PRESS RELEASE
24th January 2022

Michael Lichtenberg MD (Klinikum Hochsauerland, Arnsberg, Germany) announces the MIMICS-3D EU 3-year results at ISET 22.

Veryan Medical has confirmed the release at ISET 22 of the MIMICS-3D EU 3-year results by the study PI Michael Lichtenberg MD. MIMICS-3D EU is a prospective, multicentre, observational registry to evaluate the BioMimics 3D Vascular Stent System. The study evaluated safety, effectiveness and device performance within a real-world clinical population of 507 patients enrolled in 23 pan-European sites.

The mean age of enrolled patients was 70 years; 66% were male and 37% were diabetic. Rutherford 0-1, 2-4 and 5-6 were 1%, 82% and 17% respectively. Mean lesion length was 126mm and 57% of lesions were occlusions. Lesion calcification according to PACSS (Rocha-Singh KJ et al, 2014) was Grade #0 – 18%; #1 – 30%; #2 – 24%; #3 – 15%; #4 – 14%. BioMimics 3D placement followed atherectomy in 8% of lesions. Drug coated balloons (DCB) were combined with BioMimics 3D in 50% of lesions treated. Technical success for the BioMimics 3D implant procedure as assessed by the operator was 99%. An independent clinical events committee adjudicated major adverse events (MAE) including death and potential device-related events. The primary safety endpoint was a composite of MAE, comprising death, major index-limb amputation or clinically-driven target lesion revascularisation (CDTLR) through 30 days. The primary outcome measure for effectiveness is freedom from CDTLR through 12 months.

The Kaplan Meier (KM) estimate of freedom from CDTLR at 1 year, 2 years and 3 years in the ITT population was 90%, 82% and 78% respectively. The KM estimate of freedom from loss of primary stent patency (PSVR >2.4) through 3 years in the ITT population was 71%. There were 4/676 (0.6%) site-reported stent fractures

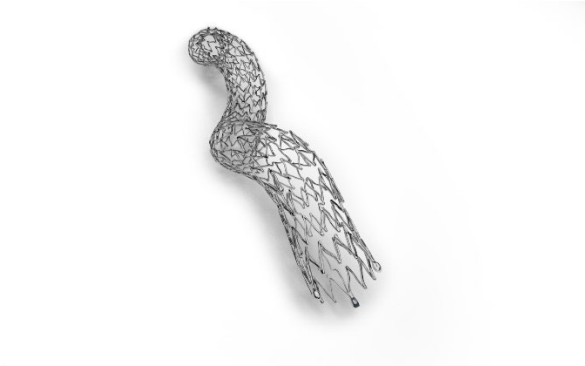
Dr Lichtenberg commented: "I have been using BioMimics in my daily clinical practice for 7 years and it is my 'go to' stent for a number of different indications, including long lesions, calcified lesions and lesions located in the distal SFA and proximal popliteal. I was delighted to be the PI for the MIMICS-3D study and am pleased that the results further validate earlier results from the MIMICS clinical programme, the combined database of which provides significant validation of the clinical benefits of swirling flow."

Nick Yeo, Veryan's CEO noted: "I would like to thank Dr Lichtenberg for his significant contribution to the successful running of the MIMICS-3D study, providing invaluable leadership and guidance throughout. I would also like to thank all the other investigators and study coordinators who contributed to the success of the study, and particularly for being so rigorous about the quality of data collected, which is unusual for a typical registry of this type. CDTLR and patency outcomes in the MIMICS-3D EU study are consistent with those of earlier MIMICS studies and are achieved in longer, more complex lesions. We are excited that these investigations into the post-market performance of BioMimics 3D support the hypothesis that imparting non-planar curvature onto the femoropopliteal arteries to promote swirling blood flow and increase wall shear stress, results in clinical outcomes that are comparable to those of drug-coated and drug-eluting devices."

END

About the 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 commercial and administrative offices in Horsham, UK, and the Veryan Innovation Centre in Galway, Ireland.
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.

For media enquiries please contact:
Vanessa Lee,
Director of Clinical Marketing, Veryan Medical Ltd.
vanessa.lee@veryanmed.com
+44 (0)1403 887396

References

1. Zeller T. Oral Presentation CX Live 2020
2. Caro et al. 2013 J R Soc Interface 10: 20130578
3. BH Smouse et al, Endovasc. Today, vol 4, no. 6, pp. 60-66, 2005
4. Scheinert D et al, J Am Coll Cardiol 2005;45:312-5