Episurf Medical receives FDA approval to initiate IDE clinical study

Episurf Medical (NASDAQ: EPIS B) announces today that the company has received approval from the US Food and Drug Administration (FDA) for its Investigational Device Exemption (IDE) application to initiate a clinical study on the Episealer® knee implant. The study will be a prospective, randomized, controlled, multi-centre study to evaluate the safety and effectiveness of the Episealer® knee system compared to microfracture for the treatment of focal femoral knee chondral or osteochondral lesions. The study will be performed both in the US and in Europe. The patients will be followed-up for 2 years, and the study will involve 180 patients.

FDA has approved with conditions the IDE application, submitted for Episurf Medical's Episealer® knee implant towards a PMA application for market approval. This means that the Episurf Medical IDE clinical study can now be initiated and subject enrollment may start once IRB approval is obtained. Additional conditions must be met to address minor outstanding issues, but the outstanding issues have not raised concerns that preclude FDA from granting approval of the study design and for initiation of subject enrollment in the clinical study.

"We are very pleased that FDA has approved our study design and that we can initiate the study. The site recruitment is far advanced, and several sites are ready to start the trial following this decision. We are convinced there is a significant number of patients in the US that can benefit from our technology and we are genuinely happy for this important step towards an introduction of the Episealer® in the US. There is a lack of efficient treatments for early knee lesions, and we are looking forward to helping the US population" says Dennis Stripe, Chairman of the Board, Episurf Medical.

"This is a significant milestone for us. We have been working towards this for several years. With a clarified and approved regulatory pathway towards an FDA approval, Episurf Medical is taking a major step into a new phase in the company's history. This project has been a top priority for us, and the outcome of this process is highly satisfactory. I am looking forward to the first surgery in the US" says Pål Ryfors, CEO, Episurf Medical.

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About Episurf Medical

Episurf Medical is endeavoring to bring people with painful joint injuries a more active, healthier life through the availability of minimally invasive and personalised treatment alternatives. Episurf Medical's Episealer® personalised implants and Epiguide® surgical drill guides are developed for treating localized cartilage injury in joints. Episurf Medical's µiFidelity® system enables implants to be cost-efficiently tailored to each individual's unique injury for the optimal fit and minimal intervention. Episurf Medical's head office is in Stockholm, Sweden. Its share (EPIS B) is listed on Nasdaq Stockholm. For more information, go to the company's website: www.episurf.com.

This information is information that Episurf Medical AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 08.15 CET on 17 December 2018.