JUVEDERM VOLUMA XC MOVES CLOSER TO MARKET

WITH MILES GRAIVIER, MD

COMING

Juvéderm Voluma™ XC

In Their Words: Allergan's Juvéderm Voluma™ XC is an injectable hyaluronic acid (HA) dermal filler for cheek augmentation to correct age-related volume deficit in the mid-face. The filler is a transparent, biodegradable, sterile, cross-linked, hyaluronic acid hydrogel formulated to neutral pH in a physiological buffer.

What it Means: If approved, Juvéderm Voluma XC would be the first HA filler approved for correction of mid-face volume deficit. It's designed to be a more robust filler with potentially longer longevity than those currently on the US market.

The Data: In the North American clinical trial of Juvéderm Voluma XC (protocol VOLUMA-002), the primary objective was to evaluate the safety and effectiveness of the filler for age-related cheek augmentation in the mid-face. Subjects with moderate to severe age-related mid-face volume deficit were followed for up to 24 months following treatment. Up to 12 ccs of Voluma was allowed to be injected on a patient in the trial. A new 6-point Mid-Face Volume Deficit Scale (MFVDS) was validated and used to quantify the results.

At six months, 86 percent of treated subjects had a 1-point or greater improvement on the MFVDS, the primary endpoint, compared to 39 percent of controls. At Month 24, 67.1 percent of treated subjects had a 1-point or greater improvement in their overall MFVDS since baseline.

What's Next: The FDA's General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee voted unanimously in May to recommend approval of Juvéderm Voluma XC. The FDA is expected to follow the panel's recommendation, and, if it is approved, Allergan anticipates launching Juvéderm Voluma XC in late 2013.

Bottom Line: When Juvéderm Voluma XC gets FDA approval for mid-face volume correction, it will be the first HA gel approved for this usage. The FDA trials showed good soft results with minimal adverse events. The correction appears to last approximately two years (average volume for both malar areas used in study ~6ccs). This will add a good option to our armamentarium for mid-face augmentation.

GOING

Zerona Laser Scanning

Despite some buzz around its launch, Zerona Laser Scanner by Erchonia, which uses low-level laser therapy (LLLT) for fat reduction and body slimming, does not appear to be making waves in aesthetic practices. The device aids in the circumferential reduction of the hips, waist, thighs, and upper arms, but aesthetic physicians appear to be more interested in cryolipolysis, ultrasound, and RF technologies.

While improvement in the endocrine function of the adipocyte has been nicely demonstrated in several large level 1 and level 2 studies, the overall results regarding demonstrable, long-lasting circumferential reduction are less impressive than with technologies demonstrating apoptosis. The trend to use the Zerona technology is more toward an assist modality as opposed to a standalone, long-lasting fat reducer. ■