Source: *Establishment Labs*
April 27, 2018 08:00 ET

Establishment Labs Announces Motiva® Implants IDE Clinical Trial Underway with First Patient Enrolled and Surgery Completed

NEW YORK, April 27, 2018 (GLOBE NEWSWIRE) -- Establishment Labs Holdings Inc., a global medical device company focused on breast aesthetics and reconstruction technologies, today announced the enrollment and successful completion of implant surgery on the first patient in its U.S. investigational device exemption (IDE) clinical trial of its Motiva® Implants, the lead product in its portfolio of innovative aesthetic technologies.

After Institutional Review Board (IRB) approval, the first patient was enrolled during the first week of April, 2018, by Dr. Andrew Wolfe a Motiva Implants clinical study investigator in Golden, Colorado. “I am excited to be participating in the Motiva Implants trial and I look forward to evaluating the performance of these implants in the upcoming years. I am optimistic that advances in materials science and manufacturing techniques, along with better understanding of implant behavior in the body, will lead to improved outcomes for our patients,” said Dr. Wolfe.

Additionally, the first surgical operation was completed in New Jersey by Dr. Caroline Glicksman, Director of the Motiva Implants clinical study. “This study will provide deeper insights on the science that Establishment Labs has applied to its breast implant technology. This milestone marks an important next step in the clinical trial process and builds on the significant work of a dedicated group of professionals in their efforts to improve breast aesthetics and reconstruction technologies. We look forward to further progress and follow up with patients who are appropriate candidates,” said Dr. Glicksman.

“Having received approvals from the IRBs at clinical sites, we were able to start enrollment and proceed with our first patient surgery on schedule,” said Juan Jose Chacon Quiros, CEO and Founder of Establishment Labs. “The commencement of the Motiva Implants clinical study highlights our commitment to bringing patient safety and technologies in breast aesthetics and reconstruction to the U.S. market, as well as advancing our global commercialization strategy.”

About the Motiva Implants IDE Clinical Trial
The Motiva Implants IDE clinical trial is a single arm, multi-center trial, designed to measure the safety and effectiveness of the Motiva Implants SmoothSilk® and Ergonomix® in female patients who are undergoing primary breast augmentation, primary breast reconstruction, or revision surgery. With a population size of approximately 750 patients over 22 years of age, at up to 40 study sites in the United States, Canada, Sweden, and Germany, all subjects will be selected according to a strict protocol established by 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 of 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 year 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.

Investor Relations Contact
Lynn Pieper Lewis or Leigh Salvo
Gilmartin Group
(415) 937-5404
leigh@gilmartinir.com