**2014-005303-24**

## Supplementary Results for Efficacy Endpoints

## Summary of conclusions of efficacy endpoints from the long-term safety of MT10109L (NivobotulinumtoxinA) for the treatment of Glabellar Lines and Lateral Canthal Lines.

Efficacy Results:

**EU Regulatory Agencies** (mITT population)

At Treatment Cycle 1, Day 30, a similar proportion of participants were seen as responders in the **MT 44 U group and MT 20 U group** compared with none/lesser proportion of participants in the placebo group for the following endpoints:

- achieved none or mild on the FWS based on the Investigator assessment of GL severity at maximum frown (77.3% and 75.5% participants).
- achieved none or mild on the FWS based on the participant assessment of GL severity at maximum frown (64.8% and 67.6% participants).
- reporting mostly satisfied/very satisfied on FLSQ follow-up version item 5 for GL across treatment groups and Day 30 of each Treatment Cycle.
- reporting ≥ 20-point improvement from baseline on the FLSQ impact domain for GL (72.5% and 75.0% participants).
- reporting ≥ 20-point improvement from baseline FLO-11 questionnaire total score for GL (75.8% and 76.4% participants).
- reporting ≥ 4-point improvement from baseline on the FLO-11 questionnaire item 2 for GL (65.9% and 66.8% participants).
- reporting ≥ 4-point improvement from baseline on the FLO-11 questionnaire item 5 for GL (57.1% and 59.6%).

At Treatment Cycle 1, Day 30, a similar proportion of participants were seen as responders in the **MT 44 U group and MT 24 U group** compared with none/less participants in the placebo group for the following endpoints:

- achieved none or mild on the FWS based on the Investigator assessment of LCL severity at maximum smile (61.7% and 59.3% participants).
- achieved none or mild on the FWS based on the participant assessment of LCL severity at maximum smile (48.3% and 48.6% participants).
- reporting mostly satisfied/very satisfied on FLSQ follow-up version item 5 for LCL across treatment groups and Day 30 of each Treatment Cycle.
- reporting a ≥ 20-point improvement from baseline on the FLSQ impact domain for LCL (54.3% and 51.4% participants).
- reporting a ≥ 20-point improvement from baseline on the FLO-11 questionnaire total score for LCL across all treatment groups and Day 30 of each Treatment Cycle.
- ≥ 4-point improvement from baseline on the FLO-11 questionnaire item 2 for LCL (60.3% and 48.1% participants).
- ≥ 4-point improvement from baseline on the FLO-11 questionnaire item 5 for LCL (49.1% and 48.1% participants).

The results of these endpoints indicated that higher number of participants receiving MT 44 U, MT 24 U, and MT 20 U groups showed efficacy in terms of reduction of wrinkles and reporting mostly satisfied or satisfaction on the patient-reported outcomes compared with the placebo group.