



Press Release

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CINVENTION and Relisys Medical Devices Enrol First Patients in Clinical Trial of the Corel+C Drug-Eluting Stent

CINVENTION and Relisys Medical announced today the enrolment of the first patients in the COREL drug-eluting stent clinical trial based on the paclitaxel-eluting Corel+C stent with a macro-porous nano-structured carbon-composite coating.

COREL is a prospective, open label randomized clinical trial that will enrol 150 patients in 10 centres in India. The primary endpoint is 9-month in-stent late loss within the stented segment post-procedure and historical comparison with 6 to 9-month in-stent late loss with other drug-eluting stents. The secondary endpoints include Angiographic Binary Restenosis, Target Lesion Revascularization (TLR), Target Vessel Revascularization (TVR) and Target Vessel Failure (TVF) rates at nine months, Major Adverse Cardiac Events (MACE), acute, sub-acute and late Stent thrombosis at 30 days and 9 and 12 months, Lesion, Device as well as Procedure success. The Principal Investigator of the study is Dr. Balram Barghava MD. of All India Institute of Medical Sciences, New Delhi, India.

Relisys' new Corel + C drug-eluting stent comprises a Cobalt-Chromium Stent that is coated with a macro-porous nano-structured carbon-composite matrix containing the active drug paclitaxel. The coating was developed and provided by CINVENTION, the Germany based company specialized in nano-composite materials and surface engineering. The coating eliminates the use of polymers and provides a bioactive coating with less thrombogenicity and pro-endothelialization surface design – thus, completely reducing tissue inflammation and reaction, but additionally enhancing engraftment and endothelialisation.

Dr. Balram Bhargava, the principal investigator, explained that he expects significant improvements in the short, mid and long-term clinical outcomes. "This is the first time that a nano-structured coating is used as an elution platform. The coating itself is made out of non-thrombogenic glassy carbon, the bioavailability of paclitaxel is nearly hundred percent and, additionally, the surface structure of the coating promotes endothelial cell attachment and proliferation. We are confident that this trial will show excellent results and demonstrate that the non-polymeric bioactive nano-composite coating will reduce the late thrombosis issue significantly", said Dr. Balram Bhargava.

The enrolment of the study will be carried out throughout 10 clinical trial centers in Bangalore, Ahmadabad, Vellore, Bangalore, Chandigarh, Hyderabad, New Delhi and Mumbai. Dr. Soheil Asgari, Chief Executive Officer and Chief Technology Officer of CINVENTION, pointed out, that the enrolment will be finished within 4 weeks. "The investigators community has access to a large collective of patients and we expect the stenting of the patients within four to five weeks." He also referred to previous pre-clinical data that showed excellent histomorphometric and histopathology data indicating the non-inflammatory and pro-healing properties of the coating. "The CINVENTION coating replaces inflammatory polymers – either durable or absorbable – by the most inert material known, i.e. carbon. CINVENTION's technology enables the embedding of drug control properties together with a surface design that attracts endothelial cells and allows attachment and proliferation on the nano-structured surface". Furthermore, he said that CINVENTION has created significant knowledge in surface design for tissue engineering and mammalian cell cultivation. This knowledge was transferred to the nano-structured design of the carbon-coating material.

Badari Narayan, Managing Director of Relisys Medical, stated that he expects a clear result demonstrating the superior performance of the Corel + C stent. "The Corel+ C stent has unique advantages. While other companies are still in the early development phase of non-polymeric stents, Relisys has gained a head start over the community. We combine the advantages of a Cobalt Chromium stent with an excellent profile and deliverability together with the proven drug paclitaxel and the most advanced coating platform. The Corel + C stent was specifically designed to eliminate the



potential complications of thrombosis that are now identified as the main issues of Drug-Eluting Stents.”

The animal trials for the advanced Corel + C drug-eluting stent were completed at the Cardiovascular Research Institute, Washington D.C., and published in April 2006. The animal data have shown the safety and efficacy of the Corel + C drug-eluting stent, including its innovative porous carbon/carbon composite coating technology.

About CINVENTION

CINVENTION AG is a leading technology company focusing on nano-composite materials in biomedical applications.

CINVENTION's unique portfolio of Nano-Composite Systems includes:

- Drug Delivery Coatings
- Multifunctional Device Coatings
- Advanced Cultivation Systems for Bio-Processing
- Systems for Tissue Engineering

CINVENTION's mission is to exploit its proprietary and highly innovative technology platform for materials and surface engineering of nano-structured composites. Providing a sustainable portfolio of applications in medical device engineering, bio-processing and chemical processing CINVENTION solutions enable its customers to acquire superior technologies for next generation applications.

About Relisys Medical

Relisys Medical Devices Limited is a leading Indian medical device manufacturer, which has taken a lead in the indigenous development of medical devices like coronary stents, catheters and critical care products in India.

Relisys focus products includes:

- Drug eluting stents
- Angiographic/Angioplasty catheters
- Occlusive devices
- Cardiac surgery disposables
- Critical care products

Relisys Medical Devices mission is to make quality medical care affordable through development of cutting edge technology and competitive pricing. Relisys Manufacturing facilities include a stent coating division and an integrated catheter manufacturing facility with in-house compounding, extrusion, injection moulding, braiding, welding, tipping, grinding, sterilisation and others.