



Establishment Labs Receives IDE Approval from U.S. FDA to Initiate Clinical Trial of Motiva Implants

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NEW YORK, March 22, 2018 (GLOBE NEWSWIRE)

Establishment Labs Holdings Inc., a global medical device company focused on breast aesthetics and reconstruction technologies with a strong emphasis on product development and innovation, announced today that it has received an investigational device exemption (IDE) from the U.S. Food and Drug Administration (FDA) to initiate a clinical trial for its Motiva Implants, the lead product in its portfolio of innovative aesthetic technologies.

The IDE approval enables Establishment Labs to move forward with a single arm, multi-center study investigating female patients receiving primary breast augmentation, primary breast reconstruction, or revision surgery. The results of the study are expected to support a Pre-Market Approval (PMA) submission to the FDA.

"I'm delighted to have the opportunity to participate in a study that has the potential to bring new insights to the breast aesthetic and reconstruction industry. Motiva Implants are innovative and differentiated, and we hope that these innovations will show significantly improved patient outcomes," said Dr. Caroline Glicksman, a board certified plastic surgeon and Medical Director of the Motiva Implants clinical trial. "Considerable time was taken to create a robust protocol that studies the safety and efficacy of Motiva Implants, and we have worked closely with the FDA to design a state of the art trial. Our investigators include experienced, knowledgeable, and caring surgeons from the United States, Canada, Sweden, and Germany. The safety of our patients remains our primary goal and we look forward to a successful trial that collects valid scientific data and advances the breast aesthetic and reconstruction industry."

Juan Jose Chacon Quiros, CEO and Founder of Establishment Labs added, "Patient safety is Establishment Labs' highest priority. Our implants are engineered with the latest scientific understanding in material sciences and surface technologies, and our advances in biocompatibility have demonstrated a favorable safety profile for patients worldwide. The start of this trial is an important milestone in our global commercialization strategy, and only adds to our leadership position as the innovator in this industry. Our decision to pursue a trial in the United States with such a rigorous study design reflects the confidence we have in both the superiority of our product and our manufacturing processes. There is a tremendous opportunity to materially improve the safety and satisfaction of patients seeking breast augmentation or reconstruction surgery."

Motiva Implants are designed with a TrueMonobloc® shell that results in a strong and durable breast implant with exceptional elasticity for ease of insertion and small incisions. The cell-friendly surface technology behind Motiva Implants has demonstrated low complication rates in recent publications. For better aesthetic outcomes, the soft, form-stable filling gel allows for optimal shape retention, a natural look, and comfortable feel for women. Establishment Labs maintains strict manufacturing practices and adherence to both United States and European standards.

Roberto de Mezerville, Chief Technology Officer of Establishment Labs, commented, "Establishment Labs is committed to bringing enhanced safety and innovative products to the breast aesthetics and reconstruction fields. Motiva Implants® have a strong and rapidly growing following around the world, and the data is suggestive that they represent a meaningful advance to the industry. I have the highest expectations for this trial, and its impact on surgeons and patients alike."

About the Motiva Implant Trial

The Motiva Implants clinical study is a single arm, multi-center trial, designed to measure the safety and effectiveness of the Motiva Implants SmoothSilk®/SilkSurface® and Ergonomix® in subjects who are undergoing primary breast augmentation, primary breast reconstruction, or revision surgery. It is scheduled to start in the second quarter of 2018, pending Institutional Review Board approvals at all selected clinical sites. With a population size of approximately 750 patients over 22 years in age and in up to 40 study sites in the United States, Canada, Sweden, and Germany, subjects will be selected per a strict protocol according to FDA regulations.

Patients meeting the inclusion and exclusion criteria may be enrolled in the study. The primary safety endpoint is based on the incidence, severity, method of resolution, and duration for all complications on a "per-implant" and "per-subject" basis. The use of 3D imaging systems, such as Divina®, performed pre-operatively and at 1-10 years visits, will supplement the data and corroborate the manual measurements performed. An MRI sub-study will be done in parallel to determine the percentage of ruptures, with a subset of the treated population selected to obtain MRIs at 1,2,4,6,8 and 10 years.

Additional information regarding the trial will be available on clinicaltrials.gov and www.motivaimplants.com/UStrial

About Establishment Labs

Establishment Labs is a global, privately held, medical technology company with a strong emphasis on innovation that designs, develops, manufactures and markets an innovative product portfolio. Its CE-marked Motiva Implants line of silicone breast implants (<http://www.motivaimplants.com>) utilizes ultra-high purity medical-grade silicone and is subject to strict quality assurance testing throughout the manufacturing process. Motiva Implants are sold in more than 60 countries worldwide. All of Establishment Labs' manufacturing facilities are fully compliant with both FDA and ISO applicable standards.

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