Episurf Medical submits IDE application to the US FDA for the Episealer® knee implant

Episurf Medical (NASDAQ: EPIS B) today announces that the company has reached an important milestone on its strategy to reach the US market. The Investigational Device Exemption (IDE) application that the company has been working on is ready for filing. The application will now be filed to the US Food and Drug Administration (FDA) prior to the end of the second quarter.

An approved IDE allows a medical device to be used in a clinical study in order to collect safety and effectiveness data for submission to the FDA. Episurf Medical is filing the IDE application for the Episealer® knee implant to get approval to initiate a clinical study in the US. The IDE must be approved by the FDA before the study is initiated.

“Episurf has performed thorough work to get the extensive submission package in place. The Episealer® technology is gaining a lot of interest among the potential study investigators and we are continuing the work of getting sites ready for participation” comments Dr. Mike Kelly, Special US Study Advisor to Episurf Medical.

“We are looking forward to getting feedback on the study design from the FDA and continue the constructive dialogue we have had with the FDA in the preparatory phase. We are eager to take the next steps towards the US market and this is a very important milestone in that respect. I think the pieces are falling in place for us. Simultaneously as we are executing on a very clear regulatory strategy in the US, we have a growing business in Europe, where we also have a high level of activity when it comes to clinical activities. Our strategy is very clear, the clinical results are very strong, and this is such an important step. Finally, I am very proud of the team that delivered this in time, it’s been a lot of hard work behind this” comments Pål Ryfors, CEO, Episurf Medical.

For more information, please contact:

Pål Ryfors, CEO, Episurf Medical

Tel:+46 (0) 709 62 36 69

Email: pal.ryfors@episurf.com

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 08.00 CEST on 28 June 2018.