



Establishment Labs Completes Enrollment of One Hundred Patient Motiva Mia IRB Study

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Establishment Labs Also Announces CE Mark Filing of Tools for Motiva Mia System

SANTA BARBARA, Calif.--(BUSINESS WIRE)--Apr. 27, 2021-- 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 completed enrollment in its one hundred patient Motiva Mia[®] case series in Costa Rica. The Institutional Review Board (IRB) approved study began in December 2020 and follows the initial 2019 case series in Asia. Establishment Labs also announced that it has submitted the tools used in the Motiva Mia[®] breast enhancement procedure for CE mark.

Fifteen board-certified plastic surgeons from Costa Rica, Sweden, England, Brazil, Austria, Italy, Belgium, and the United States participated in the case series. The single-center study is a prospective, interventional, single-arm, feasibility study of women 18 years or older in primary minimally invasive breast enhancement.

"We are at the dawn of a new era in breast aesthetics. In this series we were able to reproduce and prove the reality of this revolutionary concept based on a standardized combination of implants and tools. Enhancing and beautifying the female breast in a safer, faster, and more predictable way without general anesthesia and with a minimal scar hidden in the axilla will attract patients who were previously reluctant to have this type of procedure," said Charles Randquist, plastic surgeon from Victoriakliniken in Stockholm, Sweden.

According to Professor Marcos Sforza, head of the Medical Advisory Board at Establishment Labs, "After these one hundred patients, we have started to understand how well Motiva Mia can address many of the objections women have toward traditional breast augmentation. We were also very pleased to see how quickly plastic surgeons mastered this procedure, which we will further confirm with the IRB approved case series in Thailand."

"The completion of the one hundred patient case series in Costa Rica is not only a milestone for Establishment Labs but for all of plastic surgery," said Juan José Chacón-Quirós, founder and chief executive officer. "We have learned a tremendous amount and our initial enthusiasm for Motiva Mia has proven more than justified. The positive feedback that we have received from surgeons who have used the technology as well as from women in this series adds to our conviction that a true minimally invasive approach will open breast enhancement to a new group of women. I want to thank the clinical team and all the surgeons who were part of this important achievement."

The Motiva Mia[®] system is designed to provide a minimally invasive breast enhancement procedure in less time and with faster recovery than traditional breast surgery. The Company has received registration in Costa Rica and a Free Sale Certificate ("FSC") for the Motiva Mia[®] system to begin regulatory approval processes worldwide. The Ergonomix2 Diamond[®] implant used with Motiva Mia[®] obtained CE marking in December 2020. In addition to the now completed patient series in Costa Rica, the Company has also received IRB approval for a 60 patient multicenter study in Thailand with a similar protocol that is expected to begin later this year.

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 MotivaImagine[®] 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 Mia[®] system for minimally invasive augmentation including the Motiva Ergonomix2 Diamond[®] breast implant. 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 15, 2021, 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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