

Osprey Medical Inc. to Commence AVERT™ System IDE Clinical Trial

Minnesota, United States and Melbourne, Australia – September 17, 2013 – Osprey Medical Inc. (ASX: OSP) today announced that it has received U.S. FDA approval to undertake a clinical trial of the AVERT™ System to study a marketing claim expansion to include “*reduction of Contrast Induced Nephropathy (CIN)*” for patients undergoing angiogram or stenting procedures.

Since including the AVERT System into the PRESERV Trial, the Company has been receiving strong and consistent positive feedback from key opinion leading (KOL) physicians about the performance of the system and the potential benefits for their patients. The simplicity of use of the AVERT, for the reduction of dye used in patients, positions the AVERT (stand-alone product) as the most attractive product for reducing CIN in a significant proportion of the target market. In addition, physicians have identified other patient groups that may benefit from the system, such as patients with pre-existing diabetes and those suffering from acute heart attack (STEMI).

Following discussions with the FDA and the submission of a new clinical trial protocol, Osprey has now received approval to commence a multi-site clinical trial to support application for an expanded marketing claim to include CIN reduction. This follows the announcement in August that the U.S. FDA has already cleared the AVERT System with the marketing claim of *controlled infusion of dye*.

The Company is planning to initiate the AVERT Trial in Q4 CY2013 with the aim of completing enrolment Q1 CY2015. FDA clearance to expand its marketing claims for reduction of CIN is expected mid CY2015. In view of this, Osprey Medical now intends to focus its clinical trial program on the AVERT Trial and will likely direct its financial and personnel resources to this project in preference to the PRESERV Trial. An update on the PRESERV Trial will be made at the appropriate time.

Mike McCormick, President and CEO of Osprey Medical, commented, “The FDA’s quick approval to commence the AVERT clinical trial is reflective of the scientifically sound study protocol and simplicity of the system. AVERT has attracted strong feedback from our network of key opinion leading physicians (KOLs), due to its simplicity, immediate dye reduction, and potential to protect at-risk patients from CIN. The move toward focusing on AVERT is a very natural progression for Osprey Medical. Positive physician response to the potential benefits of AVERT has been overwhelming and has created a clear path for maximising value for the Company and its shareholders. We also find ourselves in the fortunate position where we can undertake our focused launch of AVERT in the U.S. (Texas) this coming quarter, establish its use under its current claim, whilst at the same time undertake and complete the AVERT Trial to expand the claim to include CIN reduction, in anticipation of a full global launch in 2015.”

Further information is contained in the shareholder newsletter lodged in conjunction with this announcement or available at www.ospreymed.com on the “Investor” page.

Further information:

About the AVERT™ System

The Avert System consists of a re-usable contrast modulator with easy to adjust settings. The disposable modulation reservoir easily loads into the contrast modulator unit and attaches to commonly used manual injection systems used by interventional cardiologists during heart procedures.

AVERT System Benefits

- Reduces contrast by up to 40%
- Uncompromised image visualization
- Fast and simple

US Regulatory Status

The AVERT System is U.S. FDA 510(k) cleared for the intended use of controlled infusion of radiopaque Iodixanol 270 mg/ml contrast media for angiographic procedures.

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