



## **Osprey Medical Inc. Announces AVERT™ System FDA Clearance**

**Minnesota, United States and Melbourne, Australia – August 23, 2013 – Osprey Medical Inc. (ASX: OSP) today announced that it has received U.S. FDA 510(k) clearance for the AVERT™ System.**

The AVERT System is a proprietary technology designed to reduce the amount of dye injected and exposed to patients undergoing angiogram or diagnostic heart procedures. In a pilot human clinical study, the AVERT System was shown to reduce the amount of dye by up to 40% without compromising image quality.

There are at least 4 million angiogram heart procedures performed annually in Western Europe and the United States. Utilizing the AVERT System on those patients significantly reduces the amount of dye used in these procedures.

Mike McCormick, President of Osprey Medical, commented “We are delighted to have achieved this important milestone. AVERT was not yet part of our plans when we undertook our IPO in May 2012. Developing the Avert System and obtaining FDA clearance in such a short period of time is testament to the capabilities of our team at Osprey and potentially opens up further exciting opportunities for the company. We will shortly begin to commercialize AVERT in a controlled manner to demonstrate awareness and adoption patterns among select key opinion leading physicians.”

Osprey is currently building product inventory, developing product labels to meet FDA requirements, and finalizing its U.S. sales plans. Upon completion of these activities, the Company will begin a controlled U.S. commercialization effort anticipated to commence in Texas in Q4 CY 2013.

Further information:

### **About the AVERT™ System**

The Avert System consists of a re-usable contrast modulator with easy to adjust settings to accommodate the different types of contrast dyes. 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. Osprey received its FDA clearance for a marketing claim of “controlled infusion of dye”. The Company is currently conducting a pivotal trial with the aim of expanding its marketing claim to include the “reduction of Contrast Induced Nephropathy (CIN)”.

### **AVERT System Benefits**

- Reduces contrast by up to 40%
- Uncompromised image visualization

- Fast and simple

#### US Regulatory Status

The AVERT System has received US FDA 510(k) clearance for controlled infusion of radiopaque contrast media in angiographic procedures.

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