03.20.2017 | Investors

JUVÉDERM VOLLURE™ XC Approved by U.S. FDA for Correction of Facial Wrinkles and Folds in Adults over the Age of 21

First and Only Hyaluronic Acid (HA) Dermal Filler FDA Approved for the Correction of Moderate to Severe Wrinkles and Folds, such as Nasolabial Folds, That Lasts up to 18 Months(1,2*)

DUBLIN, March 20, 2017 /PRNewswire/ -- Allergan plc, (NYSE: AGN), a leading global pharmaceutical company, today announced that the company has received approval from the U.S. Food and Drug Administration (FDA) to market JUVÉDERM VOLLURE™ XC, for correction of moderate to severe facial wrinkles and folds, such as nasolabial folds, in adults over the age of 21.[1] In the US pivotal clinical trial, a majority (59%) of subjects saw improvement in moderate to severe nasolabial folds for up to 18 months.* Patient satisfaction in the pivotal study was also high: 82% of patients said they were very satisfied at 6 months and 68% at 18 months.[2]

"The FDA approval of JUVÉDERM VOLLURE™ XC demonstrates Allergan's imperative to develop next-generation HA fillers designed to meet different patient needs," said David Nicholson, Chief Research and Development Officer at Allergan. "This commitment to ongoing scientific research and development is one of the factors that make JUVÉDERM®, the number one selling collection of dermal filler products."[3]

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.[4†] Our first product featuring VYCROSS® technology, JUVÉDERM VOLUMA® XC, was FDA-approved to increase volume lost due to aging in the cheek area,[5] followed by JUVÉDERM VOLBELLA® XC, FDA-approved for lip augmentation and correction of perioral rhytids.[6]

Now with JUVÉDERM VOLLURE™ XC, the advanced VYCROSS® technology yields a custom engineered injectable gel product which was studied in the nasolabial folds, the number one dermal treatment area. It delivers a long-lasting result, up to 18 months*, that patients appreciate.[2,4,7]

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.[2,4] "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,"[2] said Dr. Joely Kaufman, a board-certified dermatologist and clinical trial investigator. "As the number of patients seeking dermal filler treatments continues to grow,[7] 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 1 week.[2]

JUVÉDERM VOLLURE™ XC was first approved in Europe as JUVÉDERM VOLIFT® in 2013. The JUVÉDERM® family of products is marketed and sold in more than 80 countries outside the United States.

JUVÉDERM VOLLURE™ XC will be available to physicians in April 2017. For more information about JUVÉDERM VOLLURE™ XC and the JUVÉDERM® Collection of fillers or to find a doctor, please visit www.juvederm.com.

JUVÉDERM VOLLURE™ XC Important Information

APPROVED USES

JUVÉDERM VOLLURE™ XC injectable gel is for injection into the facial tissue for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds in adults over the age of 21.

IMPORTANT SAFETY INFORMATION

Are there any reasons why I should not receive JUVÉDERM VOLLURE™ XC injectable gel?

Do not use this product if you have a history of multiple severe allergies or severe allergic reactions (anaphylaxis), or if you are allergic to lidocaine or the Gram-positive bacterial proteins used in this product.

What precautions should my doctor advise me about?

- Tell your doctor if you are pregnant or breastfeeding. The safety of this product for use during pregnancy or while breastfeeding has not been studied
- The safety of JUVÉDERM VOLLURE™ XC in patients under 22 years has not been studied
- The safety and effectiveness of JUVÉDERM VOLLURE™ XC in areas other than facial wrinkles and folds have not been established in clinical studies
- Tell your doctor if you have a history of excessive scarring (e.g., hypertrophic scarring and keloid formations) or pigmentation disorders, as use of this product may result in additional scars or changes in pigmentation
- Tell your doctor if you are planning other laser treatments or a chemical peel, as there is a possible risk of inflammation at the treatment site if these procedures are performed after treatment
- Patients who experience skin injury near the site of injection with this product may be at a higher risk for side effects
- Tell your doctor if you are on immunosuppressive therapy used to decrease the body's immune response, as use of this product 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 this may result in increased bruising or bleeding at the injection site
- Minimize strenuous exercise, exposure to extensive sun or heat, and alcoholic beverages within the first 24 hours following treatment

What are possible side effects?

