

Magle Group initiates Randomized Controlled Multicenter Trial with leading European university hospitals to explore SmartPAN® efficacy

Magle Group (Nasdaq Stockholm First North Growth Market: MAGLE) today announces that the company has established a collaboration with Heidelberg University Hospital, Germany, a world leading center in pancreatic surgery. The study will compare patient outcome with and without targeted leakage closure following the use of pancreatic leakage indicator, SmartPAN®. The trial starts recruiting patients as of March 2025.

The investigator initiated randomized controlled multicenter trial will compare patient outcome with and without targeted leakage closure following the use of SmartPAN® in patients undergoing distal pancreatectomy. One hundred patients are planned to be included in the study, and the study will run over two years at three sites in Europe including Heidelberg University Hospital.

Pancreatic surgery is associated with a high rate of postoperative complications 1, 2. " Post-operative complications still affects a reasonable number of pancreatic surgeries. In this context, SmartPAN®, which is developed by our group in collaboration with Magle Chemoswed, represents a promising technological advancement. This post market clinical follow-up study aims to further investigate SmartPAN's capability in detecting and mitigating intraoperative pancreatic leaks across multiple clinical study sites. The primary focus will be on evaluating the effectiveness of the product, gauged through the incidence of post operative pancreatic fistula (POPF) after a positive SmartPAN® indicator reaction and targeted closure of the leakage sites," says principal investigator PD Dr. med. Thomas Pausch, MD.

"We are pleased to share the progress of SmartPAN®, and continue to establish the first-in-class medical device in the market. It is evidence in our commitment to delivering innovative solutions to patients in need," said Helena Ossmer Thedius, CMIO of Magle Group.

SmartPAN® Biochemical Leakage Indicator is a first in class CE-marked medical device for visualization of pancreatic fluid leakage following pancreatic surgery, for securing complete tissue closure during surgery. The product is based on Magle Group's proprietary polymer technology, DSM® (Degradable Starch Microsphere).

1. Donahue, T.R. & Reber, H.A. Surgical management of pancreatic cancer--pancreaticoduodenectomy. *Semin Oncol* 42, 98-109 (2015).

2. Parikh, P.Y. & Lillemoe, K.D. Surgical management of pancreatic cancer--distal pancreatectomy. *Semin Oncol* 42, 110-122 (2015).

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 three 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. Magle Biopolymers A/S- a specialized manufacturing organization of Dextran technology. Learn more on www.maglechemoswed.com and www.maglegroup.com and www.maglepharmaceut.com and www.maglebiopolymers.com

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Attachments

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