



17 September 2024

## Victrex plc

## US FDA Approval for Total Knee Arthroplasty Study in the US

Victrex plc is an innovative world leader in high performance polymer solutions, delivering sustainable products which support CO2 reduction and enable environmental and societal benefit in multiple end-markets.

The Group today announces that, in partnership with Maxx Orthopedics Inc, the U.S. Food and Drug Administration (FDA) has granted Investigational Device Exemption (IDE) approval for Freedom® Total Knee System with Invibio PEEK-OPTIMA™ Femoral Component, as a staged study. The study, projected to be 120 patients at clinical sites in the US, will compare using the PEEK-OPTIMA™ Femoral Knee Component to a controlled registry of the same system using traditional metal femoral components.

The US study will build on the existing clinical trial for PEEK Knee at sites in Belgium, India and Italy, which has been progressing strongly since the first implant in 2021, with no clinical intervention. A regulatory submission in India is also expected imminently, supporting the potential for a commercial PEEK Knee in the market in 2025.

Jakob Sigurdsson, Chief Executive of Victrex, said: "PEEK Knee has the potential to be a game-changer for total knee replacement. Being able to further assess its benefits through rigorous clinical evaluation in the US will build on the strong progress so far through clinical trial sites in Europe and India. We look forward to the study's progression and remain optimistic about the transformative impact this pioneering device could have on the future of joint replacement.

"In relation to the regulatory submission in India, following a tenacious focus on innovation, development and investment to scale this significant opportunity, we now look forward to the potential for a PEEK Knee being in the market during 2025 and commercial revenues. We also continue to see growing interest in PEEK Knee from across the medical device industry, beyond our existing collaborations."

## Victrex plc:

## **About Victrex:**

Victrex is an innovative world leader in high performance polymer solutions, focused on the strategic markets of Automotive, Aerospace, Energy & Industrial, Electronics and Medical. Every day, millions of people rely on products or applications which contain our sustainable materials, from smartphones, aeroplanes and cars to oil & gas operations and medical devices. With over 40 years' experience, we are moving beyond the polymer into semi-finished and finished products which shape future performance for our customers and our markets, enable environmental and societal benefit for our customers and drive value for our shareholders. Find out more at <a href="https://www.victrexplc.com">www.victrexplc.com</a>

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