JUVÉDERM VOLLURE XC FDA APPROVED FOR CORRECTION OF FACIAL WRINKLES AND FOLDS

The FDA has approved Allergan plc's Juvéderm Vollure XC for correction of moderate to severe facial wrinkles and folds, such as nasolabial folds, in adults over the age of 21. In the US pivotal clinical trial, a majority (59 percent) of subjects saw improvement in moderate to severe nasolabial folds for up to 18 months. Patient satisfaction in the pivotal study was also high with 82 percent of patients reporting that they were very satisfied at six months and 68 percent at 18 months.

Juvéderm Vollure XC is formulated with Allergan's proprietary Vycross technology, which blends different molecular weights of hyaluronic acid, contributing to the gel's duration. The first Allergan product featuring Vycross technology, Juvéderm Voluma XC was FDA-approved to increase volume lost due to aging in the cheek area, followed by Juvéderm Volbella XC, which is FDA-approved for lip augmentation and correction of perioral rhytids. Now with Juvéderm Vollure XC, the advanced Vycross technology yields a custom engineered injectable gel product that was studied in the nasolabial folds, the number one dermal treatment area. It delivers a long-lasting result—up to 18 months.

Juvéderm Vollure XC is specifically tailored with a balance of gel firmness and low cohesivity, yielding a versatile formulation that adds subtle volume for the correction of moderate to severe facial wrinkles and folds.

"What's exciting about Juvéderm Vollure XC is that it was shown to last up to 18 months from the initial or touch-up injection in a majority of subjects, which is the longest lasting result shown in a clinical study in the nasolabial folds," said Joely Kaufman, MD, a board-certified dermatologist and clinical trial investigator. "As the number of patients seeking dermal filler treatments continues to grow, I am pleased that the technology created by Allergan has also followed that same trend, with a full range of products that will allow for tailoring of treatment based on specific patient needs."

The most common side effects seen in the clinical study were temporary injection site responses at the treatment site such as swelling, tenderness, bruising, firmness lumps/bumps, redness, pain, discoloration, and itching. Most of these side effects resolved within one week.

Juvéderm Vollure XC will be available to physicians in April 2017.

Survey Shows: Many Bothered By Double Chins, Take Steps To Cover Up

Close to 50 percent of individuals are bothered by the appearance of the area under their chin, and many alter their behavior as a result, according to a new survey commissioned by Allergan plc.

The findings were presented at the American Academy of Dermatology (AAD) Meeting in Orlando, FL.

The new survey included 1,996 men and women in the US between the ages of 18 and 65. Forty-seven percent reported being bothered by the appearance of the area underneath their chin, and 49 percent said the area under their chins negatively impacts their appearance.

Nearly half (45 percent) of respondents felt people noticed the area under their chin, the survey showed. Fifty-five percent of female respondents (n=1,025) reported being bothered by the area under their chin, compared to 40 percent (n=971) of male respondents.

Survey respondents reported altering their behavior to address their double chin. For example:

- **35 percent** shy away from photos
- **35 percent** avoid video chats and conference calls (n=488)
- **29 percent** of men have grown a beard to hide the area under their chin (younger men were more likely to do this than their older peers) (n=971)

Upon evaluation of photographs of individuals with varying levels of submental fullness:

- **78 percent** of respondents admitted they are more likely to notice a double chin on a woman than a man.

"The results of this survey mimic what I hear from patients on a daily basis—they are bothered by submental fullness and are looking to address the problem. In many cases, the submental fullness is genetic and resistant to diet or exercise," says Shannon

Humphrey, a dermatologist at Carruthers & Humphrey Cosmetic Clinic Vancouver, BC, in a news release. "These findings will help physicians to better understand the impact a double chin has on our patients so we can address this issue and provide them with effective treatment options."

Modernizing Medicine and Galderma Collaborate on OTC eCommerce Platform

Modernizing Medicine, Inc. and Galderma Laboratories, L.P. are teaming up to offer new capabilities in support of improved patient experiences and outcomes through healthcare provider recommended over-the-counter (OTC) treatment regimens and patient education materials. The program, designed by Modernizing Medicine, will simplify the healthcare provider process of creating materials and educating patients about treatment regimens, which often incorporates a combination of prescriptions and OTC products and requires patients to follow very specific instructions. The enhancements are intended to streamline the dissemination of educational materials and treatment plans, with a new feature that will enable patients to easily order physician-recommended OTC products online and have the products delivered directly to them.

Galderma, Nestlé Skin Health's medical solutions business, is working with Modernizing Medicine to bring the solution to market and will be one of the first suppliers making its OTC products available through this integrated eCommerce solution.

These enhancements to Modernizing Medicine's electronic health record (EHR) system, EMA, are designed to give clinical providers the ability to use structured data to document detailed treatment regimens combining prescription and OTC products. The application intelligently sequences the information and creates a document which is easy for the patient to understand. For example, a treatment regimen might instruct a patient to first cleanse their skin before applying a prescription cream and to then use a moisturizer. The patient education can also include integrated clickable links which enable direct-to-patient eCommerce for the OTC items.

While Modernizing Medicine is working with Galderma to create and test the new functionality, the company plans to include OTC products from other manufacturers and suppliers.

