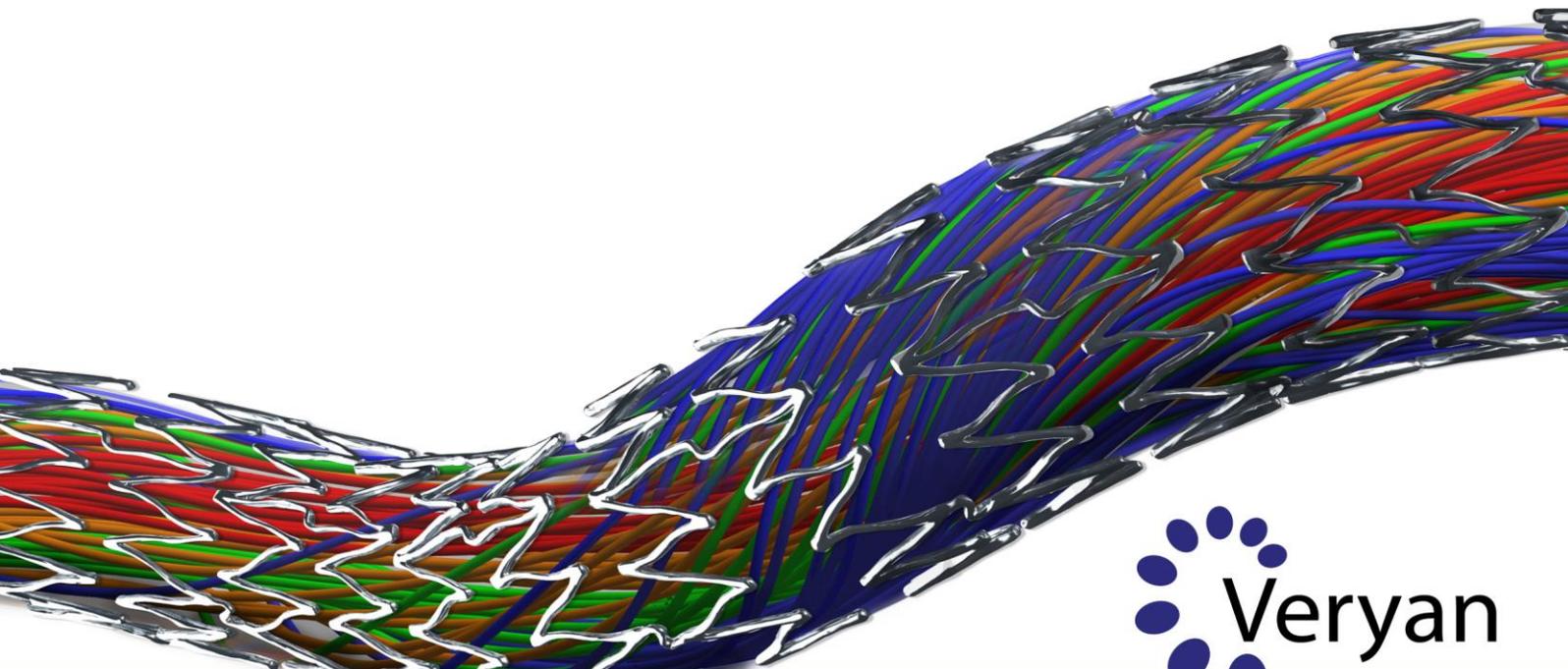


**PRESS RELEASE**

**20<sup>th</sup> June 2018, Horsham, UK:** Veryan Medical is delighted to announce completion of enrolment of the 500<sup>th</sup> subject in the MIMICS-3D pan-European registry, a prospective, multi-centre, observational registry to evaluate the BioMimics 3D Self-Expanding Stent System in the treatment of femoropopliteal artery disease. The Registry is evaluating safety, effectiveness and device performance within a real-world clinical population in combination with other therapies, including drug coated balloons and atherectomy devices, in 25 hospitals across Europe.

The MIMICS-3D Registry PI, Michael Lichtenberg MD (Arnsberg, Germany) commented: “I am delighted that this significant landmark in the MIMICS-3D registry has been reached. The clinical sites have been extremely committed to both the device and the study and the speed of enrolment and quality of the data being collected are impressive. I would like to extend my thanks to all involved for getting us to this stage.”

