



NEWS RELEASE

Evolus Announces Publication of U.S. Pivotal Study for Evolysse™ Form and Evolysse™ Smooth Injectable Hyaluronic Acid Gels

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- Data showed that both Evolysse™ Form and Evolysse™ Smooth met the primary endpoint of non-inferiority¹ and demonstrated statistical superiority¹ to Restylane®-L, the control product
- The study published in Aesthetic Surgery Journal supports long-term safety and effectiveness of Cold-X™ crosslinked injectable hyaluronic acid (HA) gels for the correction of dynamic facial wrinkles and folds

NEWPORT BEACH, Calif.--(BUSINESS WIRE)-- **Evolus, Inc.** (NASDAQ: EOLS), a performance beauty company with a focus on building an aesthetic portfolio of consumer brands, today announced the publication of the U.S. pivotal study results for Evolysse™ Form and Evolysse™ Smooth in the **Aesthetic Surgery Journal**, a leading peer-reviewed journal focusing on advances in aesthetic medicine and surgery.

The multicenter, randomized, controlled, double-blind study followed 140 patients through 12 months and evaluated the long-term safety and effectiveness of Evolysse™ Form and Evolysse™ Smooth, Cold-X™ crosslinked injectable hyaluronic acid (HA) gels, for the correction of moderate to severe dynamic facial wrinkles and folds.

Key published findings include:

- **Statistical Superiority:** Evolysse™ Form and Evolysse™ Smooth were evaluated in a head-to-head study with Restylane®-L. Both products met the primary endpoint of non-inferiority¹, and both the confidence intervals as well as the corresponding p-values (<0.001) demonstrated statistical superiority¹.
- **Durability of Results:** As assessed by the live, blinded investigators, Evolysse™ Form showed statistically significant differences² compared to Restylane®-L at all measured timepoints for the entire 12-month study

period. Evolysse™ Smooth showed statistically significant differences² compared to Restylane®-L at 6 and 9 months – even as 20% more Restylane®-L was used³.

- High Patient Satisfaction: Over 80% of subjects reported they would undergo treatment again and recommend it to a friend. FACE-Q and Global Aesthetic Improvement Scale (GAIS) assessments confirmed sustained improvements and high satisfaction through 12 months.
- Favorable Safety Profile: In the head-to-head clinical study versus Restylane®-L, the safety profile of Evolysse™ Form and Evolysse™ Smooth was similar to the control, with most adverse events being mild to moderate. There were no treatment-related serious adverse events, and no delayed-onset nodules were observed in the Evolysse™ arm, compared to 1.4% in the control arm.

“One key feature of the Evolysse™ injectable HA gels that this study and publication highlight is the efficiency of their performance,” said Dr. Rui Avelar, Chief Medical Officer and Head of R&D of Evolus. “In the case of Evolysse™ Form, the same amount of product was used as the control, yet it achieved more correction with statistical significance at every time point over 12 months. Similarly, Evolysse™ Smooth, a softer gel, delivered more correction, reaching statistical significance at 6 and 9 months, despite 20% less product being used. This speaks to the differentiation of the Evolysse™ collection and its ability to not only meet the evolving needs of both practitioners and patients but outperform one of the market leading HA gels available today.”

Evolus previously announced that EU Medical Device Regulation (MDR) approval was received for four unique injectable hyaluronic acid (HA) gels under the brand name Estyme® (pronounced “esteem”), reflecting the product’s compliance with the highest regulatory standards. Evolus is also introducing Estyme® through a limited experience program with select physician partners in Europe, to continue to expand global experience with the product’s performance. A broader European launch remains on track for the second half of 2025, further expanding Evolus’ footprint into the global dermal filler market and reinforcing its position as a leader in performance beauty.

About Evolus, Inc.

Evolus (NASDAQ: EOLS) is a global performance beauty company redefining the aesthetic injectable market for the next generation of beauty consumers through its unique, customer-centric business model and innovative digital platform. Our mission is to become a global leader in aesthetics anchored by our flagship products: Jeuveau® (prabotulinumtoxinA-xvfs), the first and only neurotoxin dedicated exclusively to aesthetics, and Evolysse™, a collection of unique injectable hyaluronic acid (HA) gels. Visit us at www.evolus.com, and follow us on [LinkedIn](#), [X](#), [Instagram](#) or [Facebook](#).

¹ Based on the primary endpoint analysis for Evolysse™ Form (95% CI [-0.500, -0.032]) and Evolysse™ Smooth (95% CI [-0.416, -0.019])

² Based on WSRS Live Investigator Assessments (p < 0.05)

³ In the clinical study, the mean injection volume for optimal correction was 1.0 mL for Evolysse™ Smooth versus 1.2 mL for Restylane®-L

IMPORTANT SAFETY INFORMATION FOR EVOLYSSE™

Are there any reasons why I should not receive treatment with EVOLYSSE injectable hyaluronic acid products?

