

Osprey Medical and GE Healthcare Launch New Educational Program to Increase Awareness of Strategies to Help Address Acute Kidney Injury (AKI)

Melbourne, Australia, and Marlborough, MA, USA — September 20, 2018 — Osprey Medical (ASX:OSP) is pleased to announce a collaboration with GE Healthcare on Osprey's Be Kind to Kidneys™ campaign. The campaign aims to increase awareness of strategies to help address acute kidney injury (AKI) following normal heart imaging procedures (angiograms) in patients with chronic kidney disease (CKD). As part of the campaign, Osprey Medical and GE Healthcare will sponsor a number of educational programs and seminars for healthcare professionals on how to address the risk of AKI.

AKI is sudden damage to the kidneys that causes them to not work properly. It can range from minor loss of kidney function to complete kidney failure.¹ With one out of four angiography patients presenting with CKD,² the risk for these patients to develop AKI is a serious concern for catheterization labs and hospitals. Patients with impaired kidneys are at a significantly increased risk for negative outcomes and for longer hospital stays.³ The American College of Cardiology and American Heart Association have issued joint guidelines for the reduction of AKI.⁴ These guidelines recommend that physicians should screen patients for risk of AKI, ensure they are properly hydrated, and minimize the volume of contrast dye used. Osprey and GE Healthcare's campaign intends to reinforce these guidelines and increase awareness so that healthcare professionals can help patients with CKD.

The campaign kicks off in September with a series of two-day educational programs in the United States for nurses and technicians. The programs will focus on strategies to reduce contrast volume using Osprey's DyeVert™ Plus system, the only system cleared by the U. S. Food & Drug Administration for contrast reduction and real-time monitoring of dye dose to patients throughout the angiogram. The programs will also focus on approaches to help reduce the risk of AKI in patients with poor kidney function undergoing heart imaging procedures.

GE Healthcare's isosmolar imaging agent Visipaque™ (iodixanol) Injection is an intravascular contrast agent that is used to assist in interventional and diagnostic procedures and will also be discussed in the educational programs.

In addition, during the Transcatheter Cardiovascular Therapeutics (TCT) 2018 Annual Meeting, Osprey and GE Healthcare will host a symposium with presentations on "[Contrast-Induced Acute Kidney Injury: Preventive Measures Worth Trying](#)" and "The Effect of Major Adverse Renal Cardiac Events (MARCE) Incidence and Economic Impact Resulting From Contrast Media Use in the Cath Lab."

Osprey Medical and GE Healthcare have a shared vision to address the real-world needs of patients with poor kidney function. Osprey's President and CEO, Mike McCormick, stated: "We are pleased to be collaborating with GE Healthcare on these joint educational efforts to address heart imaging procedures for patients with poor kidney function."

"We are very excited about the collaboration with Osprey," added Erin Schardt, General Manager Contrast Media, US and Canada, GE Healthcare. "We share a similar goal that is rooted in improving patient outcomes

through a variety of measures, including the educational efforts that we will jointly be undertaking,” concluded Schardt.

Product Indications and Use

Intra-Arterial Procedures Adult and pediatric patients 12 years of age and older: Intra-arterial digital subtraction angiography (270 and 320 mg iodine/mL); angiocardiology (left ventriculography and selective coronary arteriography), peripheral arteriography, visceral arteriography, and cerebral arteriography (320 mg iodine/mL). **Pediatric patients less than 12 years of age:** Angiocardiology, cerebral arteriography, and visceral arteriography (320 mg iodine/mL)

Intravenous Procedures

Adult and pediatric patients 12 years of age and older: Computed tomography (CT) imaging of the head and body and excretory urography (270 and 320 mg iodine/mL); peripheral venography (270 mg iodine/mL); coronary computed tomography angiography (CCTA) to assist in the diagnostic evaluation of patients with suspected coronary artery disease (320 mg iodine/mL). **Pediatric patients less than 12 years of age:** CT imaging of the head and body and excretory urography (270 mg iodine/mL).

Important Safety Information About Visipaque™ (iodixanol) Injection

WARNING: NOT FOR INTRATHECAL USE

See full Prescribing Information for complete Boxed Warning.

Inadvertent intrathecal administration may cause death, convulsions/seizures, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, rhabdomyolysis, hyperthermia, and brain edema.

CONTRAINDICATION: Visipaque Injection is contraindicated for intrathecal use. **WARNINGS AND PRECAUTIONS —**

Hypersensitivity Reactions: Visipaque can cause life-threatening or fatal hypersensitivity reactions, including anaphylaxis. Most severe reactions develop shortly after the start of the injection, but reactions can occur up to hours later. Obtain a history of allergy, hypersensitivity, or hypersensitivity reactions to iodinated contrast agents, and always have emergency resuscitation equipment and trained personnel available prior to Visipaque administration. Monitor all patients for hypersensitivity reactions.

