EAN 2016 abstract – 28-31 May 2016 – Abstract deadline 13 January

Title (25 words, limit 25 words): A new liquid formulation of abobotulinumtoxinA (Dysport®) significantly improves disease-specific quality of life (CDIP-58) and pain in cervical dystonia: a double-blind and open-label study

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Introduction:
AbobotulinumtoxinA (Dysport®) Solution for Injection (ASI) is a ready-to-use liquid formulation of abobotulinumtoxinA shown to significantly improve Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) score from baseline to Week 4 versus placebo (ASI and placebo were part of a 3-arm trial that also included the approved freeze-dried preparation of abobotulinumtoxinA)1. CD has a major negative impact on the quality of life (QoL) of patients. The effect of ASI versus placebo on disease-specific QoL, and pain, measured by Cervical Dystonia Impact Profile (CDIP-58) and VAS, respectively are reported here.

Methods:
In the Phase III, double-blind, placebo controlled study, 369 patients from 11 countries were randomized 3:3:1 to ASI 500U (n=156), abobotulinumtoxinA 500U (n=159) and placebo (n=54). In the open-label phase, patients received up to 4 further treatment cycles of ASI.

Results:
Total CDIP-58 score significantly improved from baseline to Week 4 with ASI versus placebo (9.5 vs. 0.9; p<0.0001); all CDIP-58 subscale scores were also significantly improved (ps<0.0001). CDIP-58
changes significantly positively correlated with TWSTRS total score decreases (p<0.001). ASI was also associated with a significant reduction in VAS pain score versus placebo at Week 4 (-14.8 vs. -3.4; p=0.0021). Improvements in patient QoL across the eight health domains and VAS pain were broadly maintained at week 4 of cycles 2 to 5.

**Conclusion:** Significant improvements in CDIP-58 scores and VAS pain were observed after a single injection of this ready-to-use liquid formulation of abobotulinumtoxinA (ASI) 500U compared with placebo. Improvements in these health domains appeared to be maintained after repeated treatment with ASI.

**Reference:**

1. ESPRM-SOFMER 26-31 May 2014, Marseille, France; oral CO41-006.