Osprey Medical Inc. PRESERV Clinical Trial Update

- In March 2013, Osprey Medical announced commencement of its US registration directed pivotal IDE clinical study of the CINCOR™ system with the first patient enrolled at the Leipzig Heart Centre in Germany.
- In May 2013, Dr. Richard Heuser enrolled the first two US patients at St. Luke's Medical Center in Phoenix, Arizona.
- As of May 31, 2013, twelve hospitals have Institutional Review Board (**IRB**) and contract approval and are actively screening patients for trial enrollment.
- The CINCOR dye reduction and removal system limits the amount of dye used in a heart procedure from reaching the kidneys, thereby reducing the risk of Contrast Induced Nephropathy (**CIN**), a form of acute kidney injury, in patients undergoing common heart procedures.

Minnesota, United States and Melbourne, Australia – June 7, 2013 – Osprey Medical Inc. (ASX: OSP) today announced updates in its PRESERV Clinical Trial, with Dr. Richard Heuser enrolling in May 2013 the first US patients in the PRESERV Clinical Trial at St. Luke's Medical Center in Phoenix, Arizona. Dr Heuser is an internationally recognized cardiologist, inventor, educator and author and is one of the early pioneers of the angioplasty procedure. In addition to St. Luke's Medical Center, twelve additional hospitals have Institutional Review Board (**IRB**) and contract approval and are actively screening patients for trial enrollment. An additional 25 hospitals are actively pursuing IRB and contract approval.

Mike McCormick, President of Osprey Medical commented, "We are pleased with the early response from cardiologists and hospitals that are eager to participate in the PRESERV Trial, and we are honored to have Dr. Heuser enroll our first US patients. Dr. Heuser has served as principal investigator of more than 100 medical device trials and he is a prolific inventor with nearly 30 patents granted or pending for medical devices. Osprey is targeting thought leading cardiologists and we are excited to have Dr. Heuser's contributions to the PRESERV Trial."

Dr. Heuser commented, "Osprey's CINCOR system, with its ability to reduce and remove contrast dye, has the potential to offer chronic kidney disease patients undergoing a coronary angiogram a lower risk of CIN."

Dye is routinely used to 'x-ray' heart tissue during coronary angiography and stenting procedures, but it can cause serious and irreversible damage to the kidneys. The CINCOR System is designed to provide cardiologists with an advanced level of protection against this damage known as Contrast Induced Nephropathy (CIN) in high-risk patients undergoing coronary angiography and stenting procedures. The CINCOR System is a dye reduction and removal system that both reduces the amount of dye injected and removes a significant quantity of any dye used as it leaves the coronary sinus (the heart's main drainage vein) before reaching the kidney. At present there is no effective way for cardiologists to prevent the dye from reaching the kidneys.

The registration directed IDE pivotal trial will enroll 600 patients in up to 40 centers around the world.

Approximately 25% of all patients undergoing coronary angiography and stenting procedures are at high risk of acquiring CIN due to their pre-existing kidney disease. CIN can have a significant impact on patients' lives, which can result in longer hospitalization, reduced kidney function, increased risk of heart disease, total kidney shut down and significant increase in likelihood of death.

As part of the trial in the US, Osprey will also be collecting health economic data on a subset of patients for 12 months after the procedure. This data is not required for US regulatory approval, but will be useful for marketing CINCOR by demonstrating longer-term economic outcomes to hospitals and payers.

Not only may patients benefit from the CINCOR System, but hospitals and payers are also motivated to reduce the incidence of CIN. Osprey President and CEO, Mike McCormick said, "Patients who develop CIN generally require an average of four days of additional hospitalization, often in an intensive care unit. These additional services can cost hospitals up to $4,000 per day. These costs are generally borne by the hospital, and are usually not reimbursed by insurers."

Further information:

About Contrast Induced Nephropathy (CIN)

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

About CINCOR System

The CINCOR System is designed to provide cardiologists with an advanced level of CIN protection in high-risk patients undergoing heart procedures such as coronary angiography and stenting procedures. The CINCOR System is a dye reduction and removal system. When dye is injected for heart procedures, there is often a significant general leakage of the dye, due to a process termed "reflux." The CINCOR system limits reflux; thereby, reducing the amount of dye injected into the patient. In addition, the CINCOR system captures and removes a significant quantity of dye that is used during the heart procedure as it leaves the coronary sinus (the heart's main drainage vein) before it makes its way to the kidneys.

Key CINCOR System Objectives:

- Reduce and remove toxic dye used in heart procedures
- Save patients' lives
- Improve patient outcomes
- Provide opportunity for best patient care
- Save money for hospitals and payers
- Become the accepted standard of care for CIN prevention

Regulatory Status:

- Europe – CE Mark obtained for the CINCOR Contrast Removal System and for the Reflux Reduction System
- Australia – Exclusively for Clinical Investigation
- United States – CAUTION Investigative device, limited by Federal (or United States) law to investigational use

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