Miracor Medical starts PiCSO-AMI-I randomized study in EU

Awans, Belgium, July 25th, 2019 - Miracor Medical SA (Miracor Medical) today announced the initiation and first patient enrollment in the PICSO-AMI-I study to evaluate the benefits of PiCSO® therapy compared with conventional PCI for the treatment of anterior STEMI patients.

The first patient enrolled into this study was treated at Oxford Heart Center, Oxford, UK by Professor Adrian Banning, the principal investigator of the study. “We are delighted to be initiating the PiCSO-AMI-I study. This study will explore the potential for PiCSO therapy to significantly improve the care of patients with larger heart attacks. My group and I have treated over 30 patients with the PiCSO therapy and we are excited to start this important randomized study, which builds upon the existing registry data. Improving outcomes for patients with large heart attacks is an important challenge and is an important unmet need currently. With this trial we hope to help define the long-term impact and benefits of the PiCSO therapy,” says Prof. Banning.

PICSO-AMI-I is a prospective, randomized, double-arm, multicenter study and will enroll 144 patients presenting with anterior STEMI, TIMI 0 & 1 Flow, at up to 9 clinical sites in Western Europe. The study is designed to prove superiority of PiCSO used as an adjunct to PCI over a conventional strategy of PCI alone, in reducing infarct size measured by CMR at 5 days.

Secondary efficacy endpoints include MVO and cardiac function (EF, LVESV, LVEDV) at 5 days and 6 months. Secondary clinical endpoints include death, heart failure-related hospitalization, new onset or worsening of heart failure. The clinical endpoints will be followed up annually for 3 years.

The PiCSO therapy has shown in several clinical studies positive results. Data from two recent studies (“PiCSO in ACS” and “OxAMI-PICSO”) showed that the use of the PiCSO Impulse System is associated with a significant infarct size reduction [1,2]. Furthermore, OxAMI-PICSO showed an early improvement of coronary microvascular function post PiCSO treatment. PiCSO therapy accelerates the microcirculatory recovery resulting in significantly lower IMR (Index of Microcirculatory Resistance) at 24-48 hours when compared to controls leading to overall infarct size reduction [1].

“We are thrilled to start this randomized clinical trial in Europe, and to include world-leading institutions in our clinical investigation. This study is designed to provide the definitive proof of the clinical benefit of PiCSO over conventional standard of care for STEMI patients, and has the potential to bring PiCSO to guidelines for the treatment of this STEMI patient population.”, says Olivier Delporte, CEO of Miracor Medical.

PiCSO therapy is provided during the PCI (Percutaneous Coronary Intervention) in patients enduring acute myocardial infarct (AMI). The PiCSO Impulse System clears the coronary microcirculation by intermittently occluding the coronary sinus outflow resulting in improved perfusion of the infarcted area. This mechanism of action is unique and very

differentiated. The use of the PiCSO Impulse System offers advantages of reducing the infarct size after AMI, and infarct size reductions lead to reductions in heart failure hospitalizations and reduced mortality [3]. Heart Failure develops in 18-28% of patients 90 days after their STEMI [4].

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 develops the PiCSO Impulse System, the first and only coronary sinus intervention designed to reduce infarct size, improve cardiac function and potentially reduce the onset of heart failure following acute myocardial infarction.

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NOTE: The PiCSO® Impulse System is not commercially available.

[1] 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

[2] Egred et al. Pressure-controlled intermittent Coronary Sinus Occlusion (PiCSO) reduces Infarct Size after primary PCI: A propensity - controlled matched study (EuroPCR 2018 poster/abstract)

[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] 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.

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