Implantica announces finalization of remarkable 5-year pivotal CE mark study results and gears up for the Module 2 submission of PMA application to FDA for RefluxStop™

Implantica AG (publ.), a medtech company at the forefront of introducing advanced technology into the body, including a unique device RefluxStop™ for the treatment of acid reflux, a treatment field with 1 billion sufferers, announces finalization of the 5-year CE mark study results as part of the upcoming Module 2 submission (of 3 modules) of the RefluxStop™ premarket approval application (PMA) to the U.S. Food and Drug Administration (FDA).

Implantica has prepared responses to FDA's feedback from Module 1 to be submitted together with Module 2 of the RefluxStop™ PMA application. Module 2 is planned to be submitted in the near-term (during autumn) as agreed with the FDA. The Implantica team has worked very hard to ensure that this study is thoroughly completed and analyzed as per the rigorous FDA requirements.

Module 2 is the most important of the three modules included in the PMA filing and will contain the clinical and usability data, including the results of the CE-mark clinical investigation and the results from our Human Factors Validation Study performed earlier this year with 16 US foregut/reflux surgeons in Chicago.

We are thrilled to report exemplary results from both studies mentioned above. A summary of the objective and exceptional 5-year clinical results from the CE mark study shows:

- Contrast swallow x-rays at year 5 show the devices in place and well functioning with no device dislocations, no device migration, and no re-herniation.
- 24-hour pH monitoring, measuring the acidity in the lower esophagus over 24-hours, also provides excellent results. Only one subject is dissatisfied and has a failed/pathologic 24-hour pH monitoring test.
- In comparison, our main device competitor at their FDA trial reported 42% pH test failures at year 1.

Implantica's CEO, Dr. Peter Forsell, says, "Our independent data handling partner, together with our CRO, have now performed data auditing and analyzed our CE mark study 5-year data. We are so pleased to see the fantastic final results of the CE mark study that are largely in line with recently published excellent 4-year results and several independent published real-world outcomes. These results will echo around the world and will significantly advance RefluxStop's position as a potential leading treatment option for the hugely underserved GERD patients."

Dr. Forsell continues, "Many of the articles published in prominent journals, such as Nature and Surgical Endoscopy, present consistent excellent outcomes, including the most recent results from one of Germany's largest Reflux centers in Frankfurt

performing about 250 surgeries per year, presented by Dr. Moustafa Elshafei. With over 50 RefluxStop procedures completed, Dr. Elshafei's results are in line with our pivotal CE mark study results, showing no serious complications or reoperations that once again reinforce similar outcomes witnessed by many of the other RefluxStop users in Europe."

For further information, please contact:
Nicole Pehrsson, Chief Corporate Affairs Officer
Telephone (CH): +41 (0)79 335 09 49
nicole.pehrsson@implantica.com

Implantica is listed on Nasdaq First North Premier Growth Market in Stockholm.

The company's Certified Adviser is FNCA Sweden AB, info@fnca.se

The information was sent for publication, through the agency of the contact person set out above, on September 25, 2024, at 08:30 a.m. (CET).

About Implantica
Implantica is a medtech group dedicated to bringing advanced technology into the body. Implantica's lead product, RefluxStop™, is a CE-marked implant for the prevention of gastroesophageal reflux that will potentially create a paradigm shift in anti-reflux treatment as supported by successful clinical trial results. Implantica also focuses on eHealth inside the body and has developed a broad, patent protected, product pipeline based partly on two platform technologies: an eHealth platform designed to monitor a broad range of health parameters, control treatment from inside the body and communicate to the caregiver on distance and a wireless energizing platform designed to power remote-controlled implants wirelessly through intact skin. Implantica is listed on Nasdaq First North Premier Growth Market (ticker: IMP A SDB). Visit www.implantica.com for further information.

About RefluxStop™
RefluxStop™ is a new innovative treatment that has the potential to spur a paradigm shift in anti-reflux surgery. It's unique mechanism of action differentiates it from standard of care and current surgical solutions. Longer established surgical options for GORD involve encircling the food passageway to support the lower oesophageal sphincter's closing mechanism and are commonly associated with side effects such as swallowing difficulties, pain when swallowing and inability to belch and/or vomit.

In contrast, the RefluxStop™ device treats the cause of acid reflux without encircling and putting pressure on the food passageway. It restores and maintains the lower oesophageal sphincter in its original, natural position.

The RefluxStop™ mechanism of action is focused on reconstructing all three components of the anti-reflux barrier, that if compromised could possibly result in acid reflux. It restores and supports the natural anatomical physiology of the body allowing the body to itself solve the problem with acid reflux.

Newsroom
http://www.implantica.com/media/media-kit

Community
http://ch.linkedin.com/company/implantica
http://www.twitter.com/implantica

Media Contact:
Implantica AG

Juanita Eberhart, VP Marketing & Advocacy
M: +1 925-381-4581
juanita.eberhart@implantica.com