



NEWS RELEASE

# Evolus Announces EU Approval of Estyme® Injectable Hyaluronic Acid Gels Under New Medical Device Regulation

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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 the EU Medical Device Regulation (MDR) certification was received for four unique injectable hyaluronic acid (HA) gels under the brand name Estyme® (pronounced "esteem"), branded as Evolysse™ in the U.S. market. This certification marks a key regulatory milestone for Evolus, enabling it to commercially enter the dermal filler segment and doubling its addressable market outside the U.S. to \$1.8 billion<sup>1</sup>.

The CE Mark certification, through the new MDR process represents more stringent requirements, designed to ensure the safety, efficacy, and quality of medical devices sold in Europe. Achieving this certification demonstrates that the Estyme® injectable HA gels meet the highest standards for product design, production, and performance. Evolus will introduce Estyme® through a limited experience program with select physician partners. The limited experience program will allow Evolus to collaborate with leading aesthetic practitioners across Europe, gathering valuable insights to refine its broader launch strategy. A broader European launch is planned for the second half of 2025.

"The MDR CE Mark certification for Estyme®, is a critical milestone in our strategic path to expand our product portfolio and reflects our commitment to delivering high-quality gels that adhere to the most rigorous regulatory standards," said David Moatazedi, President and Chief Executive Officer. "With Estyme®, we are bringing a new level of excellence to the dermal filler category, as we grow our product portfolio to meet growing consumer demand for premium, cash-pay aesthetic treatments."

Dr. Rui Avelar, Chief Medical Officer and Head of R&D, added, "We are proud that Estyme® has achieved CE Mark certification under the MDR's stringent standards, which reflects a commitment to the highest standards of patient safety and product efficacy. Estyme® is a differentiated line of injectable HA gels currently being studied globally and the first innovation breakthrough, with proprietary cold technology, in a decade. These gels utilize breakthrough cross-linking technology that better preserves the natural HA chain, which we believe will help distinguish it from other products in this category. Designed with the highest level of precision to meet the needs of both practitioners and patients, we look forward to seeing its positive impact on the European aesthetic market."

The company remains on track for the U.S. approval and launch of the Evolysse™ injectable HA gels beginning in 2025.

## 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 injectable hyaluronic acid (HA) gels. These injectable HA gels are currently in the late stages of the regulatory approval process, with plans, upon approval, for a launch starting in 2025. Visit us at [www.evolus.com](http://www.evolus.com), and follow us on [LinkedIn](#), [X](#), [Instagram](#) or [Facebook](#).

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

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

<sup>1</sup> Source: Medical Insights Dermal Filler Market Study, March 2023 ([www.miinews.com](http://www.miinews.com)) and Aesthetic Injectables | Market Insights | Europe 2024 © 2023 Clarivate

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