glabellar line severity at Week 4 following each DAXI treatment cycle, and duration of clinical response was not different in treatment cycles when antibodies were detected compared with those in which no antibodies were recorded. No subjects with binding antibodies to daxibotulinumtoxinA or RTP004 reported any immune-related adverse events.

Conclusions: This is the first large-scale analysis of the risk of antibody formation to DAXI. No subjects developed neutralizing antibodies to daxibotulinumtoxinA. Results from this study suggest that DAXI administration results in a low incidence of antibody formation. For the small percentage of subjects who developed transient binding antibodies to daxibotulinumtoxinA or RTP004, these were found to not impact clinical efficacy, safety, or duration of action.

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Keywords: Anti-drug antibodies; Botulinum toxin type A; DaxibotulinumtoxinA; Glabellar lines; Immunogenicity

Treatment of Cervical Dystonia Using Shorter IncobotulinumtoxinA Injection Intervals Improves Patient-Reported Outcomes in Those With Inadequate Benefits From Standard Intervals

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Introduction: There is individual variation in the reported waning of botulinum toxin (BoNT) treatment benefit in patients with cervical dystonia (CD), even among patients who experience a favorable peak response. Thus, some patients prefer injection intervals shorter than the standard 12 weeks. This study assesses whether individualized treatment intervals can lead to improved patient experience without compromising safety. The objective was to assess the impact of 2 different injection schedules of incobotulinumtoxinA on patient-reported assessments in CD.

Methods: An open-label, randomized, phase IV study (CD Flex; NCT01486264) was designed to compare 2 incobotulinumtoxinA injection intervals (short-flex: 8±2 weeks [N=142]; long-flex: 14±2 weeks [N=140]) in BoNT-responsive subjects with CD who report typical waning of clinical benefit at <10 weeks. Subjects received 8 injections over a period of up to 2 years. Patient-reported outcomes (4 weeks post-injection 8) included satisfaction (10-point scale), patient-reported global response (9-point Likert scale), and the CD impact profile (CDIP-58). Additional endpoints included a physician-assessed global response and a clinical global impression of severity.

Results: Subject satisfaction was significantly improved vs study baseline over 8 cycles in the short-flex group (mean change=1.2 points, P=0.0007), but not in the long-flex group. A significant improvement was also observed in the short-flex group in the physician-assessed global impression of severity 4 weeks after injection 8. Most domains of the CDIP-58 analysis (pain/discomfort, sleep, annoyance) demonstrated numerical trends favoring the short-flex group. At 4 weeks post-injection 8, a similar distribution of scores was observed for both groups on the subject- and physician-rated global response assessments with no relevant difference between groups. No differences in safety profile were noted.

Conclusions: Subjects with shorter incobotulinumtoxinA injection intervals reported improved satisfaction after 8 injections. Trends favoring short-flex were observed in both the CDIP-58 analysis and physician-rated clinical global impression of severity. Evidence suggests that individualizing injection intervals to treat CD may improve patient-reported outcomes without compromising safety.

Funding: This study was sponsored by Merz Pharmaceuticals, LLC.

Keywords: Botulinum toxin; Cervical dystonia; IncobotulinumtoxinA; Movement disorders

Factors Associated With Favorable Response in Real-World Use of Botulinum Toxin Type A Products for Adult Patients With Upper Limb Spasticity

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Introduction: Clinical trials have shown that botulinum toxin type A (BoNT-A) can enable achievement of treatment goals related to pain management, involuntary movements, range of motion, passive function, and active function or mobility in people with upper limb spasticity (ULS). However, real-world data are limited. This analysis aimed to examine factors associated with a favorable response (including the agent used), as well as outcomes associated with treatment response (including quality of life), in a real-world setting.

Methods: ULIS III (NCT02454803) was an international, multicenter, non-interventional, prospective, longitudinal (2-year) study of adult patients with ULS treated with abobotulinumtoxinA (aboBoNT-A), onabotulinumtoxinA (onaBoNT-A), or incobotulinumtoxinA (incoBoNT-A). Full study description and primary findings are presented elsewhere (Turner-Stokes et al, 2021). In the current analysis of ULIS III data, patients were excluded from the analysis if they changed BoNT-A formulation during follow up. Response was defined as a ≥10-point increase in the cumulated Goal Attainment Scaling (GAS) T-score vs baseline. Patient quality of life was assessed with the EQ-5D scale (US and Australia only). Multivariate logistic regression analysis of response was used to evaluate the impact of baseline characteristics, administration method, dosing, and use of rehabilitation therapy.

Results: Overall, 828 patients provided cumulated GAS-T-score data during the study (555 in the aboBoNT-A, 196 in the onaBoNT-A, and 77 in the incoBoNT-A groups). In the multivariate analysis, prognostic factors for response were: use of injection guidance techniques, patient's sex, and