ASAPS and ASPS 2016 Stats Find Cosmetic Surgery On The Rise

The American Society for Aesthetic Plastic Surgery (ASAPS) reports that surgical procedures were up 3.5 percent in 2016, with the biggest jumps seen in fat transfer to the breast (up 41 percent), labiaplasty (up 23 percent), buttock lift (up 21 percent), fat transfer to the face (up 17 percent) and breast explantation (up 13 percent).

Nonsurgical procedures were up 7 percent in 2016, with pronounced upticks in photorejuvenation (up 36 percent), hyaluronic acid injections (up 16 percent), laser tattoo removal (up 13 percent), nonsurgical skin tightening (up 12 percent) and botulinum toxin shots (up eight percent).

Annual statistics from the American Society of Plastic Surgeons (ASPS) showed similar findings. Specifically, minimally invasive cosmetic fat injections increased by 13 percent, buttock augmentation using fat grafting increased by 26 percent and breast augmentation using fat grafting increased by 72 percent from 2015 to 2016. In the same time period, injection-based procedures that target fat pockets in specific areas such as under the chin grew by 18 percent, fat freezing techniques increased by five percent as did non-invasive skin tightening procedures that target fat and tighten sagging areas.

Overall, there were 17.1 million surgical and minimally invasive cosmetic procedures performed in the United States in 2016, a three percent rise from 2015. Facelifts, which dropped from the top five most popular cosmetic surgical procedures in 2015, made a comeback in 2016, according to the new stats.

This year, overall cosmetic surgical procedures grew at a slightly higher rate of four percent compared to minimally-invasive cosmetic procedures, which grew by three percent. While body procedures are still popular, three of the five top cosmetic surgical procedures focused on the face.

Also, more seniors are getting nips and tucks, ASAPS reports. Surgical procedures in men and women aged 65 and older increased by 58 percent in five years, and non-surgical ones jumped by 93 percept in the same timeframe.

BY THE NUMBERS

$15B That's the amount of money that Americans doled out for cosmetic surgery in 2016, according to newly released statistics from the American Society for Aesthetic Plastic Surgery. That's $1.5 billion more then they spent in 2015, the group reports.

My New Favorite Thing: RESTYLANE REFYNE AND RESTYLANE DEFYNE

"I am always excited to try new technologies and use cutting edge technology in all areas of my practice. I love these two new hyaluronic acid fillers for my patients who are filler naïve and so afraid of looking over-done. Restylane Refyne is approved for the treatment of moderate to severe facial wrinkles and folds and Restylane Defyne is approved for the treatment of moderate to severe, deep facial wrinkles and folds. Both products are manufactured with XpresHAn Technology, which is responsible for the flexibility and support they provide during facial animation. They move with skin so patients will look better when they animate than they did before, which is an incentive for my patients who have had filler in the past. I use Defyne for deeper nasolabial folds, and Refyne is great for cheek lines. When a patient smiles, it fills this area beautifully. The results are so natural because it integrates into the skin so well. Refyne and Defyne have been shown to maintain effectiveness for up to 12 months. This is also a plus for patients."

Marina I. Peredo, MD, FAAD
Board-certified Dermatologist | Medical Director Skinfluence | Associate Clinical Professor of Dermatology
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Hair Loss Rx Performs Well In First In-Human Trial

The first in-human study of RepliCel Life Sciences Inc's investigational baldness cure, RCH-01, confirms the therapy's safety and demonstrates strong efficacy signals, the company reports. The autologous cell therapy involves culturing a person's own dermal sheath cup cells (DSCC) and then re-injecting them back into their scalp.

The five-year trial data set has confirmed the complete safety profile of a high-dose of DSCC for patients with pattern baldness due to androgenetic alopecia. The long-term safety of DSCC injections was demonstrated through multiple physician, patient and independent measures of local and systemic tolerance including evaluation of adverse events with respect to causality, incidence, severity, and seriousness. No serious adverse events were reported.

Local injection tolerance was confirmed with only a few minor scalp irritations reported around injection sites that resolved quickly. Histopathological evaluation of injection site biopsies taken six, 12, and 24 months after injection did not reveal any pathology that was suggestive of tumour, granuloma or foreign body formation, the study showed. An analysis of injection site biopsies taken 60.5 months after injection is currently ongoing. Long-term systemic safety of RCH-01 was also confirmed as none of the systemic adverse events reported during the extended safety evaluation were related to treatment.

The trial was designed to gather data related to the product's potential efficacy through 24 months post-injection, but was not designed for statistical significance related to any efficacy endpoints. The efficacy data collected from all 19 patients, while not statistically significant, provides useful and potentially exciting insights into the product's potential for the treatment of those with androgenetic alopecia.

The seven top-tier responders in the trial saw >10 percent increase in hair density at six months post-injection. At 24 months, the average hair density increase for these same seven participants was 8.3 percent over baseline, and three of the seven trial participants maintained a >10 percent increase in density over baseline. The largest increase in hair density over baseline observed was a 21 percent increase at 24 months.

The top 10 participants reported at least a 5 percent or greater increase in hair density at six months post-injection with an average increase of 11.8 percent. This group demonstrated a sustained response at 24 months which averaged a 4.2 percent increase over baseline hair density. While there was a high degree of variability in hair density between individual participants at 24 months post-injection compared to baseline, an overall stabilization of hair loss was observed among all the patients treated per protocol, the study showed. ■