

FDA APPROVES JUVÉDERM VOLUMA™ XC

First and Only Filler Approved in the U.S. to Correct Age-Related Volume Loss in the Cheek Area

IRVINE, Calif., (October 23, 2013) – Allergan, Inc., (NYSE: AGN) today announced that the company has received approval from the U.S. Food and Drug Administration (FDA) to market JUVÉDERM VOLUMA™ XC, the first and only filler approved to temporarily correct age-related volume loss in the cheek area in adults over the age of 21. JUVÉDERM VOLUMA™ XC helps create a more youthful appearance to the face and provides natural-looking and long-lasting results up to two years with optimal treatment.¹

“Since 2002, Allergan has remained the leader in the medical aesthetics category as a result of our continued commitment to research and development, which has led to the approval of innovative products such as BOTOX® Cosmetic and JUVÉDERM® XC,” said Scott M. Whitcup, M.D., Executive Vice President, Research and Development, Chief Scientific Officer, Allergan. “We are pleased that the FDA has now approved JUVÉDERM VOLUMA™ XC, the first product of its kind specifically formulated to correct age-related volume loss in the cheek area. JUVÉDERM VOLUMA™ XC represents the latest innovation in Allergan’s growing portfolio of facial aesthetic products developed to address previously unmet patient needs.”

Allergan conducted a pivotal clinical trial in the United States and Canada for submission to the FDA. The trial was designed to assess the safety and effectiveness of JUVÉDERM VOLUMA™ XC as a non-surgical option for patients desiring volume in the cheek area to correct age-related volume loss. The trial demonstrated that JUVÉDERM VOLUMA™ XC was an effective treatment compared to the control group, which did not receive treatment.

“As people age, the cheek area can lose volume, causing the cheeks to flatten out and the skin to droop and sag,” said Dr. Derek H. Jones, Associate Professor of Dermatology, UCLA, Founder and Medical Director, Skin Care and Laser Physicians of Beverly Hills, and clinical investigator in the JUVÉDERM VOLUMA™ XC pivotal study. “In the JUVÉDERM VOLUMA™ XC clinical trial, physicians and patients were able to see instant and visible results, including correction of age-related volume loss in the cheek area and a more youthful appearance to the face.”

JUVÉDERM VOLUMA™ XC is made with Allergan’s proprietary VYCROSS™ technology, an advanced manufacturing process that results in a smooth gel that flows easily and consistently. This unique formulation contributes to the lift capacity to correct volume loss in the cheek area and to the duration of

the product.^{2,3} Additionally, JUVÉDERM VOLUMA™ XC contains a small amount of lidocaine which helps to numb the treatment area during the injection procedure.

The JUVÉDERM VOLUMA™ formulation without lidocaine was first introduced in Europe in 2005. JUVÉDERM VOLUMA™ with lidocaine was first introduced outside the U.S. in 2009. As of August 31, 2013, JUVÉDERM VOLUMA™ with lidocaine (branded as JUVÉDERM VOLUMA™ XC in the U.S.) is distributed in 72 countries, including markets in Europe, Latin America, Middle East, Asia Pacific, and Canada. The JUVÉDERM® family of products, including JUVÉDERM® Ultra and Ultra Plus, are marketed and sold in 85 countries outside the United States.⁴

“Now, with JUVÉDERM VOLUMA™ XC, the only FDA approved filler specifically developed for the cheek area, I have a new treatment that can help correct age-related volume loss, in addition to the other JUVÉDERM® products that help to smooth away wrinkles and folds in the lower-face,” said Dr. Jones.

The most common side effects observed in the clinical trial included temporary injection-site tenderness, swelling, firmness, lumps/bumps, bruising, pain, redness, discoloration, and itching. They were predominantly moderate (uncomfortable) in severity, with a duration of two to four weeks.

JUVÉDERM VOLUMA™ XC will be available in fall 2013.

For more information about the JUVÉDERM® family of products, please visit www.juvederm.com.

INDICATION

JUVÉDERM VOLUMA™ XC injectable gel is indicated for deep (subcutaneous and/or supraperiosteal) injection for cheek augmentation to correct age-related volume loss in the mid-face in adults over the age of 21.

IMPORTANT SAFETY INFORMATION

Are there any reasons why I should not receive JUVÉDERM VOLUMA™ XC?

Do not use the product if you have severe allergies with a history of severe allergic reactions (anaphylaxis), or if you are allergic to lidocaine or the proteins (gram-positive bacterial proteins) used to make the hyaluronic acid (HA) in JUVÉDERM VOLUMA™ XC.

What precautions should my doctor advise me about?

