PRESS RELEASE

Veryan Medical announces the achievement of four significant milestones in its MIMICS clinical programme: the publication of the Mimics Study article; the enrolment of the 200th patient in the MIMICS-2 IDE Study; the 1st live case transmission from a US MIMICS-2 investigational site, and the start of its MIMICS-3D Registry

13 June 2016 - Veryan Medical has announced that results from the Mimics Randomised Controlled Trial have been published in the latest issue of Circulation: Cardiovascular Interventions.

The article entitled Helical Centerline Stent Improves patency: Two-Year Results From the Randomized Mimics Trial, was authored by Professor Thomas Zeller MD, Professor Peter Gaines MD, Gary Ansel, MD and Professor Colin Caro. The Mimics trial 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 stent design, which when implanted imparts natural curvature to the diseased artery, promoting swirling blood flow to improve the outcome of peripheral intervention.
Veryan has also announced that the 200th patient has been enrolled into the MIMICS-2 study. MIMICS-2 is a prospective, single-arm, multicentre clinical study of 280 patients at more than 40 investigational sites in the US, Germany and Japan. The Study is being conducted under an FDA Investigational Device Exemption (IDE), with Japanese PMDA concurrence through the Harmonization by Doing initiative, to provide clinical data to support parallel premarket approval reviews in US and Japan. Professor Thomas Zeller (Bad Krozingen, Germany), MIMICS-2 German National PI commented: “The outstanding effort and diligence of all investigators and research coordinators is making the MIMICS-2 Study the fastest-ever enrolling SFA stenting study of its type. There is a lot of commitment from everyone involved in this important study and we eagerly look forward to completing enrolment in the summer.” Veryan is delighted that a MIMICS-2 case was featured live via satellite at this month’s New Cardiovascular Horizons Annual Conference in New Orleans. BioMimics 3D stent implantation in a patient enrolled into MIMICS-2 by Study Principal Investigator Dr Tom Davis was transmitted live from St. John Providence Hospital and Medical Center, Detroit, MI. The case can be viewed at www.ncvh.org (see presentation at 1:50pm June 1st, 2016) or via a link on Veryan’s website www.veryanmed.com.

Veryan is also anticipating the first patient being enrolled into the Company-sponsored MIMICS-3D Registry. MIMICS-3D is a prospective, multicentre, observational registry to evaluate the BioMimics 3D Self-Expanding Stent System in the treatment of peripheral arterial disease. The Registry will evaluate safety, effectiveness and device performance within a real-world clinical population in a minimum of 500 patients across Europe. The MIMICS-3D Registry PI, Michael Lichtenberg MD (Arnsberg, Germany) commented: “Having been able to enroll a significant number of patients into the MIMICS-2 IDE Study I am delighted to be the PI of the MIMICS-3D Registry. The three studies within the MIMICS programme will provide a combined database of clinical experience that I expect to provide significant validation of the unique helical shape of BioMimics 3D and the benefits of swirling flow.”

Chas Taylor, Veryan CEO commented: “Each of these milestones illustrates Veryan’s commitment to seek high quality, compelling clinical data for our BioMimics 3D stent. We believe this demonstrates the enthusiasm that clinicians have for this novel technology and the exceptional productivity of our clinical development resources.”
BioMimics 3D Stent System

BioMimics 3D, a nitinol stent with unique three-dimensional helical geometry, has been developed by Veryan, based on pioneering research by Prof Colin Caro at Imperial College London into the link between blood flow mechanics and vascular disease. The BioMimics 3D nitinol stent has unique helical curvature to impart natural curvature to the diseased artery, promoting secondary (swirling) flow and elevated wall shear stress, which has a protective effect on the endothelium. The helical geometry of the BioMimics 3D femoropopliteal 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. 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 of clinically driven target lesion revascularization (CDTLR) rate in the BioMimics arm 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.
**About Veryan Medical Ltd.**

Veryan is developing innovative solutions to improve the performance of vascular stents using the principles of biomimicry. Veryan’s BioMimics 3D® stent technology involves adapting traditional straight stent designs to a patented three-dimensional helical shape, which more closely mimics the natural geometry of the human vascular system. BioMimics 3D technology is designed to enhance clinical performance by improving flow conditions in, and biomechanical performance of, stented vessels. The advanced, biomimetic design of the BioMimics 3D stent is intended to provide more flexibility, kink and fracture resistance than other laser-cut nitinol tube stents, making its unique design of particular importance in the hostile environment of the femoropopliteal artery. 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 for European marketing.

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)

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