Contrast-Induced Acute Kidney Injury: Acute kidney injury, including renal failure, may occur after Visipaque administration. Use the lowest necessary dose of Visipaque in patients with renal impairment. Adequately hydrate patients prior to and following Visipaque administration. Do not use laxatives, diuretics, or preparatory dehydration prior to Visipaque administration.

Cardiovascular Adverse Reactions: Life-threatening or fatal cardiovascular reactions, including hypotension, shock, and cardiac arrest have occurred with the use of Visipaque. Most deaths occur during injection or five to ten minutes later, with cardiovascular disease as the main aggravating factor. Use the lowest necessary dose of Visipaque in patients with congestive heart failure, and always have emergency resuscitation equipment and trained personnel available. Monitor all patients for severe cardiovascular reactions.

Thromboembolic Events: Serious, rarely fatal, thromboembolic events causing myocardial infarction and stroke can occur during angiocardiology procedures with both ionic and nonionic contrast agents. Use meticulous angiographic techniques, and minimize the length of the procedure. Avoid blood remaining in contact with syringes containing iodinated contrast agents. Avoid angiocardiology in patients with homocystinuria because of the risk of inducing thrombosis and embolism.

Extravasation and Injection-Site Reactions: Extravasation of Visipaque Injection may cause tissue necrosis and/or compartment syndrome, particularly in patients with severe arterial or venous disease. Ensure intravascular placement of catheters prior to injection. Monitor patients for extravasation and advise patients to seek medical care for progression of symptoms.

Thyroid Storm in Patients With Hyperthyroidism: Thyroid storm has occurred after the intravascular use of iodinated contrast agents in patients with hyperthyroidism, or with an autonomously functioning thyroid nodule. Evaluate the risk in such patients before use of Visipaque.

Hypertensive Crisis in Patients With Pheochromocytoma: Hypertensive crisis has occurred after the use of iodinated contrast agents in patient with pheochromocytoma. Monitor patients when administering Visipaque if pheochromocytoma or catecholamine-secreting paragangliomas are suspected. Inject the minimum amount of contrast necessary, assess the blood pressure throughout the procedure, and have measures for treatment of a hypertensive crisis readily

available. **Sickle Cell Crisis in Patients With Sickle Cell Disease:** Iodinated contrast agents when administered intravascularly may promote sickling in individuals who are homozygous for sickle cell disease. Hydrate patients prior to and following Visipaque administration, and use Visipaque only if the necessary imaging information cannot be obtained with alternative imaging modalities. **Severe Cutaneous Adverse Reactions:** Severe cutaneous adverse reactions (SCARs) may develop from one hour to several weeks after intravascular contrast agent administration. These reactions include Stevens-Johnson syndrome and toxic epidermal necrolysis (SJS/TEN), acute generalized exanthematous pustulosis (AGEP), and drug reaction with eosinophilia and systemic symptoms (DRESS). Reaction severity may increase and time to onset may decrease with repeat administration of contrast agents; prophylactic medications may not prevent or mitigate SCARs. Avoid administering Visipaque to patients with a history of a SCAR to Visipaque. **Pediatric Use:** Pediatric patients at high risk of adverse reactions during and after administration of contrast agents include those with asthma, hypersensitivity to other medication and/or allergens, cyanotic and acyanotic heart disease, chronic heart failure, or a serum creatinine >1.5 mg/dL. Patients with immature renal function or dehydration may be at increased risk due to prolonged elimination of iodinated contrast agents. **Geriatric Use:** While no overall differences in safety or effectiveness were observed in patients >65 years, greater sensitivity regarding some older individuals cannot be ruled out. As Visipaque is substantially excreted by the kidney, the risk of toxic reactions may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function. **Lactation:** There are no data on the presence of iodixanol in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for Visipaque and any potential adverse effects on the breastfed infant from Visipaque, or from the underlying maternal condition. Interruption of breastfeeding after exposure to iodinated contrast agents is not necessary because the potential exposure of the breastfed infant to iodine is small. However, a lactating woman may consider interrupting breastfeeding, and pumping and discarding breast milk for 10 hours after Visipaque administration, to minimize drug exposure to a breastfed infant. **ADVERSE REACTIONS:** Serious, life-threatening, and fatal reactions, mostly of cardiovascular origin, have been associated with the administration of iodine-containing contrast agents, including Visipaque Injection. Most deaths occur during injection or five to 10 minutes later. Rare reports of anaphylaxis have been documented during postmarketing surveillance. As with other contrast agents, Visipaque is often associated with sensations of discomfort, warmth, or pain. The reported incidence of adverse reactions to contrast agents in patients with a history of allergy is twice that of the general population. Patients with a history of a previous reaction to contrast agents are three times more susceptible than other patients. **DRUG INTERACTIONS — Metformin:** In patients with renal impairment, metformin can cause lactic acidosis. Iodinated contrast agents appear to increase the risk of metformin-induced lactic acidosis, possibly as a result of worsening renal function. Stop metformin at the time of, or prior to, Visipaque administration in patients with an estimated glomerular filtration rate (eGFR) between 30 and 60 mL/min/1.73 m²; in patients with a history of hepatic impairment, alcoholism, or heart failure; or in patients who will be administered intra-arterial iodinated contrast. Reevaluate eGFR 48 hours after the imaging procedure, and reinstitute metformin only after renal function is stable. **Radioactive Iodine:** Administration of iodinated contrast agents may interfere with thyroid uptake of radioactive iodine (I-131 and I-123) and decrease therapeutic and diagnostic efficacy in patients with carcinoma of the thyroid. The decrease in efficacy lasts for six to eight weeks. **Beta-Adrenergic Blocking Agents:** The use of beta-adrenergic blocking agents lowers the threshold for and increases the severity of contrast reactions, and reduces the responsiveness of treatment of hypersensitivity reactions with epinephrine. Because of the risk of hypersensitivity reactions, use caution when administering Visipaque to patients taking beta-blockers. **Oral Cholecystographic Contrast Agents:** Renal toxicity has been reported in patients with liver dysfunction who were given an oral cholecystographic agent followed by intravascular iodinated contrast agents. Postpone the administration of Visipaque in patients who have recently received an oral cholecystographic contrast agent. **OVERDOSAGE:** The adverse effects of contrast media overdose may be life-threatening, affecting mainly the pulmonary and cardiovascular systems.

