BioMimics 3D
The Swirling Flow® Stent

PRESS RELEASE

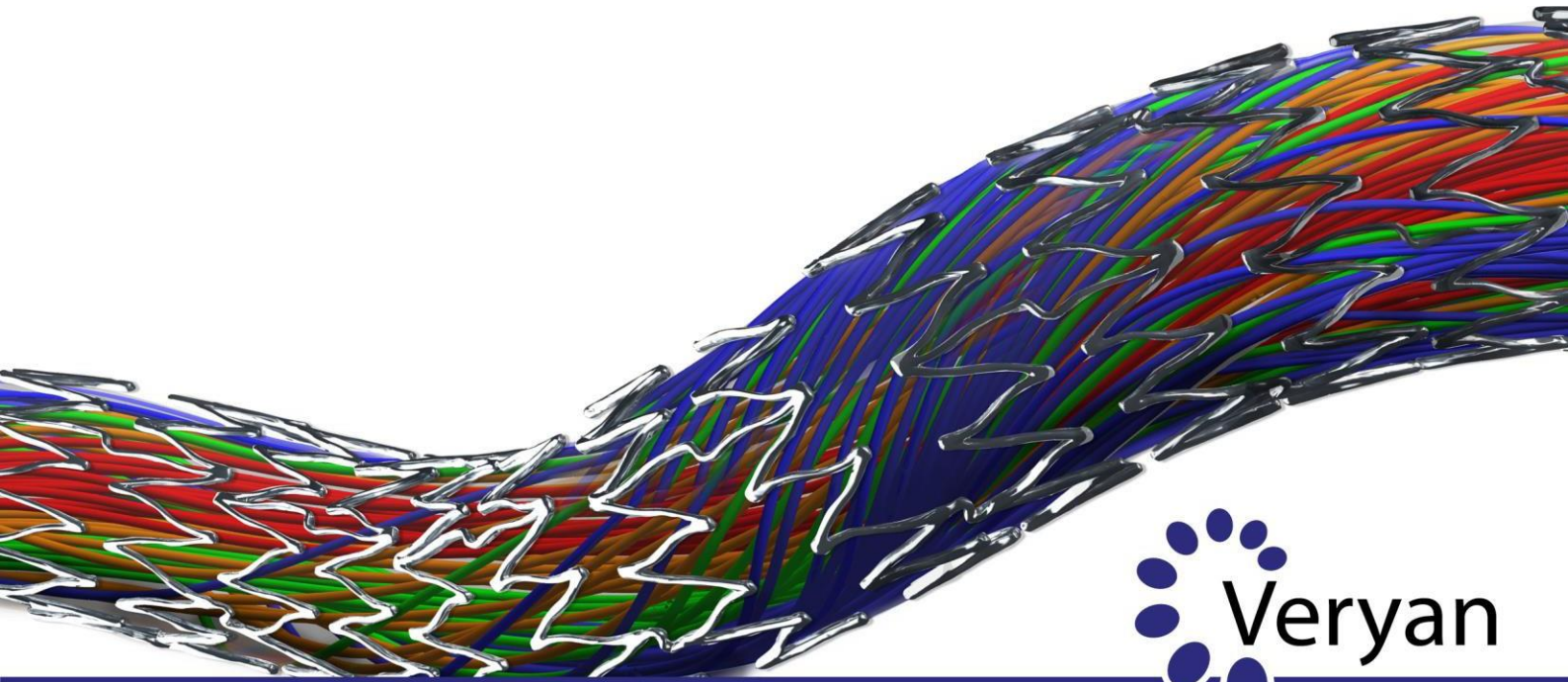
04 October 2018: Veryan Medical Ltd (Horsham, UK) today announced that the Company has received Premarket Approval (PMA) for the BioMimics 3D Vascular Stent System from the U.S. Food & Drug Administration (FDA). The device is approved for the treatment of symptomatic de novo or restenotic lesions in the native superficial femoral artery and/or proximal popliteal artery.

The BioMimics 3D stent has a unique three-dimensional helical shape, designed to impart natural curvature to the diseased femoropopliteal artery, to promote swirling flow and elevate wall shear, which has a protective effect on the endothelium.[1,2,3] Key components of the PMA application were the 12-month interim safety and effectiveness results from the Company's MIMICS-2 clinical study conducted under an FDA-approved Investigational Device Exemption (IDE) in patients with peripheral arterial disease undergoing endovascular intervention in the femoropopliteal artery. BioMimics 3D represents an innovative approach to the requirement for durable support for the arterial lumen after intervention. The helical centreline stent is designed to not only promote swirling blood flow but also to accommodate the complex biomechanical challenge associated with stenting this anatomically mobile artery.

The MIMICS-2 study enrolled 271 subjects across 43 investigational sites in US, Japan and Germany. The Principal Investigators are Timothy M. Sullivan (Minneapolis, MN, USA), Masato Nakamura (Tokyo, Japan) and Thomas Zeller (Bad Krozingen, Germany).

Both primary endpoints in the MIMICS-2 study, safety and effectiveness, were met. Freedom from major adverse events at 30 days was 99.6% (268/269) and Kaplan-Meier (KM) estimates of freedom from loss of primary patency and clinically-driven target lesion revascularization (CDTLR), were 83% and 88%, respectively, at 12-months; no stent fractures were detected in core laboratory imaging review.[4]

Chas Taylor, Veryan's Chief Executive Officer commented: "We are delighted with the US FDA Premarket Approval, which is a major milestone for Veryan as we build towards global commercialisation of our BioMimics 3D Swirling Flow stent. I thank FDA for their invaluable support throughout the IDE/PMA process and applaud the hard work of all our staff in making this approval process so swift and straightforward.



Veryan

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The compelling MIMICS-2 results reinforce those from our earlier Mimics randomised clinical trial and the combined results support our belief that BioMimics 3D stands to become a first-choice nitinol stent for both primary and complementary stenting in the femoropopliteal artery."

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, to promote swirling flow and elevate wall shear, which has a protective effect on the endothelium.[1,2,3] 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.[5,6]

1. Zeller T. - Oral Presentation VIVA 2014
2. Malek, JAMA, 282, p 2035-2042, 1999
3. Zeller T. et al; Circ Cardiovasc lnterv. 2016;9:e002930. DOI: 10.1161 2
4. Data on file at Veryan Medical
5. BH Smouse et al, Endovasc. Today, vol 4, no. 6, pp. 60-66, 2005
6. Scheinert D et al, J Am Coll Cardiel 2005;45:312-5 doi:10.1016/j.jacc.2004.11.026

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. The BioMimics 3D Vascular Stent System has FDA and CE Mark approval.

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

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