

First patients enrolled in a post-market study of Magle Group's innovative medical device SmartPAN®

Magle Group (Nasdaq Stockholm First North Growth Market: MAGLE) today announces that the first patients have been included in a post-market clinical follow-up study of SmartPAN® – an innovative first-in-class medical device developed to improve the outcome of pancreatic surgery. The study aims to further demonstrate the effectiveness of SmartPAN® in detecting pancreatic fluid leakage, which – if left undetected– can lead to significant postoperative side effects. The study results have the potential to support reimbursement applications in Europe and facilitate marketing approvals in other parts of the world.

SmartPAN® is a patented first-in-class medical device developed jointly with the University of Heidelberg and Magle Group. SmartPAN® is based on Magle Group's patented bio-compatible and bio-degradable microsphere technology (DSM). The product is approved for medical use in Europe since 2021.

Postoperative pancreatic fistula (POPF) is a common and potentially life-threatening complication after pancreatic surgery. POPF can develop due to leaking pancreatic fluid. SmartPAN® acts as an intraoperative indicator of leakage by providing a near-immediate and accurate colour indication when in contact with the pancreatic fluid. SmartPAN® provides a less complicated approach to identifying and localising pancreatic leaks in order to benefit patient outcomes.

The post-market clinical follow-up (PMCF) study is being conducted at the University Hospital of Heidelberg by (surgeon names), and will enroll up to 36 patients. The final results are expected in late 2022 or early 2023. A PMCF study is aimed at keeping up-to-date on the security and effectiveness of a medical device approved in the EU.

“Enrolling the first patients in our post-market study is a significant milestone in the go-to-market strategy for SmartPAN, but also further evidence of the overall strength of our strategy to accelerate the development and roll-out of further products based on Magle Group's proprietary degradable starch microspheres,” says Justin Pierce, Magle Group's CEO.

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About Us

The Magle Group aims to establish itself as a leader in high-quality life-changing healthcare innovations to meet medical needs through scientific excellence. The Magle Group is founded on strategic acquisitions aimed at driving growth and diversifying risk. Today, the Group includes two operational areas. Magle Chemoswed – a contract development and manufacturing organization (CDMO) with a strong reputation for its high-quality development and manufacturing expertise and Magle PharmaCept – an established sales and marketing company for development and direct sales of the Groups medical technology products. Learn more on www.maglechemoswed.com and <https://maglegroup.com/> and www.maglepharmaceut.com

Västra Hamnen Corporate Finance is the Company's certified advisor on Nasdaq First North Growth Market and can be reached at ca@vhcorp.se or +46 (0) 40 200 250.

Attachments

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