Prior to Visipaque administration, please read the full Prescribing Information.

To report SUSPECTED ADVERSE REACTIONS, contact GE Healthcare at 800 654 0118 (option 2), or the FDA at 800 FDA 1088 or www.fda.gov/medwatch.

References:

1. Acute kidney injury. National Health Service Website. <https://www.nhs.uk/conditions/acute-kidney-injury/>. Accessed September 10, 2018.
2. Tsai TT, Patel UD, Change TI, et al. Contemporary incidence, predictors, and outcomes of acute kidney injury in patients undergoing percutaneous coronary interventions. *JACC. Cardiovasc Inter.* 2014;7:1-9.
3. Subramanian S, Tumlin J, Bapat B, Zyczynski T. Economic burden of CIN: implications for prevention strategies. *J Med Econ.* 2007;10:119-134.
4. Levine GN, Bates ER, Blankenship JC, et al. 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. *Circulation.* 2011;124:e574-e651.

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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 (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 in 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 composed 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-recognized experts in heart and kidney diseases.

About GE Healthcare

Harnessing data and analytics across hardware, software, and biotech, GE Healthcare is the \$19 billion healthcare business of GE (NYSE:GE). As a leading provider of medical imaging equipment, with a track record of more than 100 years in the industry and more than 50,000 employees across 100 countries, we transform healthcare by delivering better outcomes for providers and

patients. Follow us on [Facebook](#), [LinkedIn](#), [Twitter](#) and [The Pulse](#) for latest news. For more information about GE Healthcare, visit our website at www.gehealthcare.com.

Osprey Medical: 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.

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 resale 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.

GE Healthcare: Forward-Looking Statements

This document contains "forward-looking statements" - that is, statements related to future, not past, events. In this context, forward-looking statements often address our expected future business and financial performance and financial condition, and often contain words such as "expect," "anticipate," "intend," "plan," "believe," "seek," "see," "will," "would," "estimate," "forecast," "target," "preliminary," or "range." Forward-looking statements are based on current plans, estimates, and expectations that are subject to risks, uncertainties, and assumptions. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those indicated or anticipated by such forward-looking statements. The inclusion of such statements should not be regarded as a representation that such plans, estimates, or expectations will be achieved. Important factors that could cause actual results to differ materially from such plans, estimates, or expectations include, among others: events could cause the educational program to be stopped; the Osprey collaboration could cease; changes in general economic and/or industry-specific conditions; actions by third parties, including government agencies, could delay or stop our progress; and other risk factors as detailed from time to time in GE's respective reports filed with the U.S. Securities and Exchange Commission (SEC), including GE's annual reports on Form 10-K, periodic quarterly reports on Form 10-Q, periodic current reports on Form 8-K, and other documents filed with the SEC. The foregoing list of important factors is not exclusive. Any forward-looking statements apply only as of the date of this communication. GE undertakes no obligation to update any forward-looking statements, whether as a result of new information or development, future events, or otherwise, except as required by law. Readers are cautioned not to place undue reliance on any of these forward-looking statements.