ASX ANNOUNCEMENT

Osprey Medical - AVERT Trial Results, Three FDA Expanded Claims Achieved and Full US Commercial Launch Initiation

Key Highlights

- AVERT trial results support enhanced claims for dye savings, image quality and reflux reduction
- Statistically significant reduction in CIN was not observed between the treatment and control groups
- Successful early FDA submission for three enhanced claims – FDA clearance obtained 15 October
- Initiation of full US commercialization to be brought forward to 4Q 2015
- Assessing inbound interest for worldwide marketing and sales rights to Osprey's portfolio

Minnesota, United States and Melbourne, Australia – October 19, 2015 – Osprey Medical Inc. (ASX: OSP) today announced the results of its recently completed AVERT™ Trial, FDA clearance of three AVERT expanded marketing claims and acceleration of the initiation of its full US commercial launch.

AVERT Trial Results

In July, Osprey announced that it had completed enrolment in the AVERT randomized, controlled IDE study aimed at strengthening the marketing claims of Osprey's FDA cleared AVERT System. The trial enrolled 578 patients across 38 sites and was completed on time and on budget.

The AVERT trial results are summarised below:

AVERT Trail Results Summary

Outcome	Claim	Result Summary
✓	Dye Savings	• 15% less dye used in AVERT group (p=0.022)
✓	Image Quality	• No detectable difference in image quality
✓	Reflux Reduction	• AVERT reduces dye without compromising image quality by reducing reflux
✗	CIN Reduction	• Significant difference in CIN rates between AVERT and Control groups was not observed

The trial design was predicated on evaluating the difference in the incidence of CIN and the amount of dye used in the two patient groups (Control Group and AVERT Group). The data showed that the AVERT System reduced the average amount of contrast dye used in at-risk patients by reducing reflux (AVERT's mode of action) while maintaining adequate image quality. The trial did not show a statistically significant difference

for the incidence of CIN between the 2 groups with the number of CIN events in the AVERT arm being 76 and in the Control arm 74.

The study showed that the AVERT System reduced the amount of dye injected to the patient by 15% when compared to a randomized control group. It was assumed that the difference in amount of dye used in the treatment group as compared to the control group would approximate actual dye savings that is achieved with AVERT in each case (30%-40%). In the trial we observed the difference in dye used was lower than our average AVERT dye savings per case due to:

- Differences in mix of procedure types (Angiogram vs PCI) performed in Control Group vs AVERT group.
    - On average, PCI (stenting) procedures used almost twice as much dye as Angiogram procedures (67ml vs 130ml respectively). Patients were randomized between the control and AVERT groups prior to the known procedure type. The AVERT group had more PCI procedures as compared to the control group.

- Differences in complexity of procedure performed.
    - The AVERT group had an increased number of complex (multi-vessel) cases as compared to the control.

- Range of dye required per case.
    - The range of dye required per case was widely variable and not predictable. In Angiograms the average dye used was 67ml with a range of 20ml-260ml and in PCI average dye used was 130ml with a range of 13ml-400ml. These dye volume ranges can occur for any number of reasons unrelated to the AVERT (such as physician style/experience) and were random between the control and AVERT groups.

Further evaluation of the full data cohort including CIN sub-group analysis will be performed by a steering committee of academic, key opinion leading physicians that Osprey plans to convene in November. The results of this analysis along with initial results of the on-going economic sub-study are expected to be available in late Q2 2016.

FDA Clearance Given 15 October for Three Enhanced Claims

Upon receiving its mid-point trial data, Osprey made an early submission to the FDA asserting that the data demonstrates that the AVERT System reduces the average amount of contrast dye used in at-risk patients by reducing reflux (AVERT's mode of action) while maintaining adequate image quality. On 15 October (US time) Osprey was notified by the FDA that based on that interim data, it has successfully achieved FDA clearance for three expanded marketing claims being:

- dye reduction;
- image quality; and
- reflux reduction.

As such, the AVERT System is the only product proven to reduce contrast volumes without compromising image quality cleared by the FDA.

The new expanded claims, including for dye savings, now enable physicians to comply with cardiology and radiology society guidelines that urge physicians to use dye sparing approaches with at-risk patients. The AVERT System is the only product to have a controlled, randomized, multi-center trial which proves a statistically significant reduction in dye.

AVERT Study Primary Investigator, Dr Roxana Mehran, states: "This is a very important study which has demonstrated that AVERT can reduce contrast dose in patients with renal insufficiency. Contrast reduction will help protect the most vulnerable patients' kidneys as they undergo angiographic procedures. I would like to thank the efforts of the many physician investigators for their active enrolment in this trial and Osprey for its dedication to scientifically-driven outcome studies."

Accelerating Full US Commercial Launch

Following receipt of enhanced AVERT System claims, Osprey is planning to aggressively scale up commercialisation initiatives in the US. Since early 2015 Osprey has been conducting a pilot sales program in Texas which has enabled Osprey to create a clear and executable blueprint for sales expansion. With the early FDA clearance of three expanded claims, Osprey intends to accelerate the initiation of the full US commercial launch of AVERT commencing prior to the end of 2015.

The Company expects to bring on an additional five sales reps prior to the end of this calendar year. In addition, Osprey has received expressions of interest from two leading medical device companies for worldwide sales and marketing rights to its dye savings product portfolio. The company will access this inbound interest prior to scaling up its sales force to up to 20 reps in 2016.

Osprey President and CEO, Mike McCormick, stated: "We are thrilled to have gained FDA clearance for the expanded marketing claims for dye reduction, image quality and reflux reduction. Osprey's product is now the only device available with an FDA cleared indication for dye volume reduction that allows practicing physicians to achieve the medical guidelines currently established for at-risk kidney patients."

"Successfully achieving clearance of these expanded marketing claims marks an important milestone for the Company. We are now in position to aggressively accelerate our US commercialization efforts by expanding beyond our current sales pilot program in Texas. We are proud to continue our mission of protecting kidneys from the harmful effects of contrast media and look forward to moving into full US commercialization."

- ENDS -

Further information:

About Osprey

Osprey Medical's core technologies originated from research conducted by Dr David Kaye at Melbourne's Baker IDI Heart and Diabetes Institute. Osprey is focused improving patients' quality of life by protecting those with chronic kidney disease from contrast (dye) related Acute Kidney Injury. The Company's AVERT™ Plus System, is designed to reduce and monitor the amount of dye (contrast) injected during commonly performed heart and peripheral procedures. 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 AVERT™ System 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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