Establishment Labs Celebrates 10 Years of Motiva Safety Data

October 21, 2020

- **Findings Show Less Than 1% Device Related Complications**
- **Nearly 1.3 Million Implants Placed Worldwide**

SANTA BARBARA, Calif., Oct. 21, 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, is today announcing its latest clinical data demonstrating 10 years of outstanding safety outcomes reported in women who have received the Company's Motiva ® silicone breast implants.

At today's virtual symposium "Motiva: A Decade of Contributions to Women's Health," the Company will present 10-year post-market surveillance data demonstrating an unmatched device-related complication rate of less than 1% for the key safety endpoints of capsular contracture and implant rupture, with nearly 1.3 million breast implants placed worldwide outside of the United States. These rates are consistent with data reported in the Company's patient registry of more than 145,000 patients, as well as studies reported in peer-reviewed publications. [1] There have been no cases of BIA-ALCL reported with Motiva Implants®.

Also at the symposium, plastic surgeons with extensive global experience using the Company's Motiva Implants will discuss their own results. "In 428 primary and revision breast augmentations over the last six years, the complication rate for my patients receiving Motiva is 0.3%," said Dr. Giovanni Botti, an independent plastic surgeon and clinical Professor of Plastic Surgery at the University of Padua, and author of the medical text *Aesthetic Mammaplasties*. "Importantly, my patients see more natural results in terms of softness, comfort and ergonomy with their Motiva Ergonomix ® implants."

"These 10-year findings are another validation of the rigorous science and engineering behind the strong safety profile of our Motiva Implants," said Juan José Chacón-Quirós, Chief Executive Officer of Establishment Labs. "The placement of nearly 1.3 million Motiva Implants in over 80 countries, along with positive real-world data sets, implant registries and independent publications, are evidence of the high degree of confidence plastic surgeons and patients have in Motiva. Establishment Labs has an unwavering commitment to women's health and well-being, and I want to thank each of our employees who remain united in our vision to transform this industry through science and innovation."

Data Details

The results presented are post-market surveillance data reported from patients and/or physicians to the Company's Quality Management System complaint database.[2] From October 2010 to September 2020, approximately 1,288,000 Motiva breast implants have been implanted worldwide with fewer than 400 device-related clinical events reported, including capsular contracture and implant rupture. This represents an event rate of approximately 0.03%.

Since 2010, approximately 145,000 women have registered their implants in the MotivaImagine App, a practice that denotes an additional degree of patient awareness of product warranty in case of an adverse event. Through September 2020, 216 registered patients (0.15%) reported a device-related complication that resulted in reoperation.

Since September 2015, approximately 12,500 women have purchased an extended warranty, which provides financial assistance where surgical intervention is required to address complications such as capsular contracture or rupture. Through September 2020, only 90 of these patients (0.73%) required coverage for a reoperation.

Eight peer reviewed publications with Evidence Levels 3 and 4, spanning well-designed case-control or cohort studies, and well-designed controlled trials without randomization, have been published in the major plastic surgery journals about Motiva Implants. These studies have reported device-related complications of between 0% and 1.3%, with patient follow-up ranging from six months to six years.

Symposium Details

Today's symposium will commence at 2:00 pm Eastern time. To register, please go to https://establishmentlabs.zoom.us/webinar/register/WN_82jqSm6jSseoYfrVsajcqQ. After the conclusion of the program, there will be a separate question and answer session for investors and analysts. A recording of this event will be archived on the company's website.

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 to our ability to commercialize Motiva implants. 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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[1] Motiva Implants are not yet approved or available in the United States and are investigational devices undergoing an IDE clinical trial. Safety and efficacy has not been established in the U.S.

[2] The Company's Quality Management System database does not contain U.S. IDE trial safety data.

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