RimabotulinumtoxinB (MYOBLOC) in the treatment of adult sialorrhea

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Objective: To determine the efficacy, safety and tolerability of repeat injections of rimabotulinumtoxinB (MYOBLOC) for the treatment of sialorrhea.

Background: Sialorrhea (drooling) can cause significant morbidity in several neurological disorders, including impaired oral hygiene, perioral irritation, embarrassment, swallowing impairment, and increased risk of aspiration. Local injections of botulinum toxin-B into the parotid and submandibular glands reduce saliva production.

Design/Methods: This was a double-blind, placebo-controlled (DBPC) study with open-label (OL) extension (NCT01994109). In the DBPC phase, adult subjects with Parkinson's disease, amyotrophic lateral sclerosis, medication induced drooling, stroke and other disorders were randomized (1:1:1) to receive rimabotulinumtoxinB 2500U vs 3500U vs placebo. During the OL phase, all subjects received 3500U of rimabotulinumtoxinB during the first OL treatment cycle; dose adjustments were permitted in OL cycles 2-4 (injection interval 11-15 weeks). Co-primary outcomes were change from baseline to week 4 in: Unstimulated Salivary Flow Rate (USFR) and Clinical Global Impression of Change (CGI-C).

Results: Of the 187 enrolled subjects, 176 completed the DBPC, 170 entered OL treatment and 128 completed the OL phase up to 1 year. Treatment with rimabotulinumtoxinB in the DBPC study significantly reduced USFR week 4 versus placebo (mean treatment effect: -0.30 for both doses vs. placebo, p<0.0001). CGI-C scores were significantly better at week 4 for both treatment groups versus placebo (-1.21 for 2500U and -1.14 for 3500U, both p<0.0001). Treatment benefits were seen as early as week 1 and were maintained over repeat treatment for up to 1 year. The most frequent AE with rimabotulinumtoxinB was dry mouth (38-45%); in subjects who underwent repeat treatment, the incidence of AEs reduced over time.

Conclusions: RimabotulinumtoxinB provided effective treatment for sialorrhea in a DBPC multi-center trial. Long-term, repeat treatment with rimabotulinumtoxinB was effective in reducing sialorrhea in subjects for up to 1 year.