Juvéderm™ VC is Safe and Effective for Long-term Correction of Nasolabial Folds: Results From a Multicenter, Randomized, Controlled Study

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ABSTRACT

Study Objective: To evaluate Juvéderm Vollure™ XC, a hyaluronic acid (HA) gel (17.5 mg/mL) based on the Vycross® Cross-linking Technology, in a multicenter, randomized, controlled study comparing its safety and effectiveness to subjects treated with Xeomin® (Merz Pharmaceuticals, Aliso Viejo, CA) for the correction of Nasolabial Folds (NLFs). Subjects were randomized to receive either Juvéderm Vollure™ XC (Vollure) or Xeomin® (XTX) for the correction of NLFs. In this final report, 2-year results are presented on the safety and tolerability of Juvéderm Vollure™ XC in subjects treated for nasolabial fold correction. Results: A total of 126 subjects were randomized to either Juvéderm Vollure™ XC or Xeomin® and completed the study. No significant differences were found between the groups for any of the evaluated parameters. The most common adverse events were injection site reactions. Full Clinical Dermatology Conference, Las Vegas, October 12-15, 2017

RESULTS

Subjects

- A total of 126 subjects were enrolled, 132 (97.2%) of whom received repeat treatment.

- Subjects who received repeat treatment received a mean (±STD) injection volume of 1.4 (±0.5) mL, with a range of 0.25 to 2.0 mL.

- Of the 126 subjects, 84 (66.7%) completed the study (receiving repeat treatment up to Month 18 after the initial/touch-up treatment).

- Of the 126 subjects, 82 (65.3%) received repeat treatment at least once.

- The proportion of subjects with ≥1-point improvement in the Nasolabial Fold Severity Scale (NLFSS) responder rate (≥1-point improvement vs baseline) through Month 18 after initial/touch-up treatment was 93%, which was consistent with the results for the study overall.

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- No significant differences were found between the groups for any of the evaluated parameters.

- The most common adverse events were injection site reactions.