



## Evolus Receives FDA Approval for Jeuveau™ prabotulinumtoxinA-xvfs for Injection

February 1, 2019

*Jeuveau™ is the first aesthetic-only neurotoxin approved in the U.S. – launch planned Spring 2019*

*Global clinical program in 2,100 subjects, known as TRANSPARENCY, included two Phase III U.S. trials, the largest head-to-head aesthetic pivotal trial versus Botox® and two long-term safety studies*

NEWPORT BEACH, Calif., Feb. 01, 2019 (GLOBE NEWSWIRE) -- Evolus, Inc. (NASDAQ: EOLS) today announced that the U.S. Food and Drug Administration ("FDA") has approved its lead product, Jeuveau™, for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adults.

David Moatazedi, President and Chief Executive Officer of Evolus, stated, "Evolus is the first company in nearly a decade to enter the fast-growing U.S. aesthetic neurotoxin market. What makes Evolus unique is our focus on delivering performance beauty products with a customer-centric approach. We are pleased to introduce Jeuveau™, the first FDA approved neurotoxin dedicated to aesthetics and manufactured in a state-of-the-art facility using Hi-Pure™ technology."

Ava Shamban, MD, Board Certified Dermatologist and clinical investigator, commented, "The outcomes I've seen for my clinical trial patients firsthand, combined with the comprehensive clinical data set for Jeuveau™ provide a compelling new treatment option for physicians and their aesthetic patients. The TRANSPARENCY program involved the study of over 2,100 patients globally, which included two U.S. pivotal Phase III trials and a European & Canadian Phase III head-to-head trial versus Botox®, in which all the primary and secondary endpoints were met. Importantly, there were no serious drug related adverse events reported. The comprehensive data set generated by Evolus through the TRANSPARENCY clinical program will give my peers the utmost level of confidence in providing Jeuveau™ to their patients. I look forward to incorporating Jeuveau™ into my aesthetic product offering."

Mr. Moatazedi added, "We are focusing our efforts on ensuring a successful launch of Jeuveau™ and have initiated the recruitment of a high-quality, specialized U.S. sales force. The launch of Jeuveau™ will be powered by our technology platform designed to eliminate the friction points that exist for customers today. Prior to our U.S. launch, we expect publication of our U.S. Phase III results and to submit for publication our European and Canadian head-to-head Phase III study versus Botox®. I would like to thank all the Evolus employees, clinical investigators, patients and our partner Daewoong for their diligent efforts in bringing a new option to the market."

Jeuveau™ is expected to be available throughout the United States at physician offices starting in Spring 2019. Physicians and consumers are encouraged to visit [www.evolus.com](http://www.evolus.com) and sign up for updates on product availability.

### About Jeuveau™

Jeuveau™ (prabotulinumtoxinA-xvfs) is a proprietary 900 kDa purified botulinum toxin type A formulation indicated for the temporary improvement in the appearance of moderate to severe glabellar lines in adults. Jeuveau™ is produced under strict quality and safety standards in a state-of-the-art facility, specifically built to manufacture Jeuveau™. The safety and efficacy of Jeuveau™ has been evaluated in clinical studies with over 2,100 patients enrolled.

FDA approval of Jeuveau™ was supported by clinical data from two U.S. Phase III randomized, multi-center, double-blind, placebo-controlled clinical trials both of which met the primary endpoint and demonstrated efficacy compared with placebo in the reduction of the severity of glabellar lines, defined as a 2-point composite improvement agreed upon by physician and patient, at Day 30. 67.5% of subjects in study one (EV-001) and 70.4% of subjects in study two (EV-002) met the primary endpoint, compared to 1.2% and 1.3% of patients in each placebo arm respectively.

### IMPORTANT SAFETY INFORMATION FOR JEUVEAU™ (prabotulinumtoxinA-xvfs)

**JEUVEAU may cause serious side effects that can be life threatening. Get medical help right away if you have any of these problems any time (hours to weeks) after injection of JEUVEAU:**

- **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, trouble saying words clearly, loss of bladder control, trouble breathing, trouble swallowing.

**Do not use JEUVEAU if you:** are allergic to any of the ingredients in JEUVEAU (see Medication Guide for ingredients); had an allergic reaction to any other botulinum toxin product such as rimabotulinumtoxinB (MYOBLOC®), onabotulinumtoxinA (BOTOX®/BOTOX® Cosmetic), abobotulinumtoxinA (DYSPORT®), or incobotulinumtoxinA (XEOMIN®); have a skin infection at the planned injection site; or are a child.

