NEWS RELEASE

# Evolus Announces Submission of Premarket Approval Application to the U.S. Food and Drug Administration for Evolysse™ Sculpt Injectable Hyaluronic Acid Gel Product

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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 Evolysse™ Sculpt, an injectable hyaluronic acid (HA) gel product designed to restore mid-face volume.

“This submission represents an important milestone in expanding our Evolysse™ collection of injectable HA gels,” said Dr. Rui Avelar, MD, Chief Medical Officer and Head of R&D. “Sculpt is our most structured product, manufactured using a novel technology and designed to address mid-face volume loss, a high-value segment in facial aesthetics.”

Evolus anticipates that the FDA’s review will follow the standard PMA process, with approval expected in the second half of 2026. The submission underscores Evolus’ commitment to bringing its collection of injectable hyaluronic acid gel products to market and its readiness to meet rigorous regulatory requirements.

In support of the PMA application, a U.S. pivotal study which evaluated the safety and effectiveness of the product in a multicenter, double-blinded, controlled, non-inferiority designed trial was conducted. Patients were followed for 24 months from initial treatment. A total of 304 patients were enrolled and randomized to receive Evolysse™ Sculpt or Restylane®-Lyft.

The Evolysse™ Sculpt injectable HA gel product is expected to be the flagship brand in the Evolysse™ collection.

Designed by Symatese using innovative Cold-X™ technology, which helps preserve the natural structure of the HA molecule for long-lasting, natural-looking results, Sculpt will enter the highest value segment for today's dermal filler market and be among the few products currently indicated for the mid-face area.

## 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**.

## 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 Symatese 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 June 30, 2025 filed with the Securities and Exchange Commission on August 5, 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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