



NEWS RELEASE

# Evolus Announces FDA Approval of Evolysse™ Form and Evolysse™ Smooth Injectable Hyaluronic Acid Gels

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First Major Technological Breakthrough in Hyaluronic Acid Dermal Fillers in a Decade; U.S. Launch Planned in Q2 2025

Launch Establishes Evolus as a Multi-Product Performance Beauty Company and Expands Addressable Market by 78%

NEWPORT BEACH, Calif.--(BUSINESS WIRE)-- **Evolus, Inc.** (NASDAQ: EOLS), a performance beauty company with a focus on building an aesthetic portfolio, today announced that the U.S. Food and Drug Administration (FDA) has approved Evolysse™ Form and Evolysse™ Smooth injectable hyaluronic acid (HA) gels, the first two products in the Evolysse™ collection. These approvals mark Evolus' entry into the U.S. HA dermal filler market and solidifies the company's position as a multi-product innovator in aesthetics, expanding Evolus' total addressable market by 78% to approximately \$6 billion<sup>1</sup>.

"This milestone represents an exciting new chapter in our long-term strategy to expand our portfolio and transition from a single-product company to a multi-product innovator, strengthening our leadership in performance beauty," said David Moatazedi, President and Chief Executive Officer of Evolus. "Evolysse™ Form and Evolysse™ Smooth represent the first major technological breakthrough in HA dermal fillers in a decade, offering our customers and consumers a new standard in performance and innovation. The launch of these products is a catalyst in our growth as we are focused on achieving at least \$700 million in net revenue and non-GAAP operating income margin<sup>2</sup> of at least 20% by 2028."



Evolus plans to launch Evolysse™ Form and Evolysse™ Smooth in the U.S. market in Q2 2025. This launch will leverage Evolus' scalable cash-pay business model and existing digital infrastructure, creating tremendous synergy with the company's fast-growing neurotoxin business and driving significant value for both customers and consumers.

Evolysse™ Form and Evolysse™ Smooth are part of a collection of injectable HA gels designed by Symatase, which utilizes innovative Cold-X™ technology that is designed to better preserve the natural structure of the HA molecule for long-lasting, natural-looking results. The commercial launch of these first two injectable HA gels in 2025 will be followed by Evolysse™ Sculpt in 2026, and Evolysse™ Lips in 2027.

"We are proud to partner with Evolus in bringing the Evolysse™ collection of injectable HA gels to the U.S. market. With decades of experience in biomaterial science and aesthetics, Symatase has a strong legacy of developing innovative aesthetic products that meet the evolving needs of practitioners and their patients. With one of the largest clinical trial programs undertaken for an injectable HA technology, Evolysse™ products are being evaluated for safety and effectiveness in over 2,000 patients globally," said Jean-Paul Gérardin, Chief Executive Officer of Symatase.

Dr. Rui Avelar, Evolus Chief Medical Officer and Head of R&D, added, "The FDA approval of Evolysse™ Form and Evolysse™ Smooth reflects our commitment to bringing high-quality, innovative aesthetic products to market. These additions to our portfolio reinforce Evolus' dedication to the highest standards of patient safety and efficacy. With the introduction of Cold-X™ technology, Evolysse™ offers a differentiated approach to the dermal filler category, providing healthcare practitioners with new options to address the unique needs of their patients with precision and confidence."

Dr. Michael Kaminer, MD, lead investigator for the U.S. NLF pivotal study and an internationally recognized expert in cosmetic surgery, commented, "The Evolysse™ Form and Evolysse™ Smooth injectable HA gels demonstrated impressive safety, efficacy, and versatility, with the unique property of being injectable at various depths in the skin. These products allow practitioners to achieve precise, natural-looking results, while delivering high patient satisfaction with their effectiveness and longevity." The U.S. Nasolabial Fold (NLF) pivotal study for Evolysse™ Form and Evolysse™ Smooth included 140 patients in a double-blind, prospective, randomized, active-control split-face trial. Seventy patients were treated with each product, with investigators performing the procedures, evaluating outcomes, and following a rigorous clinical protocol.

Evolysse™ Form and Evolysse™ Smooth were evaluated in a head-to-head study with Restylane® -L. Both products met the primary endpoint of non-inferiority<sup>3</sup>, and both the confidence intervals as well as the corresponding p-values (<0.001) demonstrated statistical superiority<sup>3</sup>.

As assessed by the live, blinded investigators, Evolysse™ Form showed statistically significant differences<sup>4</sup> compared to Restylane-L at all measured timepoints for the entire 12-month study period. Evolysse™ Smooth showed statistically significant differences<sup>4</sup> compared to Restylane-L at 6 and 9 months – even though 20% more Restylane-L was used<sup>5</sup>.

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.

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](http://www.evolus.com), and follow us on **LinkedIn**, **X**, **Instagram** or **Facebook**.

<sup>1</sup> Sources: Medical Insight, Inc.: The Global Aesthetic Market Study—January 2024 (US), Clarivate | DRG: Aesthetic Injectables Market Insights North America 2024—October 2023 (Canada), Clarivate | DRG: Aesthetic Injectables Market Insights Europe 2024—June 2023 (Europe), Clarivate | DRG: Aesthetic Injectables Market Insights Asia Pacific 2024—December 2023 (Australia), and company estimates.

<sup>2</sup> “Non-GAAP operating income margin” is not a measure presented in accordance with accounting principles generally accepted in the United States of America (“GAAP”). Non-GAAP operating income margin excludes (i) the revaluation of contingent royalty obligations, (ii) stock-based compensation expense, and (iii) depreciation and amortization. Management believes that disclosure of non-GAAP operating income margin enables investors to assess the company in the same way that management assesses the company’s operating performance against comparable companies with conventional accounting methodologies, however this measure has limitations as an analytical tool and may differ from other companies reporting similarly named measures. Non-GAAP measures

should not be considered superior to and are not intended to be considered in isolation or as a substitute for GAAP financial measures. Due to the forward-looking nature of the non-GAAP operating income margin, a reconciliation to the closest comparable GAAP financial measures is not available without unreasonable efforts due to the unpredictability of future adjustments impacting these measures, which could significantly affect the GAAP results.

<sup>3</sup> Based on the primary endpoint analysis for Evolysse™ Form (95% CI [-0.500, -0.032]) and Evolysse™ Smooth (95% CI [-0.416, -0.019])

<sup>4</sup> Based on WSRS Live Investigator Assessments ( $p < 0.05$ )

<sup>5</sup> 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

## 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; market conditions, market growth and consumer demand; timing of regulatory submissions and approvals; the company’s revenue and non-GAAP operating margin outlook and its financial outlook for 2025 and beyond; and the company’s operational efficiency and leverage.

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 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., our ability

to maintain regulatory approvals of Jeuveau<sup>®</sup> or obtain regulatory approvals for new product candidates or indications, our reliance on Symatase to achieve regulatory approval for the Evolysse<sup>™</sup> HA gel line 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 filed with the Securities and Exchange Commission on November 6, 2024. These filings can be accessed 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, 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.

Jeuveau<sup>®</sup> and Nuceiva<sup>®</sup>, are registered trademarks and Evolysse<sup>™</sup> is a trademark of Evolus, Inc. Hi-Pure<sup>™</sup> is a trademark of Daewoong Pharmaceutical Co, Ltd. Cold-X<sup>™</sup> and Estyme<sup>®</sup> are trademarks of Symatase Group and Symatase Aesthetics S.A.S. Restylane<sup>®</sup> is a trademark of Galderma S.A.

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