Establishment Labs Announces Publication of Landmark Breast Implant Surface Research in Nature Biomedical Engineering

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- Professor Robert Langer and a team of MIT scientists demonstrated that an optimal breast implant surface architecture leads to significantly lower levels of inflammatory foreign body response and to healthier tissue capsule formation.
- Establishment Labs to host webcast at 10am EST on Tuesday June 22 to discuss the publication and its implications with Prof. Robert Langer and other authors on the paper, including Drs. Brian Kinney and Marcos Sforza, as well as members of the company's management team.

SANTA BARBARA, Calif.--(BUSINESS WIRE)--Jun. 21, 2021-- 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 results from a landmark study investigating how different breast implant surfaces affect the host immune response. The purpose of the study was to determine the optimal breast implant surface topography that induces the least amount of adverse foreign-body response and understand better how breast implant design impacts biocompatibility.

The study, titled "Surface Topography Mediates Foreign Body Response of Silicone Breast Implants in Mice, Rabbits, and Humans", was published today in *Nature Biomedical Engineering* and demonstrates that the patented Motiva® SmoothSilk® surface* significantly reduces the foreign body response compared to implants with high degrees of roughness or completely smooth surfaces that were included in the study. The unique and patented SmoothSilk surface includes a number of elements purposefully designed to improve biocompatibility, including a topography of only 4 microns on average and specific characteristics around skewness and the number, distribution, and size of contact points.

The study, led by a team of MIT researchers under the guidance of Professor Robert Langer and lead authors Joshua Doloff and Omid Veiseh, examined the foreign-body responses and capsular fibrosis triggered by miniaturized versions and human-scale commercially available breast implants with different surface topographies (including averages that varied from 0–90 microns) placed in the mammary fat pads of mice and rabbits, respectively, for up to one year**. In both the mice and rabbit models, researchers found that tissue exposed to either implants with higher degrees of roughness or completely smooth implants showed increased levels of activity from macrophages — immune cells that normally clear out foreign cells and debris — as well as higher levels of activity in inflammatory T cells, and more scar tissue formation. Surfaces with the SmoothSilk architecture showed a significantly lower level of immune response and the most healthy and biocompatible tissue capsules compared to either completely smooth implants or those with rougher surfaces.

"Given the lack of scientific understanding regarding the optimal biocompatibility of implants over decades of studying the body's immune response, we believe these findings are particularly notable," said Professor Robert Langer, one of twelve Institute Professors at MIT and the study's senior author***. "We studied a number of different silicone breast implants, all with different surfaces. Of those tested, the results demonstrated that an implant that includes architectural features specific to the SmoothSilk surface was superior in minimizing inflammation and excessive foreign-body response. We believe that the determination of an optimal surface is a significant step forward for the breast implant and medical device communities towards designing safer and more biocompatible implants which can reduce patient complications."

Silicone breast implants have been in use since the 1960s for both breast reconstruction and augmentation and over one and a half million people receive the devices worldwide every year. However, according to data from the U.S. Food & Drug Administration (FDA) and others, many patients experience reoperations due to the buildup of scar tissue that can lead to a condition called capsular contracture and other rare but serious complications, including a rare type of lymphoma associated with textured breast implants called breast implant-associated anaplastic large cell lymphoma (BIA-ALCL).

"For the past 10 years, we have consistently seen exceptional outcomes with Motiva implants," said Juan José Chacón-Quirós, CEO and Founder of Establishment Labs. "The paper by Dr. Langer and his colleagues provides a critical understanding of our surface technology and validates the superior clinical and aesthetic outcomes reported with our devices. This study establishes a new scientific standard to which all implant technologies should be held. Most importantly, these findings will help surgeons and their patients make better informed decisions in their selection of breast implants."

After performing the animal studies, researchers analyzed tissue samples from explanted breast implant capsules at MD Anderson Cancer Center to study how human patients respond to different types of silicone breast implants. In those human samples the researchers found evidence for the same types of surface-mediated immune responses that they had seen in the animal studies. Among their findings they observed that tissue samples from patients with highly textured implants showed signs of a chronic, long-term inflammatory response. They also found that tissue capsules from patients with traditionally smooth or highly textured implants were notably thicker and less healthy as compared to those from patients with SmoothSilk implants.

“This paper speaks to the true nature of ‘bench to bedside’ device development—from concept, to preclinical models, and ultimately to clinical evidence. In this case, Establishment Labs identified the need for better devices in the breast implant space more than a decade ago,” said Dr. Brian Kinney, a board-certified plastic surgeon and Clinical Associate Professor of Plastic Surgery at the University of Southern California in Los Angeles***. “This study documents development of an implant technology that addresses the historic challenges with silicone breast implants, while demonstrating safety through strong scientific evidence. In addition, it shows that the SmoothSilk surface delivers superior biocompatibility compared to textured or traditional smooth implants.”

Establishment labs will host a virtual event on June 22 to discuss the study and its implications. The event will include Professor Robert Langer and other authors on the paper, including Drs. Brian Kinney and Marcos Sforza, as well as members of the company’s management team.

Event Details:
Date: Tuesday, June 22, 2021
Time: 10:00 -- 11:00 am EST
To register: https://establishmentlabs.zoom.us/webinar/register/WN_qY2qJi-tTkOwwoAyhZc85A

There will also be a question and answer session for investors and analysts. A recording of the event will be archived on the company's website.

From pioneering breast ergonomy to first-of-their-kind safety features like RFID enablement, Motiva Implants are based on science and user-centric design and manufactured with cutting-edge patented technologies to exacting quality standards. In March 2018, Establishment Labs received approval for an investigational device exemption (IDE) from the FDA and the Motiva Implants clinical trial is currently underway in the U.S.

* The patented surface technology in Motiva Implants is commercially referred to as SmoothSilk or SilkSurface.
** Establishment Labs provided an unrestricted research award to the Langer Lab at MIT that was used for this research.
*** Professor Langer and Dr. Kinney are members of Establishment Labs’ Scientific Advisory Board and each holds equity in the company.

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”). You can find many (but not all) of these statements by looking for words such as “approximates,” “believes,” “expects,” “anticipates,” “estimates,” “intends,” “plans,” “will,” “would,” “may” or other similar expressions in this press release. 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; 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; and other economic and competitive factors. 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 15, 2021, 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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