



Episurf Medical's toe implant – planned 510(k) application Q2 2023

Episurf Medical (NASDAQ: EPIS B) today announces that the company plans to file a 510(k) submission to the US FDA during Q2 2023 for the toe implant the company is currently developing. The company aims to receive market clearance to be able to launch the product on the US market during 2024.

The implant is intended to treat osteoarthritis (hallux rigidus) in the big toe, and more specifically of the so-called 1st MTP joint. It is based on Episurf Medical's proprietary technology for patient-specific design of implants and surgical instruments.

"I am pleased with having our plans finally confirmed, and I look forward to working with the FDA on this very interesting product. The market for osteoarthritis in the big toe is large, expanding our total addressable market in the US by about USD 400 million. Although the US market is our initial target market for this product, we aim at also launching it in non-US countries in the years to come. About 2.5% of the US population over the age of 50 suffers from OA in the big toe, and the market remains highly fragmented with no clear winner. Surgeons repeatedly mention patients' desire to retain motion by avoiding fusion, and the orthopaedic industry's lack of ability to meet this demand effectively. This is where we believe our fully individualized technology will play a meaningful role, and yet again, we are capitalising on our platform for individualized joint reconstruction products", says 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 individualised treatment alternatives. Episurf Medical's Episealer® individualised implants and Epiguide® surgical drill guides are developed for treating localised cartilage injury in joints. Episurf Medical's µFidelity® 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.