

## Osprey Medical Receives FDA Clearance for Key DyeVert™ System Claims

Minnesota, United States and Melbourne, Australia – February 8, 2016 – Osprey Medical Inc. (ASX: OSP) today announced that it has received FDA clearance for expanded marketing claims of dye savings, image quality and reflux reduction for the DyeVert™ System.

- FDA clearance of key marketing claims (dye savings, image quality and reflux reduction) received for the DyeVert System
- Clinical results of DyeVert have shown >45% average dye savings without compromised image quality
- First quarter of DyeVert sales saw faster than expected adoption rates

The new claims allow Osprey to commercialize the DyeVert and AVERT Systems as the only products to have received FDA claims for contrast savings without compromise in image quality through a randomized controlled multi-center trial. The new expanded claims enable physicians to comply with cardiology and radiology society guidelines that urge physicians to use dye sparing approaches in patients at-risk of Contrast Induced Acute Kidney Injury (CI-AKI).

The DyeVert System is a second generation product which offers performance improvements of increased dye savings and ease of use advantages over the first generation AVERT System. Clinical use of the DyeVert System in over 100 patients from three different hospitals have shown an average of >45% dye savings without compromised image quality. This compares with typical dye savings of 30-35% for the AVERT System, as seen in clinical use, and is a result of DyeVert saving dye even on puff injections.

Commercialization of the DyeVert System commenced in November 2015, following FDA clearance. In the first 3 months of commercial release, 24 hospitals evaluated the system with 11 already placing initial orders and 13 working through the approval process to purchase the DyeVert System. This initial evaluation and order rate is significantly faster than previous experience with AVERT and is reflective of the ease of use of the DyeVert System. Osprey's expanded sales force will sell DyeVert as the lead product in 2016.

Osprey President and CEO, Mike McCormick, stated: "FDA clearance of claims on our DyeVert System provides our sales reps with stronger marketing collateral when selling our products. Osprey is dedicated to supporting the efficacy of our products with Tier 1 clinical evidence and as a result, we are now the only Company with FDA clearance for products that reduce dye without compromising image quality. These are unique and powerful claims that will allow our reps to present the DyeVert System as a product that can assist physicians in complying with Cardiology Society Guidelines that stress the need for dye reduction in patients with compromised kidneys. We are encouraged by our early commercial success and continue to scale up our sales force to drive adoption of the DyeVert System in 2016."

## **About Osprey**

Osprey Medical is focused on protecting patients from the harmful effects of X-ray dye (contrast) used during commonly performed angiographic imaging procedures. The Company's core technologies originated from research conducted by Dr David Kaye at Melbourne's Baker IDI Heart and Diabetes Institute. Its proprietary dye reduction and monitoring technologies are designed to help physicians minimize dye usage. The Company's DyeVert™ System is a next-generation product that reduces contrast while maintaining image quality in a self-adjusting easy-to-use design. Osprey Medical's Board and Management are comprised of experienced and successful personnel with established track records covering medical device development,

regulatory approvals, sales and marketing, and mergers-acquisitions. Osprey Medical's advisory board comprises world-recognised experts in heart and kidney diseases.

## **Forward-Looking Statements**

This announcement contains or may contain forward-looking statements that are based on management's beliefs, assumptions and expectations and on information currently available to management. All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation our expectations with respect to our ability to commercialize our products including our estimates of potential revenues, costs, profitability and financial performance; our ability to develop and commercialize new products including our ability to obtain reimbursement for our products; our expectations with respect to our clinical trials, including enrolment in or completion of our clinical trials and our associated regulatory submissions and approvals; our expectations with respect to the integrity or capabilities of our intellectual property position. Management believes that these forward-looking statements are reasonable as and when made. You should not place undue reliance on forward-looking statements because they speak only as of the date when made. Osprey does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. Osprey may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements.

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