



Veryan | Press Release



Veryan Receives CE Mark Approval for BioMimics 3D™ Stent

14 November 2012 – Vascular disease specialist Veryan has received CE Mark approval for the BioMimics 3D™ stent, its novel platform technology designed for treatment of the superficial femoral and proximal popliteal (femoropopliteal) arteries of the leg.

The BioMimics 3D™ stent features a unique three-dimensional design that mimics the natural helical geometry of the human vascular system. The intention of the design is to improve characteristics of blood flow in the stented segment that may confer a vasoprotective effect and enhance biomechanical performance, with the prospect that kinking, deformation and consequential vessel trauma during leg flexion may be reduced, compared to a standard nitinol stent.

CE Mark approval was based on meeting the primary endpoints of the MIMICS study, a prospective randomised controlled trial comparing the safety and efficacy of the BioMimics 3D stent with a standard nitinol stent in patients with peripheral artery disease undergoing femoropopliteal artery intervention. The BioMimics 3D stent demonstrated an excellent safety profile and promising clinical performance at both 6 and 12 month time points. Follow-up assessments of patients in the MIMICS study will continue for two years.

Interim data were presented at the VIVA (Vascular InterVentional Advances) meeting in Las Vegas in October 2012. At six months, all 50 patients that received treatment with the BioMimics 3D stent were free from clinically-driven target lesion revascularisation (CD TLR), and there were no deaths or amputations. Of the 36 patients treated with BioMimics 3D stents who had reached the 12-month follow-up time point, 33(91.7%) remained free from CD TLR, compared with 18 of the 21 (85.7%) from the control group who reached the same follow-up time point. The independent core lab has not detected any stent fractures to date in either treatment group.

“Besides reducing the risk of stent fracture, the unique BioMimics 3D stent architecture has been shown in preclinical animal studies to transform a laminar flow into a swirling flow, a phenomenon known to increase wall shear stress, which may mitigate the development of neointimal hyperproliferation”, commented MIMICS Principal Investigator Professor Thomas Zeller, University Heart Centre, Freiburg-Bad Krozingen, Germany. “The six-month results of the trial have proven the safety of the new stent design, and we are eagerly awaiting the twelve-month patency results where we expect at least a positive performance signal”.

“CE Mark is an important milestone for Veryan. In conjunction with the encouraging data from the MIMICS study recently presented at the prestigious VIVA conference in Las Vegas, we are greatly encouraged that the unique geometry of the BioMimics 3D stent will be highly competitive against conventional straight nitinol stents” added Veryan Chief Executive Chas Taylor. “We believe the ability to take this differentiated platform technology to market may contribute significantly to fulfilling the need for more durable clinical outcomes in patients with PAD undergoing endovascular intervention.”

Following CE Mark approval, Veryan is now preparing plans to commercialise the BioMimics 3D stent system, both in Europe and other markets where CE Mark approval may expedite the registration process.



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About Veryan

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 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 bio-mechanical performance of, stented vessels.

Pre-clinical studies have shown that BioMimics 3D stent technology may significantly reduce restenosis (the narrowing of stented arterial segments) and confer significant mechanical benefits: the BioMimics 3D stent is more flexible, kink and fracture resistant than conventional counterparts.

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

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