Osprey Medical begins market access process to approve DyeVert™ Plus System in UK

7 September 2018 – Melbourne, Australia and Minnesota, United States – Osprey Medical (ASX: OSP) initiates European commercial activities in the National Health Service (NHS), the United Kingdom publicly funded healthcare system. The NHS is a large market that has 50,000 chronic kidney disease (CKD) patients per year who can benefit from the Osprey Medical's technology.

Osprey Medical has engaged with the UK's leading Market Access Consultancy, Device Access UK Ltd, to begin market access activities, and ultimate guidance recommendation with the National Institute for Health and Care Excellence (NICE). NICE's role is to provide guidance to the NHS and Hospitals on the adoption of safe, and clinically cost effective Medical Technologies for the benefits of its patients. The engagement process seeking NICE recommendation is expected to take approximately 12 months.

Since 2010, Device Access UK Ltd has helped over 25 Medical Devices gain NICE approval and will guide Osprey through the strategic processes required to execute a successful market access strategy. Michael Branagan-Harris, Device Access President, commented; "Osprey Medical's DyeVert Plus System has proven results in the US market. Given the high rate of Acute Kidney Injury (AKI) and clinical interest in finding a solution to this problem within the NHS, it makes strategic and economic sense that the DyeVert Plus System is supported by the NHS and is fully adopted and implemented in the routine care of NHS CKD patients undergoing endovascular heart procedures."

In addition to the partnership with Device Access, Osprey is also working with UK distributor CardioLogic as part of our commercial strategy to access leading heart centers in the U.K. CardioLogic will play a key role in leading our sales efforts in the UK which is one of our first markets expansion beyond the United States.

The UK market is an important target for Osprey Medical's expansion outside of the US, and NICE recommendation has a positive influence on European market acceptance. Once Osprey's DyeVert Plus System has NICE recommendation, UK hospitals will receive payment for coronary angiographic procedures using kidney protection protocols with the DyeVert Contrast Reduction System.

Mike McCormick, Osprey President commented; "we are pleased to be working with Device Access and CardioLogic. AKI, which can be caused by contrast dye use in heart imaging procedures, costs the UK hospital system £1.02billion annually, or about one per cent of the NHS yearly budget. This alone shows that if the DyeVert Plus System were introduced to the UK market to impact AKI rates, it will have substantial health and economic benefits."

Reducing contrast for patients with poor kidney function improves outcomes, by reducing AKI events (dye related kidney damage) and lowering hospital costs. The Company's DyeVert Plus System reduces contrast while maintaining image quality in a self-adjusting easy-to-use design that monitors dye usage. The DyeVert Plus System is the only FDA cleared and CE-marked system approved for contrast reduction and real-time monitoring of dye dose to the patients throughout the procedure.

While the new agreement creates significant new market opportunities for Osprey Medical, it is too early to predict the outcome of our NICE engagement efforts or the impact on the Company's financial results. Osprey's agreement with Device Access is for the NICE engagement process and CardioLogic's agreement is for three years.

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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.

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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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