



ESTA Reaches One Million Motiva Implants Milestone

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NEW YORK, Dec. 05, 2019 (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 – announced its one millionth Motiva® implant in market.

Juan José Chacón-Quirós, Founder and CEO of Establishment Labs, commented, "In our tenth commercial year with Motiva Implants®, we celebrate another important milestone, as we announce that we have one million Motiva Implants® in market. Most importantly, we achieved this milestone while maintaining less than a 1% complication rate for events related to Motiva Implants®. I want to thank the entire Establishment Labs team and the growing group of surgeons for helping us deliver Motiva® to patients in more than 80 countries around the world."

Juan José Chacón-Quirós continued, "With Motiva Implants®, we embarked on a journey to transform the breast aesthetics and reconstruction industry through innovative technology and a strong foundation of science and research. It is our commitment to Women's Health that has allowed us to have a positive impact on the lives of hundreds of thousands worldwide."

Capsular contracture and implant rupture are the two most common reasons for complaints and are also the most known failure modes associated with breast implants. A retrospective study on 2506 patients at up to 3 years reported complication rates with Motiva Implants® of 0.36% (95% CI, 0.19% to 0.68%) and reported no cases of device-related implant rupture, no cases of capsular contracture (Baker III/IV), no double capsules or late seromas. A six-year published prospective study on 35 patients that included an MRI cohort using Motiva Implants® reported no cases of implant rupture or malposition and no cases of capsular contracture.

Establishment Labs has reached this commercial milestone as a result of the support and partnership from patients and surgeons. Motiva Implants® are part of Establishment Labs' comprehensive portfolio of advanced smooth implants that are now available in more than 80 countries. Motiva Implants® are undergoing a clinical trial in the U.S. and are not approved for sale in the United States.

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 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, MotivaImagine® Centers and other products and services. Please visit the website for additional information: 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 to the expected growth in sales of Motiva Implants®, product development, and the PMA clinical trial currently being conducted to obtain approval of Motiva Implants® in the U.S. 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, 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, they are not guarantees of 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 20, 2019, 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.

Investor Relations

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