



NEWS RELEASE

# Evolus Announces Positive Data from Pivotal Trial for First Two Evolysse™ Dermal Filler Products at 2024 SCALE Meeting

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- Evolus dermal filler, Evolysse™ Lift, met primary endpoint of non-inferiority and demonstrated superiority to Restylane-L at 6 months; Secondary endpoints for improvement in nasolabial fold severity showed statistically significant differences compared to Restylane-L at all measured timepoints for the entire 12-month study period
- Evolus dermal filler, Evolysse™ Smooth, met primary endpoint of non-inferiority and demonstrated superiority to Restylane-L at 6 months; Secondary endpoints for improvement in nasolabial fold severity showed statistically significant differences compared to Restylane-L at 6 and 9 months
- The safety profiles were similar between the two Evolysse™ dermal filler products and Restylane-L and there were no treatment-related serious adverse events
- On track to submit Premarket Approval (PMA) applications for the first two Evolysse™ dermal filler products with the FDA within the next 90 days

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 positive topline results from a U.S. pivotal nasolabial fold (NLF) study of dermal filler products Evolysse™ Lift and Smooth. Data were presented at the 2024 SCALE Meeting on May 17, 2024, in Nashville.

“Achieving positive topline results in our NLF study is a pivotal step supporting the upcoming submission of our Premarket Approval application for the U.S. launch of our dermal filler lines. Complementing our flagship neurotoxin Jeuveau® – the fastest growing neurotoxin in the U.S. for the past three years<sup>1</sup> – our Evolysse™ line of dermal fillers expands our total addressable market by 78%,” said David Moatzedi, President and Chief Executive



Officer.

“Built on the earlier success of the European head-to-head trial, the consistency of results from this pivotal trial for Evolysse™ Lift and Smooth were impressive when compared to the previously shared European nasolabial fold data,” said Dr. Rui Avelar, MD, Chief Medical Officer and Head of R&D. “The R&D team remains on track to complete and submit the PMA to the FDA within the next 90 days and this data increases our confidence in the submission.”

“As an investigator in this pivotal trial, I had first-hand experience in treating patients with the new Evolysse™ HA filler line that is manufactured using a novel “Cold Technology” process which is aimed at preserving the natural structure of the HA molecule,” said Dr. Steven Dayan, MD. “Clinically, I found the product to be precise and I could treat patients to optimal correction. I was also struck by the fact that despite using the same amount of product between the treatment and control, there seems to be more of a difference in the correction when looking at the Evolysse™ treatment arm.”

## Study Design

The U.S. NLF pivotal study was a multicenter, blinded, split face, controlled, non-inferiority design. Patients were followed for 12 months from initial treatment. A total of 140 patients were enrolled and divided evenly across two investigational arms. Patients were randomized to receive Evolysse™ Lift or Evolysse™ Smooth in one NLF and Restylane-L in the contralateral NLF. This split face design allowed each individual patient to experience one of the Evolysse™ fillers and the control at the same time.

The 6-month primary endpoint measured the change in NLF severity from baseline and was assessed by a blinded independent photographic review panel using a validated 5-point nasolabial scale.

## Results

The Evolysse™ Lift vs Restylane-L arm met the primary endpoint of non-inferiority and demonstrated superiority, with a mean NLF severity score difference of -0.3 (95% CI: -0.500, -0.032, non-inferiority margin 0.5) and corresponding p-value of 0.03. As a secondary endpoint, the mean grade change in the NLF severity, as assessed by the blinded, live evaluator demonstrated a statistically significant difference ( $p < 0.05$ ) at all timepoints from 6 weeks to 12 months between Evolysse™ Lift and the control.

The Evolysse™ Smooth vs Restylane-L arm also met the primary endpoint of non-inferiority and demonstrated superiority, with a mean NLF severity score difference of -0.2 (95% CI: -0.416, -0.019, non-inferiority margin 0.5) and corresponding p-value of 0.02. As a secondary endpoint, the mean grade change in the NLF severity, as assessed by the blinded, live evaluator demonstrated a statistically significant difference ( $p < 0.05$ ) at 6 and 9 months between

Evolysse™ Smooth and the control.

The safety profiles were similar between the two Evolysse™ dermal filler products compared to their respective controls and there were no treatment-related serious adverse events.

Evolus remains on track to submit Premarket Approval (PMA) applications for the first two Evolysse™ dermal filler products with the FDA within the next 90 days. The Evolysse™ Lift filler will be positioned as the most versatile and highest use filler in the product line. The Evolysse™ Smooth filler is a softer product than Lift, providing additional versatility.

<sup>1</sup> Measured by comparing year-over-year revenue growth of each aesthetic neurotoxin on the market for the entirety of each comparable year.

## About Evolus, Inc.

Evolus (NASDAQ: EOLS) is a global performance beauty company evolving the aesthetic neurotoxin 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, multi-product aesthetics company based on our flagship product, 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. Evolus is expanding its product portfolio having entered into a definitive agreement to be the exclusive U.S. distributor of Evolysse™, and the exclusive distributor in Europe of Estyme®, a line of unique dermal fillers currently in late-stage development. Visit us at [www.evolus.com](http://www.evolus.com), and follow us on [LinkedIn](#), [X](#), [Instagram](#) or [Facebook](#).

## 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 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 size, conditions and consumer demand; and the timing of regulatory submissions and approvals.

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<sup>®</sup> and Evolysse<sup>™</sup>, 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<sup>™</sup> dermal filler product line 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> dermal filler product 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 Annual Report on Form 10-K Form and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2024 filed with the Securities and Exchange Commission on May 7, 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.

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Hi-Pure<sup>™</sup> is a trademark of Daewoong Pharmaceutical Co, Ltd.

Estyme<sup>®</sup> is a trademark of Symatase Aesthetics S.A.S.

Restylane<sup>®</sup> is a trademark of Galderma S.A.

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