Orteq® Sports Medicine Announces Publication of 5-year Multi- Center Clinical Data for the Actifit® Meniscal Scaffold in the American Journal of Sports Medicine (AJSM),
Receives FDA Breakthrough Device Designation

London, UK – May 24, 2020. Orteq Sports Medicine Ltd. (www.orteq.com), a developer of joint preservation solutions for orthopedic patients, announces 5-year, multi center, peer-reviewed data published in the AJSM analyzing the ACTIfit meniscal scaffold that shows more than 87% survival rates with increased knee function and reduced pain. The scaffold has been granted a Breakthrough Device Designation from the U.S. Food and Drug Administration.

Orteq's ACTIfit meniscal scaffold, has been implanted in more than 4000 patients with irreparable meniscal cartilage damage in 30 countries worldwide and has now been published in 25 peer-reviewed clinical journals. ACTIfit is a biodegradable polymer designed to preserve the knee joint and promote new tissue growth in damaged areas of an irreparable meniscus, the crescent-shaped cartilage pad that acts as a shock absorber between the thigh (Femur) and shin (Tibia) bones.

Current treatment options for the damaged, torn or irreparable medial (inner segment) or lateral (outer segment) meniscus include pain management, physical therapy, injections, repair, surgical removal of a portion of a torn meniscus (partial meniscectomy) or surgery in which a meniscus from a cadaver (meniscus allograft) is placed in the knee.

Approximately 1.5 million arthroscopic partial meniscectomies are performed globally to reduce a patient's knee pain with half of these occurring in the USA. However, numerous clinical studies have shown many patients who receive a partial meniscectomy continue to experience pain which can eventually lead to knee replacement surgery.

Professor Em Rene Verdonk (Department of Orthopaedic Surgery and Traumatology, Hospital Erasme ULB, Brussels, Belgium) said, "The recent AJSM publication on the mid- term multi centre European follow-up of 155 patients shows ACTIfit significantly improved knee joint function and reduced pain in patients with an otherwise irreparable segmental meniscus defect for more than five years after implantation. The treatment survival rates of 87.9% of inner segment (medial) scaffolds and 86.9% of outer segment (lateral) scaffolds in the present study compared favourably with MAT (meniscal allograft transplantation) for total meniscectomy. In addition, ACTIfit offers significant health economics and cost-savings over currently available transplantation products."

The FDA introduced the Breakthrough Devices Program for new medical devices in 2017 to expedite the development and review process of new technology for patients with life-threatening or irreversibly debilitating conditions. This program is designed to ensure US patients and healthcare providers have more timely access to vital devices.

"The Breakthrough Device Designation program allows companies to get a 'Fast Track' review that could lead to US patients gaining quicker access to healthcare technology. We look forward to presenting our extensive European clinical data to the FDA for analysis this year and to work in close co-operation with the agency," said Simon Coles, CEO and Director of Orteq Sports Medicine Ltd.

"This will be significant for a young patient population without many satisfactory treatment options," said Peter Kurzweil, MD, a sports medicine physician in Long Beach, CA and Orteq surgical advisory board member, "I'm delighted the FDA has granted this expedited review of the ACTIfit technology. I'm looking forward to offering ACTIfit to my patients in the future."

Mr. Coles also said the achievement of these significant milestones has accelerated Orteq's expansion activities. "We have recruited an experienced global management team, obtained a new European Union CE Mark, set-up a new EU head office in Utrecht, the Netherlands and gained regulatory approval in Korea. Our goal in the next two years is to accelerate ACTIfit regulatory approvals from 30 to 50 countries, expedite our ACTIfit US filing using the newly awarded FDA Breakthrough Designation status and rapidly develop the proprietary ACTIfit polymer platform to other musco-skeletal joints."

For further information on ACTIfit, contact us at www.orteq.com

About ACTIfit

ACTIfit is a synthetic implantable scaffold with a highly interconnected porous structure, made of a proprietary biocompatible and biodegradable polymer. When implanted in a patient's medial or lateral meniscus arthroscopically ACTIfit® allows growth of native tissue and acts as a new 'shock absorber' to relieve pain and restore functional mobility to the patient. It is designed currently only for irreparable partial meniscus loss or damage.

The lead European ACTIfit clinical investigators are Philippe Beaufils, MD, PhD, Orthopedic Department, Centre Hospitalier de Versailles, Le Chesnay, France and Professor Emeritus Rene Verdonk Department of Orthopaedic Surgery and Traumatology, Hospital Erasme ULB, Brussels, Belgium.

ACTIfit is available at the following world renowned clinics across Europe and the Gulf States.

Prof Peter Verdonk, Orthoca Orthopedic Center, Antwerp, Belgium
https://orthoca.be/dokters-orthopedie/dr-peter-verdonk

Mr Tim Spalding, Fortius Clinic, London, UK and Warwickshire Nuffield Hospital, Warwick, UK
https://www.fortiusclinic.com/specialists/mr-tim-spalding
https://www.nuffieldhealth.com/consultants/mr-tim-spalding

Emmanuel Pappacostas MD, Aspetar Clinic, Qatar
https://www.aspetar.com/person-profile.aspx?id=180&lang=en

Nicolas Pujol MD Orthopedic Department, Centre Hospitalier de Versailles, Le Chesnay, France
https://versailles-orthopedie.com/fr/qui-sommes-nous/l-equipe-versailles-arthroscopie-orthopedie//pujol-dr-nicolas/spe_id/13

Konrad Slynarski MD**,** Slynarski Knee Clinic, Warsaw, Poland
Enquiry link for patients: www.slynarski.pl
https://trustedoctor.com/konrad-slynarski/request

About Orteq Sports Medicine

Orteq is privately held by Saratoga Partners LLC. In 2005, Orteq was established to develop joint preservation solutions for patients in the fields of Orthopedics/Sports Medicine using a proprietary polymer platform and a single surgery, Autologous Chondrocyte Implantation (ACI) cell treatment.

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