

Miracor Announces Positive Interim Clinical Data with Novel PiCSO® Impulse System for AMI Patients

Clinical results in STEMI patients and promising initial clinical experiences in other applications presented at EuroPCR 2017

VIENNA, Austria, June 6, 2017 – <u>Miracor Medical Systems</u> GmbH (Miracor) announced today that interim clinical data presented earlier this month at EuroPCR 2017 in Paris demonstrated significant reductions in infarct size and improvements in cardiac function following acute myocardial infarction (AMI) with the PiCSO® Impulse System (PiCSO). In addition, promising clinical experiences were shared on applications in severe left ventricular dysfunction, high-risk percutaneous coronary intervention (PCI) and chronic heart failure.

The latest results contribute to the growing body of evidence supporting the potential use of the PiCSO System during stenting procedures to improve microcirculatory flow and perfusion of the infarcted area leading to a significantly smaller residual infarct size after AMI. Decreased infarct size after AMI has been shown to directly correlate with reduced mortality and hospitalizations for heart failure¹. Additional results demonstrated marked improvements in myocardial function and signs of reverse remodeling at 4 months.

"These positive results show that the PiCSO System is a safe and feasible adjunctive therapy during primary PCI," explains Professor Azfar Zaman, MD, Chief Investigator of the ongoing PICSO IN STEMI (ST-Elevation Myocardial Infarction) study conducted at the Freeman Hospital in Newcastle upon Tyne, UK and 3 other UK institutions. "Results from this early study demonstrate PiCSO's ability to reduce myocardial injury and has the potential to significantly change the way I currently treat AMI patients, which remains a large unmet need in my practice."

The clinical value of the PiCSO System is further supported by the OxAMI PiCSO Study, with new evidence presented by Giovanni Luigi De Maria, MD from the Heart Centre, Oxford University Hospitals in Oxford, UK. The interim results of this study support the safety and feasibility of the PiCSO System when integrated into the treatment of ST-Elevation Myocardial Infarction (STEMI) patients.

Promising evaluations of the PiCSO System were also <u>presented on additional applications</u> in severe left ventricular dysfunction, high-risk PCI and chronic heart failure. Antonio Colombo, MD, of the Centro Cuore Columbus and S. Raffaele Scientific Institute in Milan, Italy, showed use of the PiCSO System is possible for treatment of severe left ventricular dysfunction and high-risk left main PCI.^{2,3} "I am pleased to present the successful clinical experiences of the PiCSO System in elective high-risk cases for severe acute LV dysfunction and ischemia," **states** Antonio Colombo, MD. "The results are short of miraculous, demonstrating substantial improvement of myocardial ischemia and recovery of LV systolic function."

Utilizing the PiCSO System as a strong platform for novel clinical applications is further evidenced by first-of-its-kind data presented on the use of the system in treatment of chronic heart failure. Initial data presented at EuroPCR by Professor Werner Mohl, MD, Medical University of Vienna, Austria indicated a reduction in MACE and a significant risk reduction for MACE and re-infarction



medical systems

beyond salvage. This initial experience in chronic heart failure is promising and is being further evaluated.

"The clinical information presented at EuroPCR continues to support the benefits of the PiCSO System," states Olivier Delporte, CEO of Miracor. "The positive data further validates PiCSO as a promising treatment along the continuum of care from AMI to chronic heart failure."

About Miracor Medical Systems GmbH

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

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

#####

NOTE: The PiCSO® Impulse System is not available for commercial distribution and is exclusively for clinical investigation in Europe.

Contact:

Olivier Delporte CEO Miracor Medical Systems GmbH odelporte@miracormedical.com

- 1. Stone, G.W. et al. J Am Coll Cardiol. 2016;67(14):1674-83.
- Pappalardo F, Ancona MB, Giannini F, et al. First in man prolonged pressure-controlled intermittent coronary sinus occlusion to treat refractory left ventricular dysfunction and ischemia with patent epicardial coronary arteries. Interventional Journal of Cardiology. 2017 May 9. pii: S0167-5273(16)33051-0. doi: 10.1016/j.ijcard.2017.05.030. [Epub ahead of print]
- 3. Azzalini L, Montorfano M, Latib A, Colombo, A. High-risk left main percutaneous coronary intervention supported by pressure-controlled intermittent coronary sinus occlusion. EuroIntervention 2016 Dec;12:e1437 [Epub] DOI: 10.4244/EIJ-D-16-00096