Episurf Medical receives FDA 510(k) clearance for Episealer® Patellofemoral System

Episurf Medical (NASDAQ: EPIS B) today announces that the company has received 510(k) clearance from the US Food and Drug Administration (FDA) for the Episealer® Patellofemoral System.

The Episealer® Patellofemoral System is an implant system with two opposing implants, intended for patients with osteoarthritis limited to the distal patellofemoral joint in the knee. It is based on Episurf Medical's proprietary individualised implant technology.

Episurf Medical will now prepare for the market launch of the company's first product on the US market.

"Episurf has received US market clearance from the FDA for our patellofemoral implant system. To date, this likely represents the single most significant milestone in the company's history. The company now has access to the largest and most dynamic orthopaedic market in the world and we have come a very long way, indeed, since our first animal investigations nearly 15 years ago. The patellofemoral implant system replaces both sides of the patellofemoral joint of the knee. This means that our technology can now treat not only focal lesions in the cartilage but also overt osteoarthritis. Hence, we can now serve a broader span of indications. As the founder of Episurf, personally, this is a formidable Christmas gift", says Prof. Leif Ryd, Senior Medical Advisor, Episurf Medical.

"*Gaining access to the US market symbolises a significant step for any orthopaedic implant manufacturer. For Episurf, this clearance represents somewhat of a double milestone. Firstly, there is the obvious access to the US orthopaedic market, which is of significant size and by far the largest orthopaedic market in the world. However, this clearance represents not only an additional country we are able to sell into, but a new product for the company as well – and our initial entry into treating osteoarthritis as a clinical indication. The patellofemoral joint is one of the higher variance anatomic locations in the musculoskeletal system, and we're confident our individualised technology will be able to play a meaningful role towards advancing care in this area",* says Pål Ryfors, CEO Episurf Medical.

For more information, please contact:

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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 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 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 09.00 CET on 24 December 2022.