BioMimics 3D

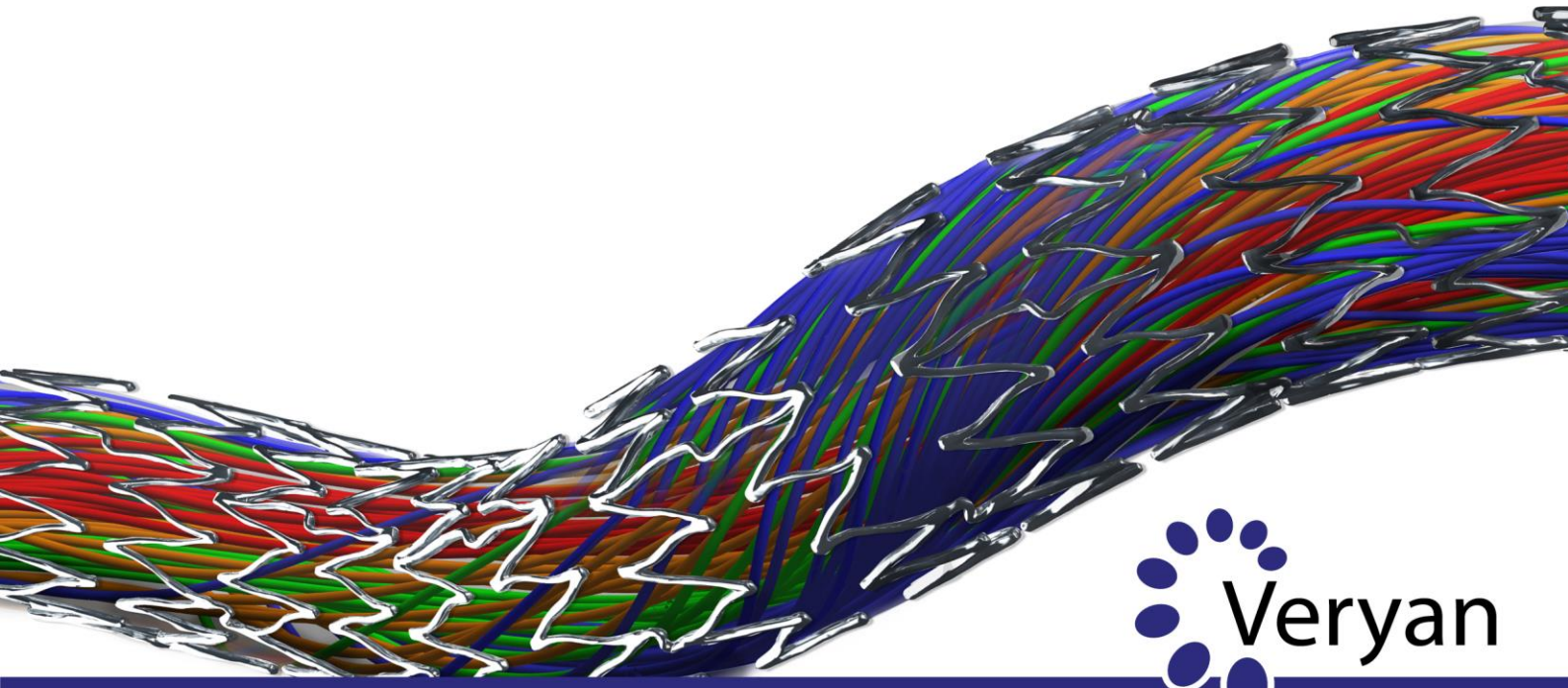
The Swirling Flow® Stent

# PRESS RELEASE

**1st February 2018**: Veryan Medical today announces that the Company has submitted a Premarket Approval (PMA) application for the BioMimics 3D Vascular Stent System to the U.S. Food & Drug Administration.

Pivotal to the content of the PMA application are the 12-month interim safety and effectiveness results from the Company's MIMICS-2 clinical study in patients undergoing endovascular intervention to relieve obstructive or occlusive disease in the femoropopliteal artery. BioMimics 3D represents an innovative approach to the requirement for durable support for the arterial lumen after intervention and the helical centreline stent is designed to promote swirling blood flow and accommodate the complex biomechanical challenge associated with stenting this anatomically mobile artery. Conducted under an FDA Investigational Device Exemption 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. Enrollment into the study was completed in 15 months, making MIMICS-2 one of the fastest enrolling peripheral stent studies and with outstanding support from these sites and the core laboratories undertaking imaging and clinical event adjudication, the Company was able to lock the database within one week of the last subject's 12-month visit. Analysis of the data, presented at LINC 2018 by co-Principal Investigator Professor Thomas Zeller, showed that both 30-day freedom from major adverse events and 12-month primary patency endpoints were met, and no stent fractures were detected.

Chas Taylor, Veryan's Chief Executive Officer commented: "The achievement of a successful outcome to our pivotal study, which has provided data for our premarket approval applications in US and Japan, is a major milestone for Veryan as we build toward global commercialisation of our BioMimics 3D swirling flow stent. The efficiency that has been achieved in compressing the cycle of clinical development has contributed substantially to business value and we are very grateful for the professional and enthusiastic support given by everyone involved in the MIMICS-2 Study.



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We are delighted in the MIMICS-2 results that reinforce those from our earlier Mimics randomised clinical trial and these combined results support our belief that BioMimics 3D stands to become the first-choice nitinol stent for both primary and complementary stenting in the femoropopliteal artery. I am also very proud of the Veryan team in being able to complete our first US PMA submission document in less than 6 weeks from database lock and anticipate the Japanese submission will be filed this quarter."

**BioMimics 3D Vascular Stent System**

The BioMimics 3D stent has 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.[1] 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.[2,3] In the Mimics trial, the Kaplan Meier (KM) survival estimate of freedom from loss of primary patency at two years was 72% for BioMimics 3D subjects vs. 55.0% for the control arm. The difference in survival estimate between the two groups by log rank test was significant (p=0.05). Importantly, there was no increase in the KM estimate for clinically driven target lesion revascularisation (CDTLR) rate in those subjects treated with BioMimics 3D between 12 and 24 months (9% at both time-points) compared to a 3-fold increase (8% at 12 months and 24% at 24 months) in the straight stent control arm.[4]


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 Cardiel 2005;45:312-5 doi:10.1016/j.jacc.2004.11.026
4. Zeller T. et al; Circ Cardiovasc lnterv. 2016;9:e002930. DOI: 10.1161 2- Data on file at Veryan Medical


**About Veryan Medical Ltd.**

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

BioMimics 3D is a registered trademark of Veryan Medical Ltd, and the BioMimics 3D Stent System has CE Mark approval.

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

For further information, please visit: www.veryanmed.com

**Media Contact:**


Richard Kenyon
Email: richardkenyon44@hotmail.com
Tel: +44 (0)7831 569940


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