ENVISION SCIENTIFIC announces initiation of global ABILITY RCT

Dr. Antonio Colombo is the Medical Director for the ABILITY randomized clinical trial which will be conducted between Abluminus DES+ and Xience (Everolimus Eluting Stent).

SURAT, India: **Envision Scientific** has announced the start of new Randomized clinical trial involving the novel Abluminus DES+, which showed consistently powerful clinical performance in real world patients including those with diabetes.

About Abluminus DES+

The Abluminus DES+, a novel sirolimus-eluting device with a unique design combining the advantages of a drug-eluting balloon and stent where the drug is positioned abluminally towards the vessel wall and not the lumen. This unique technology will allow homogenous delivery of sirolimus on the wall of the vessel. The potential is to be able to treat patients or lesions that are known to have a higher risk of restenosis. Diabetic patients will be the main focus of interest in upcoming studies. Diabetics are known to have a high late loss after stent implantation, more intimal hyperplasia and the idea behind this formulation is that if you deliver the drug in a more homogenous fashion you will improve the efficiency and we will have a lower late loss with less restenosis and repeat revascularization.

"***The stent platform with balloon platform, together, may become a gold standard device for diabetic patients.***" explained Prof. Antonio Colombo, Director, Cardiac Cath Lab and Interventional Cardiology Unit, San Raffaele Hospital, Milan, Italy and Medical director of the ABILITY Randomized clinical trial.

About the en-ABL program

The en-ABL ongoing clinical program enrolled 2,328 patients across 30 clinical trial sites in India. It is led by Dr. Sameer Dani, Director of Interventional Cardiology Department at Apollo Hospitals, Gandhinagar and Life Care Institute of Medical Science & Research Centre, Ahmedabad (Gujarat).

At one year of follow-up in the en-ABL ongoing clinical program, the results included low rates of major adverse cardiac events (MACE, 2.67%), Cardiac death (0.67%), target vessel myocardial infarction (TV-MI, 0.41%), clinically driven target lesion revascularization (TLR, 1.59%) and stent thrombosis (ST, 0.67%). These results were achieved despite 34% of the patients having diabetes, which characteristically drives worse outcomes. One year results in a subgroup analysis of patients with diabetes in the en-ABL clinical program also represents low rates of MACE (3.19%) and ST (0.87%).

"*These findings endorse the performance of Abluminus DES+ which has a unique fusion coating technology, on both the abluminal surface of the stent as well as exposed parts of the balloon*" said Dr. Luca Testa, Head of Coronary Revascularisation Unit, Head of Clinical Research Unit, Department of Cardiology, IRCCS Policlinico S. Donato, San Donato, Milan, Italy. This data was

presented at the annual Transcatheter Cardiovascular Therapeutics (TCT) 2017 scientific Session, sponsored by the Cardiovascular Research Foundation (CRF).

About ABILITY RCT

The ABILITY multi-centre, single-blinded, randomized, Investigator-initiated pilot clinical study aiming at assessing the safety and clinical performance of a novel Abluminus DES+ versus Xience (Everolimus Eluting Stent) in patients with Diabetes Mellitus. The study will be led by Dr. Azeem Latib, San Raffaele Hospital, Milano, Italy. Primary endpoint is in-stent neo-intimal volume at 6-month follow-up, measured with optical coherence tomography (OCT), following PCI with Abluminus DES+ compared with in-stent neo-intimal volume following PCI with Xience (Everolimus Eluting Stent). Secondary endpoints of the study include: Target Lesion Failure, Stent thrombosis, Cardiac death, Target vessel myocardial infarction, Target lesion revascularization at 12 months.

References

https://www.youtube.com/watch?v=-YF7GPDxEDs