AN OTSUKA MEDICAL DEVICES COMPANY

Press release

Horsham, UK

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Veryan Medical (Horsham, UK) is delighted to announce that the first patient was enrolled today in the MIMICS-3D *USA* study by John H. Rundback MD at NJ Endovascular & Amputation Prevention, NJ.

Nick Yeo, Veryan's CEO commented "We are enormously grateful to Dr. Rundback and all of the team at NJ Endovascular & Amputation Prevention for the professional and efficient way they have helped Veryan reach this significant milestone so soon after US product launch in September 2020. The MIMICS-3D *USA* registry will grow our clinical database on BioMimics 3D use to more than 1750 patients and will provide the opportunity for physicians across the world to have access to safety and effectiveness data on the BioMimics 3D Vascular Stent System, including those from a pivotal study with 3-year follow-up."

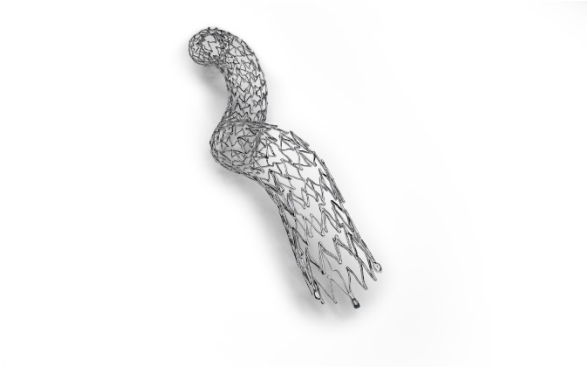
Dr. Rundback stated "We have been excited to be involved in this study based upon the impressive clinical data for BioMimics 3D, and the unique helical centerline which creates a swirling flow pattern that promotes arterial healing after intervention. In addition, the truly biomimetic design addresses the unique physical challenges and mechanical stresses inherent in the femoropopliteal arteries. We look forward to continuing to collaborate with the Veryan team as we enroll patients to further enhance the real-world data on the value of the BioMimics 3D stent technology. "

The MIMICS-3D *USA* study will evaluate safety, effectiveness and device performance of the BioMimics 3D stent within a real-world clinical population of patients undergoing femoropopliteal intervention. The study will enroll 500 patients from 40 sites within a 2-year recruitment period and the three Coordinating Principal Investigators are Dr. Sahil Parikh, Interventional Cardiologist, Columbia, NYC; Dr. Miguel Montero, Vascular Surgeon, Baylor, Houston; and Dr. Robert Beasley, Interventional Radiologist, Mount Sinai, Miami.

Nick Yeo continued, "The benefits of the BioMimics 3D helical centerline design have been well established in the MIMICS clinical research program. The most recent findings are the 3-year follow-up data from the pivotal MIMICS-2 study that were presented by Professor Thomas Zeller (University Heart Center Freiburg, Bad Krozingen, Germany) at CX 2020 Live in June. Professor Zeller reported that the 3-year freedom from clinically-driven target lesion revascularization (CDTLR) for BioMimics 3D was 81%; a result that he noted was comparable to outcomes with drug-coated and drug-eluting devices, despite treating more challenging lesions and without the need for lesion preparation. BioMimics 3D thus provides increased procedural simplicity for physicians, and durable, long-term clinical outcome benefit for patients."[1]

BioMimics 3D Vascular Stent System

The BioMimics 3D stent has a unique 3-dimensional helical shape, designed to impart natural curvature to the diseased femoropopliteal artery, promoting swirling flow and elevating wall shear, which has been proven to have a protective effect on the endothelium.[2] The helical shape of the BioMimics 3D stent is also designed to facilitate shortening of the stented segment during knee flexion and mitigate the risk of stented segment compression causing localised strains that in a straight stent may lead to stent fracture and chronic vascular injury.[3,4]



About Veryan Medical

Veryan became an Otsuka Medical Devices company in December 2018 and applies design intelligence to create medical devices for vascular intervention that improve patient care through a combination of imagination, intuition and innovation. Veryan has offices in Horsham, UK, and in Galway, Ireland, which is the location of the Veryan Innovation Centre, housing the Company's R&D activities. Veryan has direct sales teams in Germany and the US and has appointed distributors in other markets.
The BioMimics 3D Vascular Stent System has Premarket Approval in US and Japan and CE Mark approval in Europe. BioMimics 3D and Swirling Flow are registered trademarks of Veryan Medical Ltd.

About Otsuka Medical Devices

Otsuka Medical Devices focuses on the global development and commercialization of endovascular devices that provide new therapeutic options in areas where patient needs cannot be met through pharmaceutical or other conventional treatment. Otsuka Medical Devices Co., Ltd. is a subsidiary of Otsuka Holdings Co., Ltd. (www.otsuka.com/en), a leading global healthcare group listed on the Tokyo Stock Exchange (JP 4578). https://www.omd.otsuka.com/en/

About NJ Endovascular and Amputation Prevention, NJ.

NJ Endovascular & Amputation Prevention is affiliated with American Endovascular which operates specialized endovascular outpatient centers focused on limb savage. NJ Endovascular & Amputation Prevention is located in Clifton, NJ, and was the first location established for American Endovascular in May 2018. Utilizing the latest technology and the most sophisticated techniques, American Endovascular affiliated doctors have the extraordinary track record of saving more than 80% of patient limbs after they were told they needed an amputation.

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