Osprey Medical Receives US FDA Clearance for DyeVert™ PLUS

Highlights:

- FDA clearance of the DyeVert PLUS with immediate US launch
- DyeVert PLUS adds a display unit for dye management and monitoring which complies with industry guidelines for patients at risk from the harmful effects of dye
- DyeVert PLUS is the only FDA cleared product with the claim of reduced dye delivery without impacting image quality

March 9, 2017 – Melbourne, Australia and Minnesota, United States – Osprey Medical (ASX:OSP) today announced that it has received US FDA 510(k) clearance for its advanced DyeVert™ PLUS Contrast Reduction System. This new platform augments Osprey's current technology with the capability to actively manage dye administration during coronary interventions.

DyeVert PLUS received European CE Mark in 4Q 2016. The company further validated its dye savings capabilities through initial market testing with multiple physicians in Germany and Italy, which showed a 44% contrast reduction. The product received strong positive feedback on the utility of real-time contrast monitoring and ease-of-use.

Through wireless communication, the system interfaces with a "smart syringe" and reusable LCD monitor. Recently published industry guidelines communicated a strong focus on dye management for kidney-impaired patients, for which the DyeVert PLUS addresses. DyeVert PLUS allows for the minimization of contrast dose, contrast monitoring in real-time, and for physicians to be informed when limits (based on kidney function) are reached.

Osprey expects the DyeVert PLUS system will accelerate sales in 2017 with the added value of displaying dye savings per injection and per case. In addition, Cardiology guidelines for poor kidney patients stress the need to calculate dye thresholds and monitor dye volume throughout the procedure; the DyeVert offers these features in an easy to use system.

"The monitoring of dye is a valuable feature, especially in a patient with impaired kidney function – you know exactly where you are at each point during an intervention," stated Professor Steffen Desch of the Heart Centre in Lubeck, Germany.

Osprey's President and CEO, Mike McCormick, added: "DyeVert PLUS is a substantial upgrade for our customers and we will thus transition all current users on to this next generation product. This exciting new product further supports our long term company vision: to make heart imaging procedures safer for patients with poor kidney function."

Additional details on the DyeVert PLUS Contrast Reduction System can be found in a newsletter released today on www.ospreymed.com.

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About Osprey

Osprey Medical's vision is to make heart imaging procedures safer for patients with poor kidney function. The amount of dye (contrast) used during angiographic imaging procedures increases the patient's risk for dye-related kidney damage known as Contrast Induced Acute Kidney Injury (AKI). The Company's core technologies originated from research conducted by Dr David Kaye at Melbourne's Baker Institute. Its proprietary dye reduction and monitoring technologies are designed to help physicians minimize dye usage and monitor the dose of dye real time throughout the procedure. The Company's DyeVert™ Plus System reduces contrast while maintaining image quality in a self-adjusting easy-to-use design that monitors dye usage. 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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