**FDA clears XENOVIEW® 3T Chest Coil in GE HealthCare MRI Systems**

*Expands accessibility for institutions utilizing GE HealthCare MRI systems*

**DURHAM, NC and LONDON, November, 21 2024 (GLOBE NEWSWIRE)** –

Polarean Imaging plc (AIM: POLX) ("Polarean" or the "Company"), a commercial-stage medical imaging technology leader in advanced Magnetic Resonance Imaging ("MRI") of the lungs, announces that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the Company's specialized MRI Chest Coil to now include GE HealthCare 3 Tesla (3T) MRI scanners for the visualization of Xenon-129 nuclei. With this new introduction, the Company now supports Xenon MRI scanning of both clinical and research patients on all three major MRI scanner vendors: GE HealthCare, Philips, and Siemens Healthineers.

Polarean's GE HealthCare compatible XENOVIEW® 3T Chest Coil is a flexible, single-channel, transmit-receive radiofrequency coil tuned to image Xenon-129 nuclei while a patient is positioned inside a GE HealthCare SIGNA™ Premier 3T or Discovery MR750 3T MRI scanner equipped with their Multi-Nuclear Spectroscopy capability. The XENOVIEW 3T Chest Coil is indicated to be used in conjunction with hyperpolarized Xenon-129 for oral inhalation for the evaluation of lung ventilation in adults and pediatric patients, aged 12 years and older. The addition of the new Chest Coil seamlessly supports institutions with GE HealthCare compatible MRI systems looking to adopt Xenon MRI, with safety and effectiveness confirmed through testing and FDA clearance.

**Christopher von Jako, Ph.D., CEO of Polarean, commented:** "GE HealthCare is a global leader in MRI technology and we are delighted to now offer our XENOVIEW 3T Chest Coil for use on their cutting-edge 3T MRI systems. Expanding our FDA clearance to include GE HealthCare's platforms, following our previous clearance for Philips and Siemens systems, ensures that more institutions and clinicians across the U.S. can access our innovative Xenon MRI technology. This expansion further enhances our ability to provide advanced imaging solutions to support patients and clinicians in the detection and ongoing monitoring of lung disease."

**About Polarean**

Polarean is a revenue-generating medical imaging technology company revolutionizing pulmonary medicine through direct visualization 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 optimize 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 hyperpolarization science and has successfully developed the first and only hyperpolarized Xenon MRI inhaled contrast agent, XENOVIEW®, which is now FDA-approved in the United States. Polarean is dedicated to researching, developing, and commercializing 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 hyperpolarization 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.

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

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