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

What precautions should my doctor advise me about?

- Minimize exposure to extreme heat or cold as doing so may cause temporary redness, swelling, and/or itching at the injection site.
- Tell your doctor if you are using medication that can prolong bleeding, such as aspirin, ibuprofen, or other blood thinners, as this may increase bruising or bleeding at the injection site.
- Tell your doctor if you are planning laser treatment, chemical peel, or any other procedure after treatment as there is a possible risk of an inflammatory reaction at the treatment site.
- EVOLYSSE products are intended for dynamic wrinkles and folds such as NLFs. The safety and effectiveness for other treatment areas have not been established.
- Tell your doctor if you are on therapy used to decrease your immune response, which can increase risk of infection with treatment.
- Tell your doctor if you are pregnant or breastfeeding. The safety for use during pregnancy or in women who are breastfeeding has not been studied.
- Tell your doctor if you have a history of excessive scarring (thick, hard scars) or pigmentation disorders, as use of these products may result in additional scars or changes in pigmentation.
- Tell your doctor if you have a history of cold sores. Any injections, including EVOLYSSE products, around the mouth may trigger a recurrence of your cold sores.
- The use of EVOLYSSE products where skin sores, pimples, rashes, hives, cysts, or infections are present should be postponed until healing is complete. Use of EVOLYSSE products where these are present could delay healing or make your skin problems worse.

What are the possible side effects of treatment?

The most commonly reported side effects with EVOLYSSE products were tenderness, swelling, bruising, redness,

lumps, pain, discoloration, itching, and headache. Most side effects were mild and went away on their own within 1 week.

What are other possible adverse events?

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

One of the risks with using these products is unintentional injection into a blood vessel. Although the chances of this happening are very small, complications can be serious and may be permanent, and include vision abnormalities, blindness, stroke, temporary scabs, or permanent scarring of the skin. If you have changes in your vision, signs of a stroke (including sudden difficulty speaking, numbness or weakness in your face, arms, or legs, difficulty walking, face drooping, severe headache, dizziness, or confusion), white appearance of the skin, or unusual pain during or shortly after treatment, you should call your doctor immediately.

To report a side effect with any EVOLYSSE product, please call the Evolus Customer Experience at 1-877-386-5871.

EVOLYSSE products are available only by a licensed physician or properly licensed practitioner.

Forward-Looking Statements

This press release contains forward-looking statements as defined under the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties, including statements about future or anticipated events, our business, financial condition, results of operations and prospects, our industry and the regulatory environment in which we operate. Any statements contained herein that are not statements of historical or current facts are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” or the negative of those terms, or other comparable terms intended to identify statements about the future. The company's forward-looking statements include, but are not limited to, statements related to anticipated product launches and consumer demand for Evolysse™.

The forward-looking statements included herein are based on our current expectations, assumptions, estimates and projections, which we believe to be reasonable, and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by the forward-looking statements. These risks and uncertainties, all of which are difficult or impossible to predict accurately and many of which are beyond our control, include, but are not limited to uncertainties associated with our ability to comply with the terms and conditions in the Medytox Settlement Agreements, our ability to fund our future operations or obtain financing to fund our operations, unfavorable global economic conditions including trade disputes and tariffs and the impact on

consumer discretionary spending, uncertainties related to customer and consumer adoption of Jeuveau[®] and Evolysse[™], the efficiency and operability of our digital platform, competition and market dynamics, our ability to successfully launch and commercialize our products in new markets, including the Evolysse[™] Hyaluronic Acid (HA) gels in the U.S. and Estyme[®] HA gels in Europe, our ability to maintain regulatory approvals of Jeuveau[®] and Evolysse[™] or obtain regulatory approvals for new product candidates or indications, our reliance on Symatase to achieve and/or maintain regulatory approval for the Evolysse[™] HA gel products in the U.S., and other risks described in our filings with the Securities and Exchange Commission, including in the section entitled “Risk Factors” in our Annual Report on Form 10-K and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2025 expected to be filed with the Securities and Exchange Commission on or about May 7, 2025. These filings can be accessed 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, we undertake no obligation to update or revise any forward-looking statements to reflect new information, changed circumstances or unanticipated events. If we do update or revise one or more of these statements, investors and others should not conclude that we will make additional updates or corrections.

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Restylane[®] is a trademark of Galderma S.A.

Investor Contact:

Nareg Sagherian

Vice President, Head of Global Investor Relations and Corporate Communications

Tel: 248-202-9267

Email: ir@evolus.com

Media Contact:

Email: media@evolus.com

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