**Jeuveau dosing units are not the same as, or comparable to, any other botulinum.**

**Tell your healthcare provider about all your muscle or nerve conditions**, such as ALS or Lou Gehrig's disease, Myasthenia gravis, or Lambert-Eaton syndrome, as you may be at increased risk of serious side effects including difficulty swallowing and difficulty breathing from typical doses of JEUVEAU.

**Tell your healthcare provider about all your medical conditions, including:** any side effects from botulinum toxin products, including dry eye; breathing, swallowing, bleeding, or heart problems; plans to have surgery; weakness of forehead muscles; drooping eyelids; had surgery on your face; are pregnant or breastfeeding or plan to become pregnant or breastfeed (it is not known if JEUVEAU can harm your unborn baby or passes into breast milk).

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Using JEUVEAU with certain other medicines may cause serious side effects. **Do not start any new medicines until you have told your healthcare provider that you have received JEUVEAU in the past.**

**Especially tell your healthcare provider if you:** have received any other botulinum toxin product in the past and the last 4 months. and exactly which product you received (such as Botox, Botox Cosmetic, Myobloc, Dysport, or Xeomin).

**JEUVEAU** may cause loss of strength or general muscle weakness, vision problems, or dizziness within hours to weeks of treatment with JEUVEAU. **If this happens, do not drive a car, operate machinery, or do other dangerous activities.**

**JEUVEAU can cause other serious side effects including:** allergic reactions (such as itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint), heart problems (such as irregular heartbeat and heart attack), and eye problems (including dry eye, reduced blinking, and corneal problems). Tell your healthcare provider or get medical emergency help right away if you experience a serious side effect.

The most common side effects include: headache; eyelid drooping, upper respiratory tract infection, and increased white blood cell count in your blood.

#### **APPROVED USE**

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

The risk information provided here is not complete. For more information about **JEUVEAU**, the full Prescribing Information including BOXED WARNING, and Medication Guide, visit [www.evolus.com](http://www.evolus.com) or talk to your healthcare provider.

**To report side effects associated with use of JEUVEAU, please call 1-877-386-5871. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.**

Manufactured by: Evolus, Inc., 1027 Garden St., Santa Barbara, CA 93101

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#### **About Evolus, Inc.**

Evolus is a performance beauty company with a customer-centric approach focused on delivering breakthrough products. In 2019, the U.S. Food and Drug Administration approved Jeuveau™ (prabotulinumtoxinA-xvfs), the first and only neurotoxin dedicated exclusively to aesthetics and manufactured in a state-of-the-art facility using Hi-Pure™ technology. Jeuveau™ is powered by Evolus' unique technology platform and is designed to transform the aesthetic market by eliminating the friction points existing for customers today. Visit us at: [www.evolus.com](http://www.evolus.com).

#### **Forward-Looking Statements**

Statements made in this press release that relate to future plans, events, prospects or performance are forward-looking statements as defined under the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including statements containing the words "planned," "expect," "believes," "strategy," "opportunity," "anticipates," "outlook," "designed," and similar words. While these forward-looking statements are based on the current expectations and beliefs of management, such forward-looking statements are subject to a number of risks, uncertainties, assumptions and other factors that could cause actual results to differ materially from the expectations expressed in this press release, including the risks and uncertainties disclosed in Evolus' periodic filings with the Securities and Exchange Commission, including factors described in the section entitled "Risk Factors" in its Annual Report on Form 10-K for the year ended December 31, 2017 and its Quarterly Report on Form 10-Q for the Quarter ended September 30, 2018, as filed with the Securities and Exchange Commission on March 29, 2018 and November 5, 2018, respectively, all of which are available online at [www.sec.gov](http://www.sec.gov). Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, Evolus undertakes no obligation to update or revise any forward-looking statements to reflect new information, changed circumstances or unanticipated events.

Jeuveau is a trademark of Evolus, Inc.

Hi-Pure is a trademark of Daewoong Pharmaceutical Co, Ltd.

Botox®, Botox® Cosmetic, Myobloc®, Dysport®, and Xeomin® are registered trademarks of their respective owners.

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