



Aesthetic Surgery Journal Publishes Long Term Safety and Efficacy Data of Jeuveau® for the Treatment of Moderate to Severe Frown Lines

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NEWPORT BEACH, Calif., May 12, 2021 (GLOBE NEWSWIRE) -- Evolus, Inc. (NASDAQ: EOLS), a performance beauty company with a customer-centric approach focused on delivering breakthrough products, today announced two newly published peer review studies in *Aesthetic Surgery Journal* that provide supportive evidence of the safety and efficacy of repeat doses of prabotulinumtoxinA (Jeuveau®) to decrease the appearance of glabellar lines, also known as frown lines between the eyes. The two Phase II studies, conducted to support the registration and regulatory approval of Jeuveau® in the United States, Canada and Europe, demonstrate that prolonged use of Jeuveau is safe and effective with repeat treatments. The studies also reveal that the patented Hi-Pure™ manufacturing technology used to make Jeuveau® is not associated with antibody formation or neutralizing antibody formation.

"These peer reviewed studies add to the evidence base that repeat doses of Jeuveau® are safe for patients and complement the results of the Phase III studies conducted for Jeuveau®. Importantly, it's reassuring to see the adverse event rates decreasing with each subsequent treatment," said Rui Avelar, Chief Medical Officer and Head of Research & Development and an author of the study publications. "This is significant because consumers typically receive repeat treatment over time and want assurances that the product is safe and will continue to work. These results validate the positioning of Jeuveau® as an exciting option for providers and consumers looking for an alternative neurotoxin for aesthetic use."

Both studies were long-term (one-year), open-label, phase II studies designed to investigate the safety of repeat doses of 20 U prabotulinumtoxinA for the treatment of glabellar lines. The complementary studies primarily differed in the number of patients and in the product formulation process employed (freeze-dried in EV-004; vacuum-dried technology in EV-006). In both studies, among study completers, there was no evidence of shortening retreatment periods that might suggest immunogenicity and/or the development of resistance; in fact, the opposite was observed, with a trend towards longer retreatment periods. This is important because, when treating patients with a biological agent, a shortening time interval between treatments may be suggestive of increasing resistance or antibody development. In addition, the percentage of patients who experienced an adverse event (AE) after treatment decreased with repeat exposure. The most reported AE was headache. There were no serious adverse reactions related to the drug.

The two Phase II studies in reference can be accessed here:

[The First of Two One-Year, Multicenter, Open-Label, Repeat-Dose, Phase II Safety Studies of PrabotulinumtoxinA for the Treatment of Moderate to Severe Glabellar Lines in Adult Patients](#)

[The Second of Two One-Year, Multicenter, Open-Label, Repeat-Dose, Phase II Safety Studies of PrabotulinumtoxinA for the Treatment of Moderate to Severe Glabellar Lines in Adult Patients](#)

Jeuveau® is marketed in the United States by Evolus. The product is marketed by a partner in Canada as Nuveiva™ with European launch planned for early 2022.

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; have 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, trouble breathing, asthma symptoms, or dizziness or feeling faint. Tell your healthcare provider or get emergency medical help right away if you develop wheezing or trouble breathing, or if you feel dizzy or faint. **Heart problems.** Irregular heartbeat and heart attack that have caused death, have happened in some people who received botulinum toxin products. **Eye problems** such as dry eye, reduced blinking, and corneal problems. Tell your healthcare provider if you develop eye pain or irritation, sensitivity to light, or changes in your vision.

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

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®, see the full Prescribing Information including BOXED WARNING, and Medication Guide, visit Evolus.com or talk to your healthcare provider.

To report side effects associated with use of JEUVEAU®, please call 1-877-EVOLUS1/1-877-386-5871. 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.

Exclusively licensed and manufactured for: Evolus, Inc., 520 Newport Center Drive, Suite 1200, Newport Beach, CA 92660

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.

Forward-Looking Statements

This press release contains 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 that relate to the status of regulatory processes, future plans, events, prospects or performance and statements containing the words "plans," "expects," "believes," "strategy," "opportunity," "anticipates," "outlook," "designed," or other forms of these words or similar expressions, although not all forward-looking statements contain these identifying words. The company's forward-looking statements include, but are not limited to, statements made by Mr. Avelar regarding the performance, acceptance and utilization of Jeuveau®. Forward-looking statements are based on current estimates and assumptions made by management of the company and are believed to be reasonable, though they are inherently uncertain and difficult to predict.

Forward-looking statements involve risks and uncertainties that could cause actual results or experience to differ materially from that expressed or implied by the forward-looking statements. Factors that could cause actual results or experience to differ materially from that expressed or implied by the forward-looking statements include uncertainties associated with our ability to address all of our losses, costs, expenses, liabilities and damages resulting from the settlement agreement with Daewoong and our ability to comply with the terms and conditions in the Allergan/Medytox Settlement Agreements, including the effect on our pricing, discounts we may offer to our customers and the volume of purchases by our customers, the continued impact of COVID-19 on our business and the economy generally, uncertainties related to customer and consumer adoption of Jeuveau®, the efficiency and operability of our digital platform, competition and market dynamics, and our ability to maintain regulatory approval of Jeuveau® and other risks described in the section entitled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2020 as filed with the Securities and Exchange Commission on March 25, 2021, which is available online at 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. If the company does update or revise one or more of these statements, investors and others should not conclude that the company will make additional updates or corrections.

Jeuveau® is a registered trademark and Nuceiva™ 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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