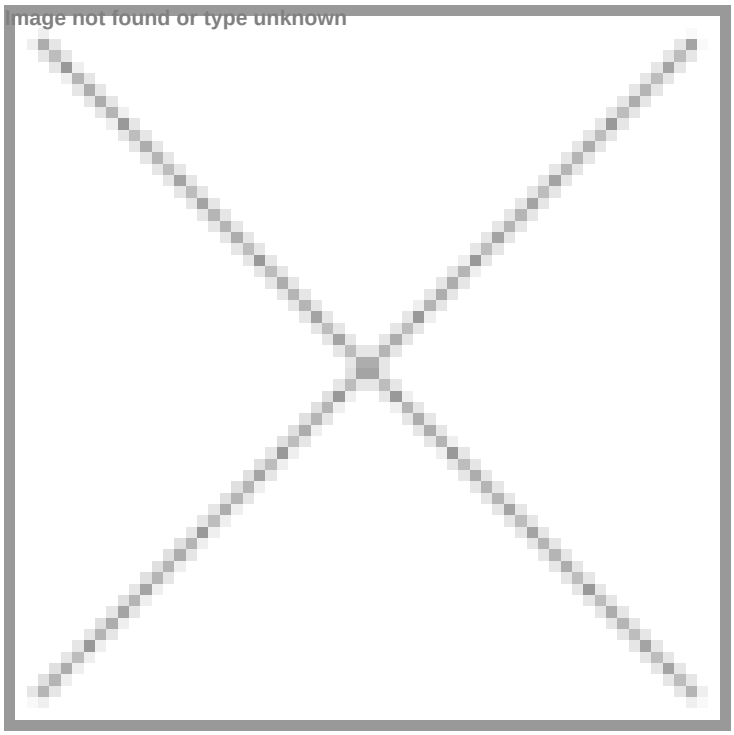
BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Osprey to capitalize on CINCOR system

04 July 2012 | Influencers | By BioSpectrum Bureau

Osprey to capitalize on CINCOR system



Contrast induced nephropathy (CIN) is a form of kidney damage caused by the toxic effects of dyes (contrast) used by cardiologists during X-ray of heart and blood vessels for commonly performed heart procedures, such as angioplasty and stenting. The dye is toxic and can reduce blood flow in kidneys, which can lead to kidney cell death and serious complications.

CINCOR System removes this toxic dye used in heart procedures, improves patient outcomes and saves money for hospitals and payers. And Osprey Medical was formed in 2005 in the US to focus on the development and commercialization of the system.

The system was developed by Dr David Kaye, head of Cardiology and Therapeutics Division at the Baker Heart and Diabetes Institute in Melbourne, Australia, to provide cardiologists with an advanced level of CIN protection in high-risk patients undergoing heart procedures. "The CINCOR System is a catheter and vacuum system that is designed to directly capture and remove a significant quantity of the dye as it leaves the coronary sinus (the heart's main drainage vein) before it makes its way to the kidneys," explains Dr Kaye.

Osprey Medical has been funded by Australian institutional funds managed by CM Capital Investments, CM Capital Partners and other Australian professional investors. On May 2, 2012, Osprey Medical completed its initial public offering (IPO) of CDIs (CHESS Depositary Interests) and began trading on the Australian Securities Exchange under the symbol OSP and has successfully raised $20.5 million.

The company has a clear strategy that the funds raised in the IPO will be used to conduct a pivotal clinical trial and seek US FDA clearance, to further develop the CINCOR platform technologies for additional applications, to conduct a medico-economic study to assist in both market adoption and reimbursement coding for the CINCOR System.

To enable the company to commercialise the CINCOR System in the US, the company is pursuing a 510(k) regulatory pathway for FDA market clearance. The applicability of the 510(k) pathway was determined by the company through communication with the FDA, and is generally considered to be a less demanding and faster approval route than alternative approval pathways for medical devices. In pursuing its 510(k) market clearance, Osprey Medical has applied for and obtained from the FDA, an Investigational Device Exemption (IDE) to conduct a pivotal clinical trial for the CINCOR System.

The company anticipates commencing its US pivotal trial in 2012 and the completion of the trial and receipt of 510(k) FDA clearance is targeted for 2014. It is aiming for the US launch of the CINCOR System in 2014. The company plans to recruit its own direct cardiology sales force in the US and believes that 20-25 sales representatives can successfully access and service the majority of the US market.

Osprey Medical intends to begin a controlled commercial launch of the CINCOR System in Europe in late 2012. The two countries planned for European market launch are Germany and the Netherlands.

"Each of these countries has a good history of adoption and reimbursement for new medical devices and is amongst the European market leaders in cardiology. Germany was also involved in the company's recent trial that successfully led to CE Mark approval," says Mr Mike McCormick, President and CEO, Osprey Medical. The company plans to target select key opinion leading physicians to establish centers of excellence in Germany and the Netherlands. "It is intended that these hospitals and physicians will refine physician training and usage practices, and report and advocate on the patient and economic benefits of using the CINCOR System. The company believes that these key opinion leading physicians will help drive market awareness, initial market adoption and penetration into these focused regions," he adds.