

Long-Term Safety and Efficacy of Repeated Cycles of RimabotulinumtoxinB in the Treatment of Chronic Sialorrhea: Results of the OPTIMYST Trial

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Supplementary Data

Table S1. Clinician and patient-reported outcomes by treatment cycle

Outcome	Cycle 1^a n = 186	Cycle 2^b n = 177	Cycle 3^c n = 50	Cycle 4^d n = 24
USFR, mean (SD)				
Baseline	0.6 (0.49)	0.49 (0.39)	0.47 (0.23)	0.43 (0.28)
Week 4	0.29 (0.28) [#]	0.27 (0.28) [#]	0.29 (0.21) [#]	0.27 (0.16) ^{**}
Week 13	0.49 (0.39) [#]	0.44 (0.35) ^{***}	0.40 (0.30)	0.41 (0.25)
CGI-S, mean (SD)				
Baseline	4.4 (0.9)	3.5 (1.2)	3.5 (1.2)	3.2 (1.2)
Week 4	2.7 (1.2) ^{***}	2.7 (1.3) ^{***}	2.6 (1.2) ^{***}	2.3 (1.2) ^{***}
Week 13	3.5 (1.2) ^{***}	3.4 (1.4)	3.2 (1.2)	3.0 (1.3)
CGI-C Improvement, mean (SD)				
Baseline	N/A	3.0 (1.2)	3.1 (1.1)	3.1 (1.3)
Week 4	2.3 (0.9)	2.4 (1.0)	2.4 (0.9)	2.5 (0.9)
Week 13	3.0 (1.2)	3.1 (1.3)	3.0 (1.1)	2.8 (0.9)
PGI-S, mean (SD)				
Baseline	5.3 (1.2)	4.5 (1.4)	4.5 (1.2)	4.6 (1.1)
Week 4	3.7 (1.4) ^{***}	3.7 (1.3) ^{***}	3.5 (1.3) ^{***}	3.3 (0.9) ^{***}
Week 13	4.5 (1.4) ^{***}	4.4 (1.5)	4.6 (1.1)	4.4 (1.1)
PGI-C Improvement, mean (SD)				
Baseline	N/A	3.0 (1.1)	3.2 (1.0)	3.3 (1.2)
Week 4	2.5 (1.1)	2.6 (1.1)	2.7 (1.0)	2.5 (0.7)
Week 13	3.0 (1.1)	3.2 (1.3)	3.2 (1.1)	3.4 (0.7)

DSFS-I, mean (SD)				
Baseline	6.4 (1.4)	5.1 (1.5)	5.0 (1.6)	4.9 (1.3)
Week 4	4.0 (1.4)***	4.0 (1.5)***	3.8 (1.4)***	3.4 (1.0)***
Week 13	5.1 (1.6)***	5.0 (1.7)	5.0 (1.4)	4.6 (1.1)*
DSFS-P, mean (SD)				
Baseline	5.9 (1.3)	4.8 (1.4)	4.3 (1.2)	4.0 (1.1)
Week 4	4.4 (1.3)***	4.1 (1.4)***	4.0 (1.2)***	3.5 (0.8)
Week 13	4.8 (1.4)***	4.5 (1.4)***	4.2 (1.2)	3.8 (1.1)
DIS, mean (SD)				
Baseline	21.1 (5.8)	17.7 (5.5)	17.9 (4.3)	18.0 (4.0)
Week 4	15.9 (5.1)***	15.3 (4.6)***	15.2 (4.2)***	14.3 (3.3)***
Week 13	17.6 (5.5)***	18.0 (6.2)	17.7 (4.0)	17.6 (4.5)

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$, # $p < 0.0001$. *P* value is from paired *t* test. Abbreviations: CGI-S, Clinical Global Impression-Severity; DSFS-I, Drooling Frequency and Severity Scale-Investigator; DSFS-P, Drooling Frequency and Severity Scale-Patient; DIS, Drooling Impact Scale; PGI-S, Patient Global Impression-Severity; USFR, unstimulated salivary flow rate.

^aCycle 1 includes Baseline (Pre-Injection [Day 1]), weeks 4, 8, and 13.

^bCycle 2 includes Baseline (Pre-Injection [Week 13]), weeks 17 and 26.

^bCycle 3 includes Baseline (Pre-Injection [Week 26]), weeks 30 and 39.

