

Miracor Medical starts 2nd randomized study, targeting expanded indications.

300 patients have been treated with PiCSO®

Awans, Belgium, March 29, 2022 - Miracor Medical SA (Miracor Medical) today announced the first patient enrolled in the PiCSO-AMI-V study to evaluate the benefits of PiCSO® (Pressure-controlled intermittent Coronary Sinus Occlusion) therapy as an adjunct to conventional primary percutaneous coronary intervention (PCI) for patients presenting with inferior ST-Elevation Myocardial Infarction (STEMI).

The first patient enrolled was treated at the University Hospital of Toulouse, France by the team of Professor Didier Carrié (Drs T. Lhermusier and F. Campelo). *“Our team started using the PiCSO therapy for anterior STEMI patients in 2021. We are delighted to explore new indications and now start using PiCSO for inferior STEMI patients in the context of the PiCSO-AMI-V study,”* says Prof. Carrié.

The principal investigator of the study is Professor Adrian Banning, Oxford Heart Center, Oxford, UK. *“We are pleased to be initiating the PiCSO-AMI-V study. It will explore the potential for PiCSO therapy to improve the outcomes of patients with heart attacks affecting the inferior side of the heart. The study builds upon the data from the First-In-Man study that we published in 2021³. We know that improving outcomes for patients with large heart attacks remains an important unmet need, especially because these patients often progress to develop heart failure.”* says Prof. Banning.

PiCSO-AMI-V is a prospective, randomized, multicenter feasibility study and will enroll 75 inferior STEMI patients presenting with TIMI 0 & 1 flow, at up to 10 clinical sites in Europe. In the study, patients will be randomized 2:1 to a group receiving PiCSO as an adjunct to their primary PCI procedure versus a conventional strategy of primary PCI alone. Adverse Device Effect (ADE) rate at 30 days post index procedure will be assessed as the primary endpoint. In addition, cardiac function and clinical safety endpoints - including death, heart failure-related hospitalization, new onset or worsening of heart failure – will be assessed. The patients will be followed for 1 year.

PiCSO therapy has demonstrated positive results in several clinical studies. 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 in anterior STEMI patients ^{1,2}. Furthermore, OxAMI-PiCSO³ showed an early improvement in coronary microvascular function post PiCSO treatment in both anterior and inferior STEMI patients. PiCSO therapy accelerates the microcirculatory recovery resulting in significantly lower IMR (Index of Microcirculatory Resistance) and RRR (Resistive Reserve Ratio) post procedure when compared with controls.

“We are thrilled to start this second randomized clinical trial in Europe, and to progress our strategy to expand indications beyond our initial indication of anterior STEMI. The PiCSO-AMI-V Inferior STEMI study will complement the ongoing PiCSO-AMI-I (Anterior STEMI) study, which has enrolled more than 100 anterior STEMI patients and is anticipated to complete enrollment during the second semester of this year. We also

recently treated the 300th patient with the PiCSO therapy, illustrating the acceleration of usage and experience with the therapy,” says Olivier Delporte, CEO of Miracor Medical.

PiCSO therapy is used during the primary PCI procedure in acute myocardial infarct (AMI). Via its unique differentiated mechanism of action the PiCSO Impulse System clears the coronary microcirculation by intermittently occluding the coronary sinus outflow. The use of the PiCSO Impulse System has been associated with a reduction in infarct size after STEMI, which has been shown to lead to reductions in heart failure hospitalizations and reduced mortality⁴. Heart Failure develops in 18-28% of patients 90 days after their STEMI⁵.

The PiCSO-AMI-V Inferior STEMI study is partially funded by a recoverable cash advance granted by the Walloon Region to Miracor Medical.

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.

#####

NOTE: The PiCSO[®] Impulse System is commercially available for anterior STEMI patients in EU, UK and EFTA. It is not commercially available for inferior STEMI patients.

¹ De Maria, et al. (2018). 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 Eged, et al. (2020). Effect of Pressure-controlled intermittent Coronary Sinus Occlusion (PiCSO) on infarct size in anterior STEMI: PiCSO in ACS study. *Int J Cardiol Heart Vasc*, 28, 100526. <https://doi.org/10.1016/j.ijcha.2020.100526>

³ Scarsini, et al. (2021), Oxford Acute Myocardial Infarction, S., Kharbanda, R., Ferreira, V. M., Channon, K. M., De Maria, G. L., & Banning, A. P. (2021). Pressure-controlled intermittent coronary sinus occlusion improves the vasodilatory microvascular capacity and reduces myocardial injury in patients with STEMI. *Catheter Cardiovasc Interv*, Epub ahead of print (doi: 10.1002/ccd.29793). <https://doi.org/10.1002/ccd.29793>

⁴ Stone, et al. (2016). 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.

⁵ Cahill, et al. (2017). 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.

Contact:

Olivier Delporte
CEO

Miracor Medical SA

odelporte@miracormedical.com