

UK NICE Issues Positive MedTech Innovation Briefing on DyeVert™

February 10, 2020 - Minnesota, United States and Melbourne, Australia — Osprey Medical (ASX: OSP) today announces the National Institute of Health and Care Excellence (NICE) has issued a MedTech Innovation Briefing (MIB)¹ on DyeVert™ for reducing contrast media in coronary and peripheral angiography. MIBs are designed to educate Hospital personnel and healthcare providers within the National Health Service (NHS) of the United Kingdom (UK) on new medical devices with the potential to improve patient care and reduce healthcare costs.

Additionally, a peer-reviewed publication to accompany the MIB on the cost-utility of DyeVert commissioned by Osprey has been published in the The Open Pharmacoeconomics & Health Economics Journal². The analysis undertaken as part of the MIB submission showed that the introduction of DyeVertTM PLUS EZ system led to cost savings of £3,878 per patient over a lifetime time horizon, with 100% probability of being cost-effective and 100% probability of being cost saving to the UK healthcare system.

DyeVert was considered a dominant intervention by the study authors as it was less costly and more effective compared to current practice. Long term cost effectiveness analysis from the simulation showed savings from the initial intervention, CI-AKI within the first three months of treatment and the cost of subsequent disease management of £176 million to the healthcare system, within the specific patient group studied. The authors concluded "The economic analysis presented in this study has shown that introduction of the DyeVert™ PLUS EZ system has the potential to reduce costs for the UK health care service, and lead to improved quality of life and clinical outcomes for patients with CKD stage 3-4 undergoing angiographic procedures."

Osprey Medical CEO Mike McCormick said, "We are pleased with the NICE MIB issued on DyeVert, the clinician feedback on our device and the independent modelling done on its cost-effectiveness for the UK Healthcare system. Although the MIB is not a specific NICE recommendation that results in implementation of payment throughout the NHS, we are hopeful of securing such a recommendation in late 2020 to early 2021.

The MIB is an important part of the overall NICE process, where Osprey intends to seek a specific recommendation from NICE on the use of DyeVert in coronary angiogram procedures to reduce contrast media volumes and therefore the likelihood of Contrast-Induced Acute Kidney Injury (CI-AKI). In December 2019 NICE updated its formal Clinical Guidance on Acute Kidney Injury with additional guidance on intra-arterial administration of contrast and the specific risk of first-pass renal exposure³. First-pass renal exposure refers to contrast that is not diluted before it reaches the kidneys, such as contrast refluxed in the aorta during a coronary angiogram. Osprey's DyeVert is the only product with clinical trial backed claims for the reduction of contrast reflux.

In the UK, DyeVert is commercially available for £350 (exclusive of VAT) per patient. The reusable monitor assembly is included in the cost of the set of disposable components to the hospital.

There are approximately 50,000 CKD patients each year in the UK that undergo coronary angiograms each year in the UK who could see a reduction in the risk of developing CI-AKI with DyeVert. AKI costs the UK hospital system approximately £1 billion annually.

This release has been authorised for lodgement to ASX by Mike McCormick, CEO of Osprey Medical and lodged by Brendan Case, Company Secretary.

¹ The MIB [MIB196] for DyeVert can be viewed at the following link: https://www.nice.org.uk/advice/mib196.

² The publication can be found online at (https://link.springer.com/article/10.1007/s41669-020-00195-x.

³ Guidance on first-pass renal exposure can be viewed at the following link: https://pathways.nice.org.uk/pathways/acute-kidney-injury/risk-assessment-and-prevention-of-acute-kidney-injury#content=view-node:nodes-person-aged-18-or-over-having-contrast-media

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About Osprey Medical (ASX: OSP)

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 (CI-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 DyeVertTM 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.

About Medtech Innovation Briefings

NICE Medtech Innovation Briefings (MIBs) are designed to support NHS and social care commissioners and staff who are considering using new medical devices and other medical or diagnostic technologies. The information provided includes a description of the technology, how it's used and its potential role in the treatment pathway. A MIB also includes a review of relevant published evidence and the likely costs of using the technologies, but they are not NICE guidance and do not make any recommendations on the value of using the technologies. The briefings will help avoid the need for organisations to produce similar information locally, so saving staff time, effort and resources. MIBs are designed to be fast, flexible and responsive to the need for information on innovative technologies. MIBs are commissioned by NHS England and produced in support of the NHS 5 Year Forward View, specifically as one of a number of steps which will accelerate innovation in new treatments and diagnostics.

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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