Establishment Labs Hosts Investor Event for its Motiva MIA® System for Minimally Invasive Augmentation

February 9, 2021

- **Minimally Invasive creates a new product category in breast aesthetics with a total addressable market of $4-5 billion**
- **Clinical study shows significant benefits compared to traditional breast augmentation surgery, with procedures performed without general anesthesia and women experiencing faster recovery with reduced post-operative pain**
- **Company has approval from IRB to extend study to 100 patients and now has Free Sales Certificate for the Motiva MIA System**

SANTA BARBARA, Calif.--(BUSINESS WIRE)--Feb. 9, 2021-- Establishment Labs Holdings Inc. (NASDAQ: ESTA), a medical technology company focused on women's health, initially in the breast aesthetics and reconstruction market, is hosting a virtual investor event today, February 9, 2021, 1:00 - 2:30 p.m. ET to discuss its Motiva MIA system for minimally invasive breast augmentation.

The Motiva MIA study demonstrates a significant advancement in breast aesthetics. Relative to traditional augmentation surgery, MIA offers a shorter procedure time without the need for general anesthesia, reduced recovery time, lower post-operative pain, and a short learning curve for surgeons. The Motiva MIA system includes the Company's Ergonomix2 Diamond implant, which received CE mark in December 2020, and its proprietary tools, including the Motiva MIA Inflatable Balloon and the Motiva MIA Injector.

The Company reported that it received registration in Costa Rica and a Free Sale Certificate ("FSC") for the Motiva MIA system to begin regulatory approvals processes worldwide. The Company received approval from the Institutional Review Board ("IRB") to extend the current study to evaluate the performance and safety of the Motiva MIA system on a total of 100 patients in Costa Rica. The Company has also received IRB approval for a 60 patient multi-center study in Thailand with a similar protocol that is set to begin later this year.

Additionally, Establishment Labs has commissioned extensive third-party market research from multiple firms that surveyed approximately 4,300 women, ages 18-55, across eleven key markets. The research concluded that the annual global market size for Motiva MIA is 1.9 million procedures, which translates to a total addressable market of $4-5 billion. A key finding of the research is that approximately 50% of respondents, while aware of traditional breast augmentation, would not undergo traditional surgery, but would pursue the Motiva MIA procedure within the next 12 months based on its expected benefits over existing surgical practices and implant characteristics.

"Our success with the initial 30 patients in Costa Rica marks an important achievement, as we advance what we believe is a revolutionary platform for breast enhancement," said Juan José Chacón-Quirós, Chief Executive Officer. "The incredibly high post-operative satisfaction reported by patients suggests we can successfully commercialize this minimally invasive augmentation procedure safely to women worldwide following regulatory approval. We see the Motiva MIA system as a significant growth driver for Establishment Labs and a new category in breast aesthetics that we believe is multiples larger than the existing total addressable market for breast augmentation surgery," concluded Chacón-Quirós.

The Study

Establishment Labs conducted an IRB approved clinical study to evaluate the performance and safety of the Motiva MIA system. The first 30 patients underwent the Motiva MIA procedure in December 2020 in Costa Rica. Establishment Labs has received approval to extend this study with an additional 70 patients which began this month. The study is a prospective, interventional, single-arm, feasibility study of women 18 years or older in primary breast augmentation.

Key metrics from the initial group include:

- Average cup size increase of 1.64 (based on the International Bra Measurement System) with 69% of women receiving more than 1 cup size up;
- Low reported pain levels, with an average of 3.13/10 at 24 hours, and 1.87/10 at 3 to 7 days, allowing for a return to normal activities in less than two days following the procedure;
- High patient satisfaction, with an average of 94.6/100, measured using the Breast-Q validated measurement (PRO) tool, at one month follow up; and
- Minimal, non-visible scars at one month follow up.

The Company is currently pursuing regulatory approvals for Motiva MIA in Europe and other geographies and is expecting to commence pre-commercial procedures in select markets in the second half of 2021.

The Motiva MIA® system is 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.

Event Details
Date: Tuesday, Feb. 9, 2021
Time: 1:00 – 2:30 p.m. EST
To register: https://establishmentlabs.zoom.us/webinar/register/WN_55ESTwYRTCKbhtVrzkTzfg

After the conclusion of the program, there will be a question and answer session for investors and analysts. A recording of the event will be archived on the Company's website.

About Establishment Labs

Establishment Labs Holdings Inc. 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. Establishment Labs has 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"). Our preliminary revenue and cash figures for the fourth quarter of 2020 are forward-looking and actual results may differ from these estimates following the completion of our financial closing procedures and related adjustments. 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 our ability to obtain regulatory approvals for, and commercialize, the Motiva MIA 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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