- The safety of JUVÉDERM VOLUMA™ XC injectable gel for use during pregnancy, in women who are breastfeeding, or in patients with very thin skin in the cheek area has not been studied
- The safety for use in patients under 35 years or over 65 years has not been studied
- The safety and effectiveness for treatment in areas other than the cheek area have not been established
- The safety for use in patients with a history of excessive scarring or pigmentation disorders has not been studied and may result in additional scars or changes in pigmentation

- The long-term safety of repeat treatments has not been established
- Patients who experience skin injury near the site of injection may be at a higher risk for side effects
- Tell your doctor if you are on therapy used to decrease the body's immune response (immunosuppressive therapy). Use may result in an increased risk of infection
- Tell your doctor if you are using medications that can prolong bleeding, such as aspirin, ibuprofen, or other blood thinners; as with any injection, this may result in increased bruising or bleeding at the injection site
- Minimize strenuous exercise and exposure to extensive sun or heat within the first 24 hours following treatment

What are possible side effects?

Side effects are typically moderate (uncomfortable) and generally last 2 to 4 weeks. The most common side effects include temporary reactions at the treatment site such as tenderness, swelling, firmness, lumps/bumps, bruising, pain, redness, discoloration, and itching.

To report a side effect, please call Allergan Product Surveillance at 1-877-345-5372.

For more information, please see the [About Safety](#) page at www.juvederm.com or call the Allergan Product Support line at 1-800-766-0171.

JUVÉDERM VOLUMA™ XC injectable gel is available by prescription only.

JUVÉDERM® XC Important Information

Indication

JUVÉDERM® injectable gel is indicated for injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).

IMPORTANT SAFETY INFORMATION ABOUT JUVÉDERM® XC

Your physician will ask about your medical history to determine if you are an appropriate candidate for treatment. The product should not be used in patients who have:

- Severe allergies marked by a history of anaphylaxis or history or presence of multiple severe allergies
- A history of allergies to lidocaine or Gram-positive bacterial proteins. The safety and effectiveness for the treatment of areas other than facial wrinkles and folds (such as lips) have not been established in controlled clinical studies.

The following are important treatment considerations for you to discuss with your physician and understand in order to help avoid unsatisfactory results and complications:

- Patients who are using substances that can prolong bleeding, such as aspirin or ibuprofen, as with any injection, may experience increased bruising or bleeding at injection site. You should inform your physician before treatment if you are using these types of substances
- If laser treatment, chemical peeling, or any other procedure based on active dermal response is considered after treatment with JUVÉDERM[®], there is a possible risk of an inflammatory reaction at the treatment site
- JUVÉDERM[®] injectable gel should be used with caution in patients on immunosuppressive therapy, or therapy used to decrease the body's immune response, as there may be an increased risk of infection
- The safety for use during pregnancy, in breast-feeding females, or in patients under 18 years has not been established
- The safety in patients with a history of excessive scarring (e.g., hypertrophic scarring and keloid formations) and pigmentation disorders has not been studied

Most side effects are mild or moderate in nature, and their duration is short lasting (7 days or less). The most common side effects include, but are not limited to, temporary injection-site reactions such as: redness, pain/tenderness, firmness, swelling, lumps/bumps, bruising, itching, and discoloration.

As with all skin-injection procedures, there is a risk of infection.

To report a problem with JUVÉDERM[®], please call Allergan Product Surveillance at 1-800-624-4261.

For more information, please see the [About Safety](#) page at www.juvederm.com or call the Allergan Product Support line at 1-800-433-8871.

JUVÉDERM[®] injectable gel is available by prescription only.

BOTOX[®] Cosmetic Consumer Important Information

BOTOX[®] Cosmetic (onabotulinumtoxinA) Important Information

Approved Uses

BOTOX[®] Cosmetic is a prescription medicine that is injected into muscles and used to improve the look of moderate to severe frown lines between the eyebrows (glabellar lines) in adults for a short period of time (temporary).

BOTOX[®] Cosmetic is a prescription medicine that is injected into the area around the side of the eyes to improve the look of moderate to severe crow's feet lines in adults for a short period of time (temporary).

IMPORTANT SAFETY INFORMATION

BOTOX[®] Cosmetic may cause serious side effects that can be life threatening. Call your doctor or get medical help right away if you have any of these problems any time (hours to weeks) after injection of BOTOX[®] Cosmetic:

- **Problems swallowing, speaking, or breathing**, due to weakening of associated muscles, can be severe and result in loss of life. You are at the highest risk if these problems are pre-existing before injection. Swallowing problems may last for several months
- **Spread of toxin effects.** The effect of botulinum toxin may affect areas away from the injection site and cause serious symptoms including: loss of strength and all-over muscle weakness, double vision, blurred vision and drooping eyelids, hoarseness or change or loss of voice (dysphonia), trouble saying words clearly (dysarthria), loss of bladder control, trouble breathing, trouble swallowing. **If this happens, do not drive a car, operate machinery, or do other dangerous activities**

The dose of BOTOX[®] Cosmetic is not the same as, or comparable to, any other botulinum toxin product.

There has not been a confirmed serious case of spread of toxin effect when BOTOX[®] Cosmetic has been used at the recommended dose to treat frown lines or crow's feet lines.

