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MicroPort
Targeted therapy with a localised abluminal groove, low-dose sirolimus-eluting, biodegradable polymer coronary stent (TARGETT All Comers): a multicentre, open-label, randomised non-inferiority trial

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FIREHAWK® CLINICAL DATA FROM THE TARGET AC EUROPEAN CLINICAL TRIAL HAS BEEN ACCEPTED FOR PUBLICATION IN THE PRESTIGIOUS MEDICAL JOURNAL THE LANCET

Shanghai, China – September 4, 2018. MicroPort Scientific Corporation (“MicroPort™”, HK:0853) announced today that the clinical trial results for its Firehawk® Rapamycin Target Eluting Coronary Stent System (“Firehawk™”) which conducted a multi-center, randomized controlled trial called TARGET AC has been published online in The Lancet, a world leading medical journal currently ranked second out of 154 journals in the Medicine, General & Internal subject category. The title of The Lancet publication regarding Firehawk® is Targeted therapy with a localised abluminal groove, low-dose sirolimus-eluting, biodegradable polymer coronary stent (TARGET All Comers): a multicentre, open-label, randomised non-inferiority trial.

The TARGET AC trial was a prospective, multi-center, randomized controlled clinical trial consisting of entirely European based patients. This clinical study enrolled its first patient in December 2015 and completed enrollment of its last patient in October 2016. In total, there were 1,653 patients enrolled from 21 clinical study sites throughout Europe including countries such as the United Kingdom, France, Spain, Italy, Belgium, the Netherlands, Poland, Germany, Austria and Denmark.
Firehawk® met the trial’s non-inferiority primary endpoint which was the TLF (Target Lesion Failure) rate at 12 months as compared to the control arm represented by the Xience stent family, 6.1 percent versus 5.9 percent (pnon-inferior=0.004), respectively. No statistically significant differences in TLF components were observed between the two stents. The following data were also observed at 12 months post implantation for the Firehawk® stent and Xience family stents, respectively: cardiac death (1.2 percent vs. 0.9 percent, p=0.60), myocardial infarction (MI) related to the target vessel (4.5 percent vs. 3.9 percent, p=0.59), ischemia-driven target lesion revascularization (TLR, 1.2 percent vs. 2.4 percent, p=0.08), stent thrombosis rate (ARC definite, 1.2 percent vs. 1.2 percent, p=0.99). Of note, the TLR rate was lower in the Firehawk® stent group and the stent thrombosis rate was the same for both Firehawk® and Xience family stents.

“TARGET AC confirms that the Firehawk®, a low dose sirolimus eluting biodegradable polymer DES, is safe and effective across a broad spectrum of patient and lesion complexity,” said lead author Professor Alexandra Lansky, Yale University School of Medicine.
“This is a landmark achievement by MicroPort® given that this is the first time that clinical data from a China manufactured drug eluting stent has been published in such a prestigious medical journal such as The Lancet,” said Dr. Zhaohua Chang, Founder Chairman and CEO of MicroPort®. “With the Firehawk® clinical results having been validated in such a rigorous peer-reviewed publication, clinicians and patients should have every confidence in the safety and efficacy of Firehawk® to treat patients with coronary artery disease. We strongly believe and expect that the Firehawk® stent will be used to save millions of patients globally in the years to come. As a company, MicroPort® will continue to be at the forefront of developing and providing revolutionary medical technology solutions to meet the unending demand for health and longevity in extending patient lives.”

Firehawk® is MicroPort®’s third generation drug eluting stent developed to treat patients with coronary artery disease. The unique innovation of Firehawk® is the design where the drug and biodegradable polymer are eluted from micro grooves laser-cut on the abluminal side of the stent struts. The total surface area of all the grooves is less than 5% of the total surface area of the stent struts while 95% of the stent surface area remains bare metal. This target eluting design allows Firehawk® to achieve the same level of clinical efficacy as the “best-in-class” drug-eluting stents, but with the lowest drug dosage. Furthermore, Firehawk® overcomes the late thrombosis event weakness inherent in drug eluting stents while maintaining a long-term safety profile commensurate of bare metal stents.”
Late thrombosis is an extremely dangerous event for the patients, and once the event occurs the mortality rate can be as high as 50%. Delivering drug from the stent to the arterial wall of the coronary artery can be both beneficial and harmful, and resolving both restenosis and late stage thrombosis has been a dilemma that has challenged interventional cardiologist experts for more than a decade. This concept of target elution from Firehawk® has now been clinically proven to offer an ideal solution by delivering the lowest amount of drug to prevent restenosis while also exhibiting very low late-thrombosis rates.

As of end of 2017, approximately 4.5 million coronary stents manufactured by MicroPort®, including the Firehawk® stent, have been implanted in over 3.5 million patients worldwide. Firehawk® has now been approved for use and marketed in 36 countries and territories globally.

MicroPort® plans to continue to advance the robust clinical program supporting the Firehawk® stent with the initiation of the TARGET Short Dual Anti-Platelet Therapy ("DAPT") Study which will assess the effectiveness and safety on shortening DAPT for PCI patients with Firehawk® implantation. The enrollment of TARGET DAPT is expected to complete by 1H 2020.

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