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Polarean Imaging PLC
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Polarean Imaging Plc
("Polarean" or the "Company")

CMS grants reimbursement code for the Polarean XENOVIEW™ MRI Technology
Code effective from 1 October 2023

Polarean Imaging plc (AIM: POLX), a commercial-stage medical device leader in advanced MRI scanning of the lungs, announces that the US Centers for Medicare & Medicaid Services ("CMS") has established a new reimbursement code for the Polarean XENOVIEW™ (xenon Xe 129, hyperpolarised) technology, effective from 1 October 2023.

The code (C9791) 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*". This was announced as part of the release of the October 2023 Healthcare Common Procedure Coding System (HCPCS) code set. The payment level associated with the XENOVIEW™ MRI code is yet to be announced and is expected to be received in the coming weeks.

Christopher von Jako, Ph.D., Polarean's Chief Executive Officer said: "*We have been working diligently with CMS, our clinicians and hospital-based billing stakeholders over the past several months and view this as an important step towards enhancing accessibility to this innovative technology. We look forward to learning the payment details tied to the new code, in the coming weeks, as we continue to increase access to XENOVIEW™ MRI for patients suffering from ventilation-associated lung diseases.*"

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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 revolutionize 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 commercializing 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 hyperpolarized MRI contrast agent to be approved in the United States. On Dec. 23, 2022, the FDA granted approval for Polarean's first drug device combination product, XENOVIEW™ (Xenon Xe^{129} hyperpolarized). Xe^{129} MRI is also currently being studied for visualization and quantification of gas exchange regionally in the smallest airways of the lungs, across the alveolar tissue membrane, and into the pulmonary bloodstream for future clinical indications.

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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