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Polarean Imaging PLC
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Polarean Imaging Plc

("Polarean" or the "Company")

U.S. Patent granted for dynamic cardiopulmonary blood flow imaging with Xenon MRI

New patent expands the utility of hyperpolarised Xenon MRI in the diagnosis and monitoring of diseases of the pulmonary vasculature

Polarean Imaging Plc (AIM: POLX), a commercial-stage medical device leader in advanced Magnetic Resonance Imaging ("MRI") of lung function, announces the issuance of U.S. Patent 11,944,424, covering the use of Xenon MRI for cardiopulmonary blood flow imaging. The Company met with the FDA in October 2023 regarding the gas exchange indication, including cardiopulmonary blood flow imaging, and is continuing to work towards completing its plans for a clinical trial to expand the label for XENOVIEW™, the Company's hyperpolarised Xenon MRI contrast agent.

The newly granted patent marks a significant milestone, expanding the utility of hyperpolarised Xenon MRI in the diagnosis and monitoring of diseases of the pulmonary vasculature. With this patent, the Polarean Xenon MRI platform is poised to revolutionise the imaging of pulmonary blood flows and pressures.

Pulmonary vascular disease ("PVD") poses a significant global health challenge, affecting the intricate network of blood vessels within lung tissue and connecting the lung to the heart. There is currently no straightforward method for directly measuring blood flow and pressure in the lungs, with the conventional approach requiring the insertion of an invasive catheter through either the arm or leg into the right side of the heart.

No other techniques currently exist to visualise blood flows and pressures in the very small vessels surrounding the lung air sacs. This region represents a "silent zone" to most modalities and is precisely where the crucial exchange of oxygen and carbon dioxide occurs. The absence of effective non-invasive tools for assessing pulmonary vascular function remains a persistent barrier to early diagnosis and monitoring of PVD.

XENOVIEW is inhaled by the patient which then dissolves into lung tissue and enters the pulmonary microvasculature. This allows for dynamic measurement of its distribution. This ability to reveal regional microvascular blood flow impairment can be used to noninvasively detect pre- and post-capillary pulmonary hypertension.

Christopher R. von Jako, Ph.D., CEO of Polarean, said:*"This new patent represents an important advancement for our intellectual property portfolio, strengthening our market position and marking a pivotal step toward achieving our vision of optimising lung health and minimising preventable loss. Through our innovative, non-invasive, radiation-free pulmonary functional imaging platform, we aim to illuminate hidden diseases, including those within the pulmonary vasculature. This breakthrough has the potential to empower early intervention and significantly improve patient outcomes."*

Bastiaan Driehuys, Ph.D., Chief Scientific Officer of Polarean, said:*"This exciting new technology introduces a fundamentally new contrast mechanism for Xenon MRI that opens the door to non-invasive characterisation of haemodynamics that are altered in patients with pulmonary hypertension. In our research, we have seen this core new capability pave the way to better diagnosis and monitoring of these patients and comprehensive assessment of dyspnea."*

Enquiries:

Polarean Imaging plc www.polarean.com / www.polarean-ir.com
Christopher von Jako, Ph.D, Chief Executive Officer *Via Walbrook PR*
Charles Osborne, Chief Financial Officer

Stifel Nicolaus Europe Limited (NOMAD and Sole Corporate Broker) +44 (0)20 7710 7600
Nicholas Moore / Samira Essebiyea / Kate Hanshaw (Healthcare Investment Banking)
Nick Adams / Nick Harland (Corporate Broking)

Walbrook PR Tel: +44 (0)20 7933 8780 or polarean@walbrookpr.com
Anna Dunphy / Phillip Marriage Mob: +44 (0)7876 741 001 / +44 (0)7867 984 082

About Pulmonary Hypertension

Pulmonary hypertension (PH) is a serious condition that is characterised by abnormally high blood pressure in the lungs, impacting at least 1% of the global population and commonly manifesting as dyspnea (shortness of breath). While left-sided heart and lung diseases are primary contributors to PH, distinct subgroups such as Group 1 (Pulmonary Arterial Hypertension) and Group 3 (Pulmonary Hypertension due to lung diseases and/or hypoxia) require focused attention due to their unique pathophysiological mechanisms involving the pulmonary vasculature. Without proactive management and timely intervention, PH can progress to heart failure and result in mortality.

About Polarean

Polarean is a revenue-generating medical imaging technology company revolutionizing pulmonary medicine through direct visualisation of lung function by introducing the power and safety of MRI to the respiratory healthcare community. This community is in desperate need of modern solutions to accurately assess lung function. The Company strives to optimise lung health and prevent avoidable loss by illuminating hidden disease, addressing the global unmet medical needs of more than 500 million patients worldwide suffering from chronic respiratory disease. Polarean is a leader in the field of hyperpolarisation science and has successfully developed the first and only hyperpolarised Xenon MRI inhaled contrast agent, XENOVIEW™, which is now FDA-approved in the United States. Polarean is dedicated to researching, developing, and commercialising innovative imaging solutions with its non-invasive and radiation-free pulmonary functional MRI platform. This comprehensive drug-device platform encompasses the proprietary Xenon gas blend, gas hyperpolarisation system, as well as software and accessories, facilitating fully integrated modern respiratory imaging operations. Founded in 2012, with offices in Durham, NC, and London, United Kingdom, Polarean is committed to increasing global awareness of and broad access to its XENOVIEW MRI technology platform. For the latest news and information about Polarean, please visit www.polarean.com.

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.

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