The most commonly reported side effects with JUVÉDERM VOLLURE™ XC injectable gel included injection-site redness, swelling, pain, tenderness, firmness, lumps/bumps, bruising, discoloration, and itching. Most side effects were mild or moderate and lasted 7 days or less.

One of the risks with using this product is unintentional injection into a blood vessel, and, while rare, the complications can be serious and may be permanent. These complications, which have been reported for facial injections, can include vision abnormalities, blindness, stroke, temporary scabs, or permanent scarring.

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

To report a side effect with JUVÉDERM VOLLURE™ XC please call Allergan at 1-800-433-8871. Please visit Juvederm.com or talk to your doctor for more information.

Available by prescription only.

***** Including optional touch up at 1 month for optimal correction

† Gel properties assessed with *in vitro* studies. Clinical significance is unknown.

1. JUVÉDERM VOLLURE™ XC Directions for Use, 2017.
2. JUVÉDERM VOLLURE™ XC Patient Labeling, 2017.
3. Data On File Allergan, Inc.; Proforma Sales JUVÉDERM VOLUMA® XC, 2015.
4. Bernardin A et al. VYCROSS ®: An innovative dermal filler technology. Poster presented at: 1st Annual Anti-Aging Medicine European Congress (AMEC); October 11-12, 2013; Paris, France
5. JUVÉDERM VOLUMA® XC Directions for Use, 2013.
6. JUVÉDERM VOLBELLA® XC Directions for Use, 2016.
7. Data On File Allergan, Inc.; Facial Injectables Patient Records Tracking Study – Fillers, 2016.

About Allergan plc

Allergan plc (NYSE: AGN), headquartered in Dublin, Ireland, is a bold, global pharmaceutical company and a leader in a new industry model – Growth Pharma. Allergan is focused on developing, manufacturing and commercializing branded pharmaceuticals, devices and biologic products for patients around the world.

Allergan markets a portfolio of leading brands and best-in-class products for the central nervous system, eye care, medical aesthetics and dermatology, gastroenterology, women's health, urology and anti-infective therapeutic categories.

Allergan is an industry leader in Open Science, the Company's R&D model, which defines our approach to identifying and developing game-changing ideas and innovation for better patient care. This approach has led to Allergan building one of the broadest development pipelines in the pharmaceutical industry with 70+ mid-to-late stage pipeline programs in development.

Our Company's success is powered by our more than 16,000 global colleagues' commitment to being Bold for Life. Together, we build bridges, power ideas, act fast and drive results for our customers and patients around the world by always doing what is right.

With commercial operations in approximately 100 countries, Allergan is committed to working with physicians, healthcare providers and patients to deliver innovative and meaningful treatments that help people around the world live longer, healthier lives every day.

For more information, visit Allergan's website at www.Allergan.com.

Allergan Forward-Looking Statement

Statements contained in this press release that refer to future events or other non-historical facts are forward-looking statements that reflect Allergan's current perspective of existing trends and information as of the date of this release. Except as expressly required by law, Allergan disclaims any intent or obligation to update these forward-looking statements. Actual results may differ materially from Allergan's current expectations depending upon a number of factors affecting Allergan's business. These factors include, among others, the difficulty of predicting the timing or outcome of FDA approvals or actions, if any; the impact of competitive products and pricing; market acceptance of and continued demand for Allergan's products; difficulties or delays in manufacturing; and other risks and uncertainties detailed in Allergan's periodic public filings with the Securities and Exchange Commission, including but not limited to Allergan's Annual Report on Form 10-K for the year ended December 31, 2016. Except as expressly required by law, Allergan disclaims any intent or obligation to update these forward-looking statements.