

Miracor Medical's PiCSO® System receives CE Mark

Awans, Belgium, June 23, 2020 - Miracor Medical SA (Miracor Medical) has announced the award of the CE Mark for its latest generation of PiCSO Impulse Catheter and PiCSO Impulse Console, which is indicated for the treatment of anterior STEMI patients. The new system features improvements in ease of use.

PiCSO therapy is delivered by interventional cardiologists during the primary PCI (Percutaneous Coronary Intervention) procedure in patients experiencing anterior ST-elevated myocardial infarction (STEMI). Despite all improvements and widespread use of reperfusion strategies and adjuvant pharmacological therapies¹ the one-year mortality rate for STEMI has plateaued at 14% and heart failure occurs in up to 28% of patients within the first 90 days². However, via its unique mechanism of action, the PiCSO Impulse System reduces the infarct size by intermittently occluding the coronary sinus outflow leading to improved microcirculatory function. Infarct size is strongly associated with reductions in heart failure hospitalizations and reduced mortality³.

The CE Mark file was supported by clinical data from both the PiCSO in ACS⁴ study, which was recently published, and the OxAMI-PiCSO⁵ study, confirming that the use of the PiCSO Impulse System is associated with statistically significant infarct size reduction. Furthermore, OxAMI PiCSO showed improvement of coronary microvascular function post PiCSO treatment by accelerating the coronary microcirculation recovery resulting in significantly lower IMR (Index of Microcirculatory Resistance) at 24 to 48 hours when compared to controls, also leading to overall infarct size reduction.

"We are very excited to have CE Mark for the next-generation PiCSO Impulse System. This was an intense effort by everyone at Miracor and I wish to congratulate the Miracor team, our physician partners and clinical steering committee members for this achievement! The CE Mark is a great milestone and our market access strategies over the next 12-18 months will generate new clinical data and facilitate the commercial roll-out in the second half of 2021." said Olivier Delporte, CEO.

Miracor is currently recruiting patients in a landmark European randomized controlled trial, PiCSO-AMI-I, to further demonstrate the benefits of PiCSO therapy as compared with conventional PCI for the treatment of anterior STEMI patients.

The development of Miracor's PiCSO technology is supported by a reimbursable cash advance from the Walloon Region since August 2017. This financial grant covers 55% of the technical and clinical research for the product.

About Miracor Medical

Miracor Medical (www.miracormedical.com), located in Awans, Belgium, provides innovative solutions for the treatment of severe cardiac diseases, aiming to improve short and long-term clinical outcomes and reduce associated cost.

Miracor Medical has developed the PiCSO Impulse System, the first and only coronary sinus intervention designed to reduce infarct size, improve cardiac function by clearing

microcirculation and potentially reduce the onset of heart failure following acute myocardial infarction.

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NOTE: The PiCSO® Impulse System is not approved for use in the United States.

- ¹ Szummer, K., et al., Improved outcomes in patients with ST-elevation myocardial infarction during the last 20 years are related to implementation of evidence-based treatments: experiences from the SWEDEHEART registry 1995–2014. *European Heart Journal*, 2017. 38(41): p. 3056-3065.
- ² Cahill et al. Heart failure after myocardial infarction in the era of primary percutaneous coronary intervention: Mechanisms, incidence and identification of patients at risk. *World J Cardiol*. 2017 May 26;9(5), 407-415.
- ³ Stone et al. Relationship Between Infarct Size and Outcomes Following Primary PCI: Patient-Level Analysis From 10 Randomized Trials. *J Am Coll Cardiol*. 2016 Apr 12, 67(14), 1674-1683.
- ⁴ Egred, M., et al., Effect of Pressure-controlled intermittent Coronary Sinus Occlusion (PiCSO) on infarct size in anterior STEMI: PiCSO in ACS study. *IJC Heart & Vasculature*, 2020. 28: p. 100526.
- ⁵ De Maria et al. Index of microcirculatory resistance-guided therapy with pressure-controlled intermittent coronary sinus occlusion improves coronary microvascular function and reduces infarct size in patients with ST-elevation myocardial infarction: the Oxford Acute Myocardial Infarction - Pressure-controlled Intermittent Coronary Sinus Occlusion study (OxAMI-PiCSO study). *EuroIntervention* 2018;14(3):e352-e359.

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