Serious and/or immediate allergic reactions have been reported. They include: itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint. Tell your doctor or get medical help right away if you are wheezing or have asthma symptoms, or if you become dizzy or faint.

Do not take BOTOX[®] Cosmetic if you: are allergic to any of the ingredients in BOTOX[®] Cosmetic (see Medication Guide for ingredients); had an allergic reaction to any other botulinum toxin product such as *Myobloc[®]* (rimabotulinumtoxinB), *Dysport[®]* (abobotulinumtoxinA), or *Xeomin[®]* (incobotulinumtoxinA); have a skin infection at the planned injection site.

Tell your doctor about all your muscle or nerve conditions, such as amyotrophic lateral sclerosis (ALS or Lou Gehrig's disease), myasthenia gravis, or Lambert-Eaton syndrome, as you may be at increased risk of serious side effects including severe dysphagia (difficulty swallowing) and respiratory compromise (difficulty breathing) from typical doses of BOTOX[®] Cosmetic.

Tell your doctor about all your medical conditions, including: plans to have surgery; had surgery on your face; weakness of forehead muscles, such as trouble raising your eyebrows; drooping eyelids; any other abnormal facial change; are pregnant or plan to become pregnant (it is not known if BOTOX[®] Cosmetic can harm your unborn baby); are breast-feeding or plan to breast-feed (it is not known if BOTOX[®] Cosmetic passes into breast milk).

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal products. Using BOTOX[®] Cosmetic with certain other medicines may cause serious side effects. **Do not start any new medicines until you have told your doctor that you have received BOTOX[®] Cosmetic in the past.**

Especially tell your doctor if you: have received any other botulinum toxin product in the last 4 months; have received injections of botulinum toxin, such as *Myobloc*[®], *Dysport*[®], or *Xeomin*[®] in the past (be sure your doctor knows exactly which product you received); have recently received an antibiotic by injection; take muscle relaxants; take an allergy or cold medicine; or take a sleep medicine.

Other side effects of BOTOX[®] Cosmetic include: dry mouth, discomfort or pain at the injection site, tiredness, headache, neck pain, and eye problems: double vision, blurred vision, decreased eyesight, drooping eyelids, swelling of your eyelids, and dry eyes.

For more information refer to the Medication Guide or talk with your doctor. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see BOTOX[®] Cosmetic full [Product Information](#) including **Boxed Warning** and [Medication Guide](#).

About Allergan

Allergan is a multi-specialty health care company established more than 60 years ago with a commitment to uncover the best of science and develop and deliver innovative and meaningful treatments to help people reach their life's potential. Today, we have approximately 11,200 highly dedicated and talented employees, global marketing and sales capabilities with a presence in more than 100 countries, a rich and ever-evolving portfolio of pharmaceuticals, biologics, medical devices and over-the-counter consumer products, and state-of-the-art resources in R&D, manufacturing and safety surveillance that help millions of patients see more clearly, move more freely and express themselves more fully. From our beginnings as an eye care company to our focus today on several medical specialties, including eye care, neurosciences, medical aesthetics, medical dermatology, breast aesthetics, obesity intervention and urologics, Allergan is proud to celebrate more than 60 years of medical advances and proud to support the patients and customers who rely on our products and the employees and communities in which we live and work. For more information regarding Allergan, go to: www.allergan.com.

Forward-Looking Statements

This press release contains "forward-looking statements," including the statements by Dr. Whitcup, and other statements regarding the potential FDA approval and product launch of JUVÉDERM VOLUMA™ XC. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from Allergan's expectations and projections. Risks and uncertainties include, among other things, general

industry and medical device market conditions; challenges related to achieving regulatory approval from the FDA on a timely and cost-efficient manner; technological advances and patents attained by competitors; inconsistency of treatment results among patients; potential difficulties in manufacturing; challenges related to new product marketing, such as the unpredictability or market acceptance for new products and/or the acceptance of new indications for such products; and governmental laws and regulations affecting domestic and foreign operations. Allergan expressly disclaims any intent or obligation to update these forward-looking statements except as required by law. Additional information concerning these and other risks can be found in press releases issued by Allergan, as well as Allergan's public filings with the U.S. Securities and Exchange Commission, including the discussion under the heading "Risk Factors" in Allergan's most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q. Copies of Allergan's press releases and additional information about Allergan are available at www.allergan.com or you can contact the Allergan Investor Relations Department by calling 1-714-246-4636.

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¹ JUVÉDERM VOLUMA™ Patient Labeling, 2013

² JUVÉDERM VOLUMA™ Directions for Use 2013, pg 11

³ Carruthers J, Carruthers A, Tezel A, Kraemer J, Craik L. Volumizing with a 20-mg/mL smooth, highly cohesive, viscous hyaluronic acid filler and its role in facial rejuvenation therapy. *Dermatol Surg.* 2010; 36(suppl3): 1886-1892. p1887A,B

⁴ Data on file, Allergan, Inc.