Establishment Labs Receives Korean Regulatory Approval for Motiva Implants

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Establishment Labs, a global medical device company focused on breast implant technologies with a strong emphasis on product development and innovation, announced today that it has received approval from the Korean Food & Drug Administration (KFDA). Establishment Labs also announced a 10 year distribution agreement with Seoul-based Human Wellness Corporation (HWC) to market Motiva Implants® and the MotivaImagine™ platform, combining the latest breast implant technology with integrated 3D capabilities and the latest surgical and consultation tools.

“I am thrilled to announce approval from the KFDA for Motiva Implants®,” said Juan José Chacón Quirós, Founder and Chief Executive Officer of Establishment Labs, “This is a crucial step in Establishment Labs becoming the worldwide market leader in breast implant technology. Given the product safety record, Motiva Implants® have quickly become the breast implants of choice for patients who are seeking the most advanced devices for breast aesthetics.”

“As we expand to new markets globally,” Mr. Chacón Quirós added, “we will continue to invest in research and development, intellectual property and clinical studies that create innovative product and platform technologies. South Korea is a very important market for both us and the industry, and I expect we will have continued regulatory approvals globally throughout this year.”

Worldwide, there have been over 150,000 implantations performed with Motiva Implants® with an unparalleled safety record. Motiva Implants® are available with the Q Inside Safety Technology™, an FDA cleared and CE approved RFID solution that allows Plastic Surgeons to connect patients through the MotivaImagine™ App to an electronic passport that contains all of the relevant information about their breast implants for increased safety and peace of mind.

According to John Lim, Chairman of HWC, “Korea is the largest market for breast aesthetics in Asia. We are honored to be the long term partner of Establishment Labs, with a mission of bringing next generation breast implant technology to Korean women. With KFDA clearance, we believe that Motiva Implants® and MotivaImagine™ will provide best-in-class technology for the sophisticated Korean consumer.”
The KFDA approval in Korea is the most recent of regulatory clearances for Motiva Implants®, adding to its existing regulatory approvals in over 60 countries worldwide.

About Establishment Labs:
Establishment Labs is a global, privately held, breast implant and medical technology company that designs, develops, manufactures and markets an innovative product portfolio consisting of advanced silicone-filled breast and body shaping implants (http://www.motivaimplants.com). Utilizing only the highest quality of medical grade silicones, the CE-marked Motiva Implants® line is rigorously scrutinized by professional quality engineers throughout the entire manufacturing process. All of its products are manufactured in full compliance with ISO and EU requirements, and are certified under the Medical Device Directive 93/42/EEC.