



Establishment Labs Announces Complete Enrollment in Motiva US IDE Study

August 3, 2022

SANTA BARBARA, Calif.--(BUSINESS WIRE)--Aug. 3, 2022-- Establishment Labs Holdings Inc. (NASDAQ: ESTA), a global medical technology company dedicated to improving women's health and wellness, principally in breast aesthetics and reconstruction, today announced it has completed enrollment in the Motiva US IDE clinical study. The final surgery in the primary reconstruction cohort was completed at Northwestern Memorial Hospital. The Augmentation cohort, which finished enrollment in August of 2019, will complete its third year of study follow-up this month.

"Completing such a rigorous FDA clinical trial during a global pandemic while maintaining a high level of patient follow-up is a testament to the dedication of the study surgeons, medical professionals, and Establishment Labs," said Dr. Caroline Glicksman, Medical Director of and Investigator in the Motiva IDE Study. "The entire investigative team can be proud of their efforts to provide women access to new options in breast surgery."

The Motiva US IDE study enrolled 827 patients at 32 centers in the US, Germany, and Sweden. The study is designed to assess the safety and effectiveness of Motiva breast implants in primary breast augmentation, primary breast reconstruction, and revision breast procedures. The study included 562 patients in the augmentation cohorts and 265 in the reconstructive cohorts. The study includes a Magnetic Resonance Imaging (MRI) cohort of 250 patients who receive MRIs at years 1, 2, 3, 5, 7, and 10 to assess for silent rupture.

"Having completed full enrollment in the IDE study across all patient groups, we are diligently working with the plastic surgeons in the trial to maintain high patient follow-up," said Juan José Chacón-Quirós, Founder and CEO of Establishment Labs. "We are very pleased with our progress in the augmentation cohort, and we expect to file our PMA submission with the FDA in Q4 of this year for the aesthetic indications."

"Motiva implants have created a new standard in my practice for post-mastectomy reconstruction," added Prof. Dr. Phillip Blondeel, Professor of Plastic Surgery and chairman of the Department of Plastic and Reconstructive Surgery at the University Hospital Gent, Belgium; President of European Society of Plastic Surgery (EURAPS); and Director of the Beautiful After Breast Cancer Foundation. "With Motiva, we can routinely achieve the aesthetic outcomes that women hope for in their reconstruction and in doing so, we are helping transform breast cancer into a treatable disease from which women can fully recover."

The Motiva Core pivotal study is an ongoing US clinical trial of an investigational medical device under an FDA-approved Investigational Device Exemption. The Motiva device has not been approved by the Food and Drug Administration and is not commercially available in the United States.

About Establishment Labs

Establishment Labs Holdings Inc. is a global medical technology company dedicated to improving women's health and wellness. The company's initial focus is breast health, principally breast aesthetics and reconstruction. Establishment Labs offers a portfolio of advanced silicone gel-filled breast implants, branded as Motiva Implants® that include a number of innovative and patented features designed to deliver improved aesthetic and clinical outcomes. Since commercial launch in 2010, over 2.0 million Motiva Implants® have been delivered to plastic surgeons in over 80 countries. The company also offers or has under development a number of related products and technologies, including the Motiva Flora® tissue expander and Mia®, the company's minimally invasive breast enhancement procedure. In 2018, Establishment Labs received an investigational device exemption (IDE) from the FDA for the Motiva Implant® and began a clinical trial to support regulatory approval in the United States. Motiva Implants® are manufactured at the company's two facilities in Costa Rica, which are compliant with all applicable regulatory standards under ISO13485:2016 and FDA 21 CFR 820 under the MDSAP program. 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," "intends to," "would," "will," "may" or other similar expressions in this press release. Any statements that refer to projections of our future financial or operating performance, anticipated trends in our business, our goals, strategies, focus and plans, including related product development and commercialization and regulatory approvals, 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 and the timing of events may differ from our expectations, and those differences may be material. Factors, among others, that could cause actual results and events to differ materially from those described in any forward-looking statements include risks and uncertainties relating to: our ability to successfully, timely and cost-effectively develop, seek and obtain regulatory clearance for and commercialize our product offerings; the rate of adoption of our products by healthcare providers or other customers; the success of our marketing

initiatives; the safe and effective use of our products; our ability to protect our intellectual property; our future expansion plans and capital allocation; our ability to expand upon and/or secure sources of credit or capital; our ability to develop and maintain relationships with qualified suppliers to avoid a significant interruption in our supply chains; our ability to attract and retain key personnel; our ability to scale our operations to meet market demands; the effect on our business of existing and new regulatory requirements; the effect on our business of the current Russia-Ukraine conflict; the impact of foreign currency exchange rates; the impact on our business of an economic downturn or deterioration of general macroeconomic conditions, including slower growth or recession, inflation or decreases in consumer spending power or confidence; other economic and competitive factors; and the other risks and uncertainties discussed in Item 1A, Risk Factors, in the company's annual report on Form 10-K filed on March 1, 2022 and on Form 10-Q for the three months ended March 31, 2022, filed on May 10, 2022. These and other factors that could cause or contribute to actual results differing materially from our expectations may also be amended, updated or superseded from time to time in the future in 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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Source: Establishment Labs Holdings Inc.