13 August 2020

CE Marking received for core European product, DyeVert Power XT

Key Highlights

- **Osprey Medical has received European CE Marking approval for the 2nd generation DyeVert Power XT device**
- **Approval of DyeVert Power XT (for automatic injection) means the full coronary angiography market is now available to Osprey's DyeVert franchise**
- **Device is expected to be a core product in the product portfolio being commercialised by GE Healthcare**
- **Publication of clinical literature supporting effectiveness of Osprey DyeVert technology by renowned cardiologist in Europe (Dr Briguori)**
- **Update on GE Healthcare Strategic Alliance**

Minnesota, United States and Melbourne, Australia – 13 August 2020 – Osprey Medical, Inc. (ASX:OSP) (**Osprey** or **the Company**) is pleased to announce that the Company has received CE Marking for the DyeVert Power XT 2nd generation device.

The CE Marking approval for its DyeVert Power XT device means the product can now be marketed and sold across Europe. Europe is a core market for Osprey and a significant player in the global power injector market. Our DyeVert Power XT device is expected to form a core product in the portfolio that is being commercialised by GE Healthcare.

Osprey Medical President & CEO, Mike McCormick, commented:

"We are delighted to have received CE Mark approval for our Power XT device. The CE Mark is a very significant achievement as it ultimately enables Osprey to target the full coronary angiography market as our portfolio is now compatible with both automatic and manual injection methods.

The approval was a critical building block in our European roll-out and the timing is perfect, following the strategic alliance formed with GE Healthcare in July. With the CE Mark ensuring a comprehensive product range, plus a recently published paper by renowned cardiologist, Dr Briguori; we are confident of a strong launch in Europe through the GE Healthcare sales force later this year"

The main feature of the device is its compatibility with automated power injectors, thus complementing the Company's existing DyeVert EZ product which is compatible with manual injection. The regulatory clearance marks a critical evolution in Osprey's DyeVert technology, as the Company now has full coverage of the coronary angiography market in Europe.

This marks another key milestone in the Company's European strategy following the exclusive distribution agreement with GE Healthcare announced on 30 July 2020.

Clinical update

In addition to the CE Mark approval, recently an important peer reviewed manuscript was published by Dr Carlo Briguori, a key opinion leading heart physician in Italy. This study further validates the effectiveness of Osprey's DyeVert technology at improving patient outcomes and lowering hospital cost. This important publication will form a key part of Osprey's European sales strategy with GE Healthcare.

Some of the key findings from this paper included:

- **Study Design**
  - Patients studied had heart attacks (STEMI and NSTEMI)
  - 339 control patients (no-DyeVert) were compared to 112 patients who received DyeVert
  - Hydration (IV fluid administration) protocol was the same in both DyeVert and no-DyeVert
  - Observed, retrospective, propensity matched study in a single center in Naples Italy

- **Results**
  - 38% dye reduction in the DyeVert group compared to the no-DyeVert group
  - 58% Acute Kidney Injury reduction in the DyeVert group compared to the no-DyeVert group
  - 25% reduction in hospital length of stay in the DyeVert group compared to the no-DyeVert group

A link to the abstract is available at https://pubmed.ncbi.nlm.nih.gov/32682348/ .

GE Healthcare update

On 30 July 2020, Osprey announced that it had signed an exclusive agreement with GE Healthcare to distribute its products across Europe, Russia, Middle East, Africa, Central Asia and Turkey ('the Region'). Osprey can now provide some guidance on the agreement which is significant to Osprey. Relevantly, the agreement is expected to contribute materially to Osprey's revenue over the 4-year contracted period. Previously, the Company's operations were primarily in the US with sales outside US (OUS) contributing an immaterial amount to group revenues. This agreement represents a significant shift for the company and means that OUS sales will now contribute materially to Osprey's group revenues and complement the existing growth of sales generated within the US.

Under the contract with GE Healthcare, there are prescribed minimum order quantities increasing each year with further upside when sales exceed these quantities. Conservatively, under the minimum order quantities agreed, the distribution agreement is expected to add +20% to Osprey's total expected revenues in 2021 with this expected to scale in importance each year, reaching +40% by the fourth year. Additionally, under the contract, transfer prices for all products are fixed over the 4-year period whereby Osprey will experience margin certainty during the contract period.

The agreement with GE Healthcare includes key provisions of an exclusive distribution agreement between the parties. The terms were disclosed in the prospectus dated 3 April 2020 remain, and are set out below for convenience:

(a) GE Healthcare's large and dedicated commercialisation team (in excess of 120) will be tasked with selling products in the Osprey portfolio in the Region;
(b) GE Healthcare will be granted a right of first refusal to distribute and promote any new products introduced by Osprey in the Region;
(c) in order for GE Healthcare to maintain its exclusive distribution rights it must meet the minimum purchase levels (which increase on an annual basis during the term);
(d) transfer prices are fixed over the 4-year term and provide appropriate gross margin returns for Osprey; and
(e) during the term, GE Healthcare will liaise with Osprey in relation to marketing, business plans and provide sales reports.

This release dated 13 August 2020 has been authorised for lodgement to ASX by Mike McCormick, CEO of Osprey Medical.

– ENDS –

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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.

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 CHESS 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.