



Motiva Ergonomix2 Platform and Motiva Mia Implant Receive CE Mark

December 14, 2020

- **Commercial Launch of Ergonomix2 Planned for 2021**
- **Approval Accelerates Path to Europe for Motiva Mia**
- **Pre-Commercial European Mia Procedures to Begin in Second Half of 2021**

SANTA BARBARA, Calif., Dec. 14, 2020 (GLOBE NEWSWIRE) -- Establishment Labs Holdings Inc. (NASDAQ: ESTA), a medical technology company focused on women's health, initially in the breast aesthetics and reconstruction market, today announced it has received a CE mark for its next generation Motiva Ergonomix2[®] silicone breast implant platform. The CE mark also includes the Motiva Ergonomix2 Diamond[®] breast implant, which is the implant that will be used in the Motiva Mia[®] minimally invasive breast augmentation system when it is approved.

Ergonomix2 incorporates the latest innovations by Establishment Labs, including its most advanced ultra-high purity chemistries for enhanced device mechanical properties and improved patient ergonomics. Ergonomix2 also features the Company's patented SmoothSilk[®] surface technology, which is the basis of Motiva Implants' low inflammatory characteristics that have contributed to the lowest capsular contracture rates in the industry. Ergonomix2 has CE mark labeling for use in both aesthetic and reconstruction procedures and following its planned commercialization will become Establishment Labs' most premium implant to date.

"Motiva Ergonomix2 technology is another significant advancement for the breast implant industry," said Marcos Sforza, MD, UK-based plastic surgeon and member of Establishment Labs' Medical Advisory Board. "By design, this implant has biomechanical characteristics specifically adapted to the breast anatomy for greater comfort and softness. It is exciting to see Establishment Labs innovate with its advanced ultra-high purity silicone technology for breast implants, which should reduce complications and allow, for the first time, the possibility of a true minimally invasive breast enhancement with Motiva Mia."

"This regulatory approval will enable Establishment Labs to bring the next generation of our best-selling Motiva Ergonomix[®] implant to Europe in the first half of 2021 followed by a broad commercial launch later in the year," said founder and chief executive officer Juan José Chacón-Quirós. "Equally important, the inclusion of the Motiva Ergonomix2 Diamond breast implant in this CE mark shortens our European regulatory approval timeline for the Motiva Mia system by as much as three years. We are now expecting the first pre-commercial Motiva Mia procedures in Europe to begin in the second half of 2021."

Motiva Implants[®], Motiva Ergonomix2[®], Motiva Ergonomix2 Diamond[®] and the Motiva Mia[®] system are currently not approved for commercial distribution in the United States. Motiva Implants[®] are undergoing clinical investigation pursuant to U.S. FDA regulations for investigational medical devices.

About Establishment Labs

Establishment Labs Holdings Inc. (NASDAQ: ESTA) is a global medical technology company focused on women's health, initially in the breast aesthetics and reconstruction market, by designing, developing, manufacturing and marketing an innovative portfolio of silicone gel-filled breast implants, branded as Motiva Implants[®], the centerpiece of the Motivalmagine[®] platform. Motiva Implants[®] are produced at our two manufacturing sites that are compliant with ISO13485:2016, FDA 21 CFR 820 under the MDSAP program, and are currently commercially available in more than 80 countries through exclusive distributors or the Company's direct salesforce. In March 2018, Establishment Labs received approval for an investigational device exemption (IDE) from the FDA and initiated the Motiva Implant[®] clinical trial in the United States in April 2018. In addition to Motiva Implants[®], Establishment Labs' product and technologies portfolio includes the Divina[®] 3D Simulation System and other products and services. Please visit our website for additional information at www.establishmentlabs.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). You can find many (but not all) of these statements by looking for words such as "approximates," "believes," "expects," "anticipates," "estimates," "intends," "plans," "would," "may" or other similar expressions in this press release, and includes statements related our ability to commercialize the Motiva Ergonomix2[®] silicone breast implant platform, the Motiva Ergonomix2 Diamond[®] breast implant, and the Motiva Mia[®] minimally invasive breast augmentation system. Any statements that refer to projections of our future financial or operating performance, anticipated trends in our business, our goals, strategies, focus and plans, and other characterizations of future events or circumstances, including statements expressing general optimism about future operating results, related to the Company's performance are forward-looking statements. We claim the protection of the safe harbor contained in the Private Securities Litigation Reform Act of 1995. We caution investors that any forward-looking statements presented in this report, or that we may make orally or in writing from time to time, are expressions of our beliefs and expectations based on currently available information at the time such statements are made. Such statements are based on

assumptions, and the actual outcome will be affected by known and unknown risks, trends, uncertainties, and factors that are beyond our control. Although we believe that our assumptions are reasonable, we cannot guarantee future performance, and some will inevitably prove to be incorrect. As a result, our actual future results may differ from our expectations, and those differences may be material. Factors that could cause or contribute to these differences include, among others, those risks and uncertainties discussed in the Company's annual report on Form 10-K filed on March 16, 2020, quarterly reports on Form 10-Q, and other filings made by the Company with the Securities and Exchange Commission. The risks included in those documents are not exhaustive, and additional factors could adversely affect our business and financial performance. We operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for us to predict all such risk factors, nor can we assess the impact of all such risk factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. We are not undertaking any obligation to update any forward-looking statements. Accordingly, investors should use caution in relying on past forward-looking statements, which are based on known results and trends at the time they are made, to anticipate future results or trends.

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