Juvéderm Vollure™ XC Is Safe and Effective for Correcting Nasolabial Folds: Results From a Randomized Controlled Study

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ABSTRACT

OBJECTIVE: To evaluate Juvéderm Vollure™ XC, a hyaluronic acid (HA) gel (17-24 mg/mL) cross-linked with the<br>Genipin® cross-linking agent, in a randomized, non-blinded, multicenter, parallel-group, non-inferiority trial for nasolabial fold (NLF) treatment.

METHOD: Adults (N=123) were randomized in a 1:1 ratio to treatment with a single injection of Juvéderm Vollure™ XC in 2 fully visible nasolabial folds. Subjects were followed for 6 months and treated with touch-up injections as needed at investigator discretion. The primary effectiveness analysis was a non-inferiority analysis. Non-inferiority was evaluated using a 1-sided 0.025-level t-test. The prespecified margin of non-inferiority was a difference of 0.5 points in the mean nasolabial fold severity scale (NLFSS) score between treatment groups. Primary endpoints were: (a) the responder rate (NLFSS improvement of 2 or more points from baseline) at Month 6, compared with control; (b) improvement in NLFSS scores at Month 6, compared with baseline; and (c) investigator’s overall satisfaction with Vollure™ XC treatment at Month 6.

RESULTS: Subjects were aged 18 years or older; 57.7% female, with a mean ± SD age of 56.3 ± 11.3 years and Fitzpatrick skin phototype III (44.0%), IV (43.8%), and V (12.2%). Across 12 investigational sites, 105 (86.1%) were white, 7 (5.7%) were black, and 11 (8.9%) were other; 66 (53.7%) were women. Median follow-up time was 278 days (range, 70-409 days).

Subjects were randomized 1:1 to receive a single injection of Juvéderm Vollure™ XC (17.5 mg/mL) in 2 fully visible nasolabial folds. The median volume of initial/touch-up treatment was 1.7 mL for both products. Mean NLFSS score for Juvéderm was 7.1 ± 1.7 at 3 days and 6.2 ± 1.7 at 6 months. Mean NLFSS score for control was 7.3 ± 1.7 at 3 days and 6.5 ± 1.7 at 6 months.

The primary effectiveness endpoint, responder rate, was non-inferior to control (86.9% vs. 79.5%; 95% CI: 0.73, 1.47; P=0.097; Table 1). The secondary effectiveness endpoints were: (a) improvement in NLFSS score at Month 6 (70.6% vs. 29.4%; Table 2); (b) investigator’s overall satisfaction with treatment (93% vs. 86.9%, respectively); and (c) subject satisfaction (93% for Vollure™ XC vs. 86.9% for control) (Figure 5).

At Month 6, the mean (standard deviation) improvement from baseline in NLFSS score was 3.5 ± 2.0 (P<0.001) for Juvéderm and 2.6 ± 0.49 (P<0.001) for control (Figure 3). NLFSS scores at Baseline, Month 1, 3, and 6 were significantly lower for Juvéderm than with control, and severity of ISRs was notably lower with Juvéderm (Figure 4).

The incidence of AEs was low; most AEs at both NLFs resolved within 60 days and were mild or moderate, and no serious AEs were reported. No subjects discontinued the study due to AEs. In total, 18 AEs were reported by 17 subjects (13.8%) with Juvéderm and 15 AEs were reported by 14 subjects (11.4%) with control.

CONCLUSIONS

Juvéderm Vollure™ XC is safe and effective for correcting nasolabial folds, with a treatment time in most subjects lasting at least 6 months. Juvéderm Vollure™ XC provided a more natural look in twice as many patients as control. Juvéderm Vollure™ XC has the potential to change the way physicians interpret nasolabial folds, with greater satisfaction and lower inconvenience for the patient.