



NEWS RELEASE

Evolus Announces Submission of Premarket Approval Application to the U.S. Food and Drug Administration for First Two Evolysse™ Dermal Filler Products

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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 that it has submitted the final module of its premarket approval (PMA) application to the U.S. Food and Drug Administration (FDA) for the Evolysse™ Lift and Evolysse™ Smooth dermal filler products for the nasolabial fold (NLF).

“We are pleased to have submitted the final module of the PMA application,” said Dr. Rui Avelar, MD, Chief Medical Officer and Head of R&D. “This submission is a key fundamental milestone for Evolus and we look forward to our continued collaboration with the Agency in the upcoming thorough review process.”

Evolus anticipates that the FDA’s review process will adhere to the standard timeline, with approval expected in the second half of 2025. The submission underscores Evolus’ commitment to bringing the dermal filler products to market and its readiness to meet regulatory requirements.

The PMA application includes results from the U.S. pivotal study, which evaluated the safety and effectiveness of the products in a multicenter, blinded, split face, controlled, non-inferiority designed trial. 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.

Both the Evolysse™ Lift and Evolysse™ Smooth dermal filler products met their primary endpoint of non-inferiority

and demonstrated superiority to Restylane-L at 6 months. More information on the study is available [here](#).

The Evolysse™ Lift filler will be positioned as the most versatile for treating facial wrinkles and folds (such as NLFs) and is expected to be the highest use filler in the product line. The Evolysse™ Smooth filler will be positioned as an alternative softer formulation option to Evolysse™ Lift.

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, 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 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® 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™ dermal filler product line in the U.S., our ability to maintain regulatory approvals of Jeuveau® or obtain regulatory approvals for new product candidates or indications, our reliance on Symatse to achieve regulatory approval for the Evolysse™ 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 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. 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® and Nuceiva® are registered trademarks and Evolysse™ is a trademark of Evolus, Inc.

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

Estyme® is a trademark of Symatse Aesthetics S.A.S.

Restylane® is a trademark of Galderma S.A.

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