

## Osprey expands into Canada with MDL approval and exclusive GE Healthcare distribution agreement

### Key highlights

- Osprey has received approval for a Canadian Medical Device License (MDL) for the DyeVert™ Plus EZ and DyeVert™ Power XT Systems
- Osprey has signed an exclusive distribution agreement with GE Healthcare Canada Inc. for commercialization of the DyeVert System in Canada
- Complements recently signed distribution agreement with GE Healthcare in Europe

**Minnesota, United States and Melbourne, Australia – 20 July 2021** – Osprey Medical, Inc. (ASX:OSP) (Osprey or the Company) is pleased to announce the expansion of the company into the Canadian market with Medical Device License (MDL) approval and an exclusive distribution agreement with GE Healthcare Canada Inc.

Osprey recently received approval from Health Canada for a Medical Device License (MDL) for the DyeVert Systems. This MDL was approved as the DyeVert technology has positive scientific evidence that supports its quality, safety, and efficacy in reducing Contrast Induced Acute Kidney Injury (CI-AKI). The DyeVert portfolio reduces the amount of contrast dye used in heart imaging procedures and has been proven to reduce CI-AKI by on average 55% without compromising image quality<sup>1-8</sup>.

“We are thrilled the DyeVert portfolio has received MDL approval from Health Canada,” says Osprey’s President and CEO, Mike McCormick. “This approval acknowledges the efficacy and safety of our DyeVert technology in improving clinical outcomes by reducing CI-AKI rates in high-risk patients.”

The MDL approval mirrors the FDA approval process in the US and provides Osprey with the opportunity to distribute in Canada with the approval of Health Canada. Following on from this approval, Osprey has signed an exclusive 4-year distribution agreement with GE Healthcare Canada Inc. for commercialisation of the DyeVert System in Canada.

Luke Chrusciel, Commercial Manager, Pharmaceutical Diagnostics, GE Healthcare Canada Inc commented on the agreement. “GE Healthcare Canada are pleased to be partnering with Osprey Medical to exclusively distribute the DyeVert technology in Canada.”

“The product portfolio has shown great efficacy in improving patient outcomes which continues to be a main focus for us, so this agreement highlights the aligned goals of both GE Healthcare Canada and Osprey Medical.”

This agreement follows the GE Healthcare agreement in Europe, which expanded global commercialisation of Osprey’s product portfolio in Europe, Russia, Middle East, Africa, Central Asia and Turkey.

Osprey has several sales agreements in place including Regional Health Care Group to distribute across Australia and New Zealand and utilises several Independent Sales Agency agreements for distribution across the US.

***This release has been authorised for lodgement to ASX by Mike McCormick, CEO of Osprey Medical.***

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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 DyeVert™ 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 GE Healthcare

GE Healthcare is the \$16.7 billion healthcare business of GE (NYSE: GE). As a leading global medical technology and digital solutions innovator, GE Healthcare enables clinicians to make faster, more informed decisions through intelligent devices, data analytics, applications and services, supported by its Edison intelligence platform. With over 100 years of healthcare industry experience and around 50,000 employees globally, the company operates at the center of an ecosystem working toward precision health, digitizing healthcare, helping drive productivity and improve outcomes for patients, providers, health systems and researchers around the world.

Visit our website [www.gehealthcare.com](http://www.gehealthcare.com) for more information.

## 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. Forward-looking statements involve known and unknown risks, uncertainties, contingencies and other factors, many of which are beyond the Company's control (including but not limited to the COVID-19 pandemic), subject to change without notice and may involve significant elements of subjective judgment and assumptions as to future events which may or may not be correct.

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. Given the current uncertainties regarding the impact of the COVID-19 on the trading conditions impacting the Company, the financial markets and the health services world-wide, investors are cautioned not to place undue reliance on the current trading outlook.

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.

#### **Foreign Ownership Restriction**

Osprey's CHES Depositary Interests (CDIs) are issued in reliance on the exemption from registration contained in Regulation S of the US Securities Act of 1933 (Securities Act) for offers or sales which are made outside the US. Accordingly, the CDIs have not been, and will not be, registered under the Securities Act or the laws of any state or other jurisdiction in the US. The holders of Osprey's CDIs are unable to sell the CDIs into the US or to a US person unless the re-sale of the CDIs is registered under the Securities Act or an exemption is available. Hedging transactions with regard to the CDIs may only be conducted in accordance with the Securities Act.