BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Clinical trial of new stent begins in Europe

16 May 2012 | News | By BioSpectrum Bureau

Clinical trial of new stent begins in Europe

Singapore: Arterial Remodeling Technologies (ART) received regulatory approval in Europe to begin its first-in-man Arterial Remodeling Transient Dismantling Vascular Angioplasty, 'ARTDIVA', clinical trial next month at five medical centers. ART's in vivo data strongly suggest that its next-generation bio-resorbable stent is designed to promote positive arterial remodeling.

Dr Jean Fajadet is the principal investigator for the ART first-in-man study. He is the co-director of the interventional cardiology unit, Clinique Pasteur, Toulouse, France; is a member of the board of directors, EuroPCR; and is also a member of ART's scientific advisory board.

ART's bioresorbable stent is designed to provide a transient effective scaffold that dismantles and relinquishes its primary mechanical scaffolding function after three months. According to Mr Machiel van der Leest, CEO, ART, who has developed and successfully introduced 15 Class III medical devices during his career, a three-month scaffolding period is commonly recognized by experts as the requisite length of time necessary to allow the healing process to stabilize the artery following trauma generated by angioplasty, and to avoid recoil and constrictive remodeling.

As previously reported by ART in a news release on April 4, 2012, "Our analysis of ART's in vivo data confirms that stent dismantling is occurring at around three months, and the overall safety data look encouraging thus far," said Dr Renu Virmani, medical director and president, CVPath Institute, Gaithersburg, Maryland. Dr Virmani is also clinical professor, department of pathology at Georgetown University, University of Maryland-Baltimore, Uniform University of Health Sciences, and Vanderbilt University.

"We are extremely pleased with this significant milestone in the development of the ART bioresorbable stent," said Dr Antoine LaFont, professor of medicine, head, interventional cardiology department, Georges Pompidou Hospital (Paris); and former chairman, interventional cardiology working group, European Society of Cardiology (ESC). Professor LaFont is also a co-founder of ART.

"We are very much looking forward to the results of ART's First-In-Man study. The key features of ART's next-generation bioresorbable stent are that it is made of non-aggressive material and is designed to have a programmed transitory presence in order to facilitate natural remodeling," concluded Mr Van der Leest.

ART is developing bioresorbable coronary polymer stents that promote the natural remodeling of an injured artery after angioplasty. The company's technology is based on intellectual property originating from three esteemed institutions: the Cleveland Clinic; the French national research institute, CNRS (Centre National de Recherche Scientifique), Montpellier, France; and, Descartes University, Paris.