Veryan’s CEO Chas Taylor commented: “The fact that 500 patients were enrolled in just 18 months is testimony to the commitment of the participating clinical sites. I’d like to thank Dr Lichtenberg the PI for leading this important study and all of the investigators and the research personnel who contributed. To date, the MIMICS clinical programme has gathered impressive data on over 1000 patients in a growing database of clinical experience that is providing significant validation of the unique helical shape of BioMimics 3D and the benefits of Swirling Flow<sup>®</sup>. It is notable that there have been no fractures confirmed in any of these clinical study devices nor, indeed, in any BioMimics 3D device since the first one was implanted in February 2010.”



### **About BioMimics 3D Vascular Stent System**

The BioMimics 3D stent has a unique three-dimensional helical shape, designed to impart natural curvature to the diseased femoropopliteal artery, promoting swirling flow and elevating wall shear, which has a protective effect on the endothelium.<sup>1</sup> 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.<sup>2,3</sup>

### **About previous clinical studies in the MIMICS Clinical Programme**

#### ***MIMICS-2 - Evaluation of Safety and Effectiveness of the BioMimics 3D Stent System in the Femoropopliteal Arteries of Patients with Symptomatic Peripheral Arterial Disease.***

MIMICS-2 IDE study is a prospective, single-arm, multi-centre clinical study to evaluate the safety and effectiveness of the BioMimics 3D<sup>®</sup> Vascular Stent System in the treatment of patients with symptomatic atherosclerotic disease of the femoropopliteal artery. Conducted under an FDA Investigational Device Exemption (IDE) with concurrence of the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) under the FDA/PMDA Harmonisation By Doing collaboration, MIMICS-2 enrolled 271 subjects undergoing femoropopliteal intervention across 43 investigational sites in US, Japan and Germany 12-month safety and efficacy data.

Both the primary safety and effectiveness endpoints were met; there were no stent fractures; the Kaplan-Meier estimate of freedom from loss of primary patency at 12 months was 81.9% at Day 365 and the Kaplan-Meier estimate of freedom from clinically driven target lesion revascularisation (CD TLR) at 12 months was 88.8%.<sup>4</sup> These MIMICS-2 results reinforce the results of the Company's earlier MIMICS-RCT study in a larger, more challenging patient population.

#### ***MIMICS-RCT (Randomised Controlled Trial)***

MIMICS-RCT is the first randomised trial that compared two bare-metal stents to treat symptomatic disease of the superficial femoral and popliteal arteries and demonstrated that stent design influences clinical outcome. Use of the BioMimics 3D helical stent resulted in higher patency at 2 years when compared with a straight stent. This study is the first demonstration of the benefits of the BioMimics helical stent design, which when implanted imparts natural curvature to the diseased artery, promoting swirling blood flow to improve the outcome of peripheral intervention. The 2-year results from MIMICS-RCT were published by Zeller et al. in *Circulation Cardiovascular Interventions Helical Centerline Stent Improves patency: Two-Year Results From the Randomized Mimics Trial. June 2016.*

1. Zeller T. - Oral Presentation VIVA 2014.
2. BH Smouse et al, *Endovasc. Today*, vol 4, no. 6, pp. 60-66, 2005
3. Scheinert D et al, *J Am Coll Cardiol* 2005;45:312-5 doi:10.1016/j.jacc.2004.11.026
4. Zeller T. – Oral Presentation LINC 2018

### **About Veryan Medical Ltd.**

Veryan's Head Office is in Horsham, UK and its Research & Development facility is located in Galway, Ireland.

BioMimics 3D and Swirling Flow are registered trademarks of Veryan Medical Ltd., and the BioMimics 3D stent has CE Mark approval.

CAUTION: Investigational Device. Limited by Federal (or United States) Law to Investigational Use.

For further information, please visit: [www.veryanmed.com](http://www.veryanmed.com)

**Media Contact:**

Vanessa Lee

Email: [vanessa.lee@veryanmed.com](mailto:vanessa.lee@veryanmed.com)

Tel: +44 (0)1403 258984

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