^bCycle 4 includes Baseline (Pre-Injection [Week 39]), weeks 43 and 52.

Table S2. Changes from baseline in clinician and patient-reported outcomes by treatment cycle

Outcome	Cycle 1 ^a n = 186	Cycle 2 ^b n = 177	Cycle 3 ^c n = 50	Cycle 4 ^d n = 24
Change in USFR, mean (SD)				
Week 4	-0.3 (0.4) [#]	-0.2 (0.3) [#]	-0.2 (0.2) [#]	-0.2 (0.2) ^{**}
Week 13	-0.1 (0.3) [#]	-0.1 (0.2) ^{***}	-0.1 (0.2)	-0.0 (0.1)
Change in CGI-S, mean (SD)				
Week 4	-1.7 (1.3) ^{***}	-0.8 (1.1) ^{***}	-0.9 (1.1) ^{***}	-0.9 (1.0) ^{***}
Week 13	-0.9 (1.0) ^{***}	-0.1 (1.0)	-0.2 (0.9)	-0.3 (1.0)
Change in PGI-S, mean (SD)				
Week 4	-1.6 (1.6) ^{***}	-0.8 (1.3) ^{***}	-0.9 (1.3) ^{***}	-1.4 (1.3) ^{***}
Week 13	-0.8 (1.4) ^{***}	-0.1 (1.3)	0.0 (1.2)	-0.3 (1.3)
Change in DSFS-I, mean (SD)				
Week 4	-2.3 (1.5) ^{***}	-1.2 (1.5) ^{***}	-1.1 (1.4) ^{***}	-1.5 (1.4) ^{***}
Week 13	-1.2 (1.4) ^{***}	-0.2 (1.3)	0.0 (1.3)	-0.3 (0.7) [*]
Change in DSFS-P, mean (SD)				
Week 4	-1.4 (1.4) ^{***}	-0.7 (0.9) ^{***}	-0.4 (0.6) ^{***}	-0.4 (1.0)
Week 13	-1.0 (1.5) ^{***}	-0.3 (1.0) ^{***}	-0.0 (1.0)	-0.2 (1.4)
Change in DIS, mean (SD)				
Week 4	-5.2 (5.3) ^{***}	-2.5 (4.2) ^{***}	-2.8 (3.4) ^{***}	-3.6 (3.1) ^{***}
Week 13	-3.4 (5.0) ^{***}	0.3 (3.9)	-0.1 (2.1)	-0.5 (2.6)

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$, # $p < 0.0001$. *P* value is from paired *t* test. Abbreviations: CGI-S, Clinical Global Impression-Severity; DSFS-I, Drooling Frequency and Severity Scale-Investigator; DSFS-P, Drooling Frequency and Severity Scale-Patient; DIS, Drooling Impact Scale; PGI-S, Patient Global Impression-Severity; USFR, unstimulated salivary flow rate.

^aCycle 1 includes weeks 4, 8, and 13.

^bCycle 2 includes weeks 17 and 26.

^cCycle 3 includes weeks 30 and 39.

^dCycle 4 includes weeks 43 and 52.

Table S3. Subgroup Analysis of Unstimulated Salivary Flow Rate (USFR) in patients with ALS

USFR (g/min), mean (SD)	Cycle 1^a	Cycle 2^b	Cycle 3^c	Cycle 4^d
Baseline	0.61 (0.83) n = 26	0.51 (0.68) n = 26	0.38 (0.09) n=7	0.40 (0.19) n=5
Week 4	0.33 (0.51) n=26	0.30 (0.50) n=25	0.25 (0.15) n=7	0.29 (0.07) n=5
Week 8	0.36 (0.51) n=26	N/A	N/A	N/A
Week 13	0.51 (0.68) n=26	0.49 (0.61) n=22	0.36 (0.19) n=7	0.30 (0.11) n=4

N/A, not applicable (no week 8 assessment in this cycle)

^aCycle 1 includes Baseline (Pre-Injection [Day 1]), weeks 4, 8, and 13.

^bCycle 2 includes Baseline (Pre-Injection [Week 13]), weeks 17 and 26.

^bCycle 3 includes Baseline (Pre-Injection [Week 26]), weeks 30 and 39.

^bCycle 4 includes Baseline (Pre-Injection [Week 39]), weeks 43 and 52.