

Implantica's RefluxStop™ trial shows exceptional three-year follow-up result

Implantica AG (publ) today announced the three-year follow-up results of their medical implant RefluxStop™. After three years, results were remarkable; none of the 47 patients in the study were in need of regular daily use of PPIs (proton-pump inhibitors), which were taken by all before surgery.

"These three-year follow up results are very special as not one single patient took regular daily medication after three years. The device is safe with no serious adverse event reported since the 1-year data was published. This strong data is invaluable as we introduce RefluxStop™ to the medical community and advance our commercialization efforts, and we see the potential of RefluxStop™ causing a paradigm shift in acid reflux treatment," said Dr. Peter Forsell, CEO of Implantica.

In 2017, the study reached its primary endpoint; to show that RefluxStop™ is safe and effective in preventing gastroesophageal reflux (GERD). The strong results of the study formed the basis of Implantica's CE-mark for RefluxStop™. Full data from the 1-year results have already been published and the data from the 3-year follow-up is under further analysis and will be published in a scientific journal after peer-review.

About the RefluxStop™ clinical trial

The trial objective of the prospective, open-label, multi-centre, single arm study started in December 2016 was to evaluate the safety and effectiveness of RefluxStop™ in the management of gastroesophageal acid reflux disease, GERD. The outcome measures were: 1) serious adverse device effects (SADEs) and procedure-related serious adverse events (SAEs) and 2) objective measurement of acid in the lower esophagus so called 24-hour pH monitoring as well as percent reduction from baseline of GERD symptoms based on a patient questionnaire, GERD-HRQL, score measured after the procedure.

About RefluxStop™

RefluxStop™ is a passive CE-marked silicone implant based on a new treatment principle that restores natural anatomy, thereby eliminating the need for proton-pump inhibitors (PPIs) and thus offering a novel approach for the treatment of GERD.

RefluxStop™ is implanted through a minimally invasive keyhole surgery and prevents reflux by hindering the lower esophageal sphincter (LES) from entering the chest. Since no pressure is applied on the food passageway complications are reduced.

For further information, please contact:

Nicole Pehrsson, Investor Relations
Telephone (CH): +41 (0)79 335 09 49
nicole.pehrsson@implantica.com

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

The company's Certified Adviser is FNCA Sweden AB, +46 (0)8 528 00 399, info@fnca.se

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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 energising 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.