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## Polarean Imaging Plc

("Polarean" or the "Company")

# First order for XENOVIEW<sup>TM</sup> gas blend received from Cincinnati Children's Hospital Medical Center

Clinical cylinder sale marks key milestone and execution of commercial plan

Polarean Imaging plc (AIM: POLX), the medical imaging technology company, announces that it has received its first order for a gas blend cylinder for the production of XENOVIEW (xenon Xe 129 hyperpolarized) from Cincinnati Children's Hospital Medical Center ("Cincinnati Children's"). XENOVIEW is the only hyperpolarised contrast agent approved by the U.S. Food and Drug Administration for use with magnetic resonance imaging (MRI) for the evaluation of lung ventilation in adults and paediatric patients aged 12 years and older. XENOVIEW has not been evaluated for use with lung perfusion imaging.

The cylinder should provide adequate doses for over 100 patient scans. Cincinnati Children's, which conducted much of the pioneering research in adolescent children, expects to begin scanning of hospital clinic patients in May.

XENOVIEW expands the opportunity to visualise lung ventilation without exposing patients to ionising radiation and its associated risks. The dose of XENOVIEW, created through the Polarean HPX hyperpolarisation system, is administered in a single 10 to 15 second breath hold MRI procedure. More than 37 million Americans suffer from a chronic lung disease and there is a significant unmet need for non-invasive diagnostic technology. XENOVIEW can provide pulmonologists, surgeons and other respiratory specialists with regional maps of ventilation in their patients' lungs to assist them in managing their disease.

Richard Hullihen, CEO of Polarean, said:"Since receiving FDA approval at the end of 2022, we have been working diligently to clear the path for commercial distribution of our proprietary gas blend to sites that already have Xenon MRI infrastructure. We are delighted to secure our first sale of a cylinder and cartons of dose delivery bags for clinical use as we continue to execute our commercial plan."

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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. On Dec. 23, 2022, the EDA granted approved for Polarean's first drug device combination product

States. On Dec. 25, 2022, the LDA granted approval for rolateans mist drug device combination product,

XENOVIEW<sup>™</sup> (Xenon Xe<sup>129</sup> hyperpolarised). Xe<sup>129</sup> MRI is also currently being studied for visualisation 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**

## **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 <u>www.xenoview.net</u>

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