



Establishment Labs' Motiva Flora Tissue Expander Receives CE Mark

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NEW YORK, June 11, 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 CE Mark for the Motiva Flora Tissue Expander.

"Unlike traditional tissue expanders with magnetic ports, a patient with a Motiva Flora Tissue Expander can be safely scanned immediately after placement using MR systems operating at 1.5- or 3-Tesla," said Frank G. Shellock, Ph.D., Adjunct Clinical Professor of Radiology and Medicine, and Director of MRI Safety, University of Southern California, and author of the widely used *Reference Manual for Magnetic Resonance Safety, Implants, and Devices*. "I am extremely gratified to finally see technology that can enhance the standard of care for patients undergoing tissue expansion for breast reconstruction that may need an MRI exam for health reasons."

"We are pleased that oncologists, plastic surgeons and patients will now have access to advanced, patented and patent pending technology that offers substantial improvements over existing tissue expander products," said Juan José Chacón Quirós, Chief Executive Officer of Establishment Labs. "Motiva Flora is another example of our unwavering commitment to women's health as we continue to transform the breast aesthetics and reconstruction industry through science and innovation."

The Motiva Flora Tissue Expander, with its proprietary SmoothSilk surface, is the only such product with an integrated RFID port with no magnets, allowing for use of the expander safely alongside MRI scanning. Recently published research¹ concluded that Flora offers potential advantages for patients undergoing MRI compared with tissue expanders that have magnetic ports that create substantial signal losses and distortion on MR images. Motiva Flora and Motiva Implants offer the SmoothSilk surface, a bioengineered nanosurface that has demonstrated a very low rate of capsular contracture and no reported cases of BIA-ALCL to date.

Already a leader in the European breast enhancement market with its portfolio of Motiva branded products, Establishment Labs intends to extend its presence into the reconstruction market with the introduction of its Flora tissue expander alongside Motiva Implants. The Company expects to immediately commence pre-marketing activities in Europe for Flora in preparation for a broad commercial launch in early 2021.

Motiva Flora's unique surface and shell technology and RFID features are protected by 3 issued U.S. patents and 11 patent applications pending in several jurisdictions, including the United States and Europe. The Motiva Flora Tissue Expander is not available for sale or approved in the United States.

Dr. Shellock, who created and maintains the internationally popular website www.MRIsafety.com, has performed scientific advisory services for Establishment Labs.

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 to the timing of the commercial launch of the Motiva Flora Tissue Expander. 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.

¹ Bayasgalan et al., "Breast Tissue Expander with Radiofrequency Identification Port: Assessment of MRI Issues," *American Journal of Roentgenology*, 2020; 215:1-6

Investor/Media Contact: David K. Erickson Establishment Labs Holdings Inc. 949-447-6671 derickson@establishmentlabs.com