# **Polarean Imaging Plc** ("Polarean" or the "Company")

## Reimbursement code price range for the Polarean XENOVIEW™ MRI Technology

Payment range between \$1,201 to \$1,300, in-line with expectations

Polarean Imaging plc (AIM: POLX), a commercial-stage medical device leader in advanced magnetic resonance imaging ("MRI") of the lungs, announces that following the RNS on 29 August 2023the reimbursement code for the Polarean XENOVIEW™ (xenon Xe 129, hyperpolarised) technologyhas been assigned to a new technology Ambulatory Payment Classification code (APC 1551) which corresponds to a payment range of between \$1,201 to \$1,300 as part of the 2023 Medicare Hospital Outpatient Prospective Payment System final rule.

The codes enables healthcare providers a path to bill for "magnetic resonance imaging with inhaled hyperpolarised xenon-129 contrast agent, chest, including preparation and administration of agent".

For further information on the details of the reimbursement code established by the US Centers for Medicare & Medicaid Services ("CMS"), please see the link to the latest RNS here.

Christopher von Jako, Ph.D., Chief Executive Officer of Polarean said!"We've been working hard with CMS and welcome this news today from which aligns with our original expectation on pricing reimbursement, and whilst the new code does not guarantee coverage or payment, its effectiveness marks a key commercialisation milestone for the Company."

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) 596/2014, as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

### **Enquiries:**

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### About Polarean (www.polarean.com)

The Company and its wholly owned subsidiary, Polarean, Inc. (together the "Group") are revenue-generating, medical imaging technology companies operating in the high-resolution medical imaging space. Polarean aspires to revolutionise pulmonary medicine by bringing the power and safety of MRI to the respiratory healthcare community in need of new solutions to evaluate lung ventilation, diagnose disease, characterise disease progression, and monitor response to treatment. By researching, developing, and commercialising novel imaging solutions with a non-invasive and radiation-free functional imaging platform. Polarean's vision is to help address the global unmet medical needs of more than 500 million patients worldwide suffering with chronic respiratory disease. Polarean is a leader in the field of hyperpolarisation science and has successfully developed the first and only hyperpolarised MRI contrast agent to be approved in the United States. The Company also commercialises systems (such as the HPX hyperpolarisation system), accessories (such as Xe-specific chest coils and phantoms), and FDA-cleared post-processing software (to support ventilation defect analysis), to support fully integrated modern respiratory imaging operations.

## **XENOVIEW IMPORTANT SAFETY INFORMATION**

#### Indication

XENOVIEW™, prepared from the Xenon Xe 129 Gas Blend, is a hyperpolarized contrast agent indicated for use with

magnetic resonance imaging (MRI) for evaluation of lung ventilation in adults and pediatric patients aged 12 years and older.

### Limitations of Use

XENOVIEW has not been evaluated for use with lung perfusion imaging.

### CONTRAINDICATIONS

None.

### Warnings and Precautions

Risk of Decreased Image Quality from Supplemental Oxygen: Supplemental oxygen administered simultaneously with XENOVIEW inhalation can cause degradation of image quality. For patients on supplemental oxygen, withhold oxygen inhalation for two breaths prior to XENOVIEW inhalation, and resume oxygen inhalation immediately following the imaging breath hold.

Risk of Transient Hypoxia: Inhalation of an anoxic gas such as XENOVIEW may cause transient hypoxemia in susceptible patients. Monitor all patients for oxygen desaturation and symptoms of hypoxemia and treat as clinically indicated.

#### **Adverse Reactions**

Adverse Reactions in Adult Patients: The adverse reactions (> one patient) in efficacy trials were oropharyngeal pain, headache, and dizziness. Adverse Reactions in Pediatric and Adolescent Patients: In published literature in pediatric patients aged 6 to 18, transient adverse reactions were reported: blood oxygen desaturation, heart rate elevation, numbness, tingling, dizziness, and euphoria. In at least one published study of pediatric patients aged 6 to 18 years, transient decrease in SpO2% and transient increase in heart rate was reported following hyperpolarized xenon Xe 129 administration. XENOVIEW is not approved for use in pediatric patients less than 12 years of age.

### Please see full prescribing information at www.xenoview.net

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