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

FDA Approves Polarean's XENOVIEW™ (xenon Xe 129 hyperpolarized) for use with MRI for the evaluation of lung ventilation

- *XENOVIEW represents the first and only hyperpolarized MRI contrast agent*
- *FDA approved indication includes both adolescents and adults representing a significant market opportunity*

Polarean Imaging plc (AIM: POLX), the medical imaging technology company, announces that the U.S. Food and Drug Administration ("FDA") has granted approval for its drug device combination product, XENOVIEW. 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. XENOVIEW has not been evaluated for use with lung perfusion imaging.

XENOVIEW expands the opportunity for pulmonary medicine to utilize the first and only inhaled MRI hyperpolarized contrast agent for novel visualization of lung ventilation without exposing patients to any ionizing radiation and its associated risks. The dose of XENOVIEW, created through the Polarean HPX hyperpolarization system, is administered in a single 10-15 second breath hold MRI procedure.

More than 30 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, Chief Executive Officer of Polarean said: *"FDA approval represents achievement of a major milestone for Polarean's technology. This was only possible in close collaboration with multiple research clinicians and scientists globally, who we thank for their tireless and enthusiastic work. Approval of XENOVIEW represents a major step forward in modern respiratory imaging and we are proud to have pioneered this exciting new technology for clinical use. The commercial team at Polarean is prepared to rapidly launch XENOVIEW for clinical application."*

Dr. Jason Woods, Director of Research in Pulmonary Medicine at the Cincinnati Children's Medical Center added: *"My colleagues and I in the Xenon MRI research community are thrilled that this technology is now available to reach both adolescent and adult patients. With the availability of XENOVIEW in the clinical setting, we will have the ability to evaluate regional lung ventilation, delivered with a benign safety profile, which has been a major unmet need for the patients that look to us to better understand their lung disease."*

Polarean also announces that, simultaneously with the approval of the XENOVIEW NDA, two 510(k) devices were cleared by the FDA that will further support a successful launch of the technology into the clinical marketplace:

XENOVIEW VDP is image processing software that analyzes a pulmonary hyperpolarized 129-Xe MR image and a proton chest MR image to provide visualization and evaluation of lung ventilation in adults and pediatric patients aged 12 years and older. This image analysis platform quantifies normalized xenon intensity of a ventilated space using a pulmonary hyperpolarized 129-Xe ventilation MR image and accompanying proton chest MR image. The software will be used by clinicians to assist in the interpretation and numerical classification of hyperpolarized 129-Xe ventilation MR images.

The Polarean XENOVIEW 3.0T Chest Coil is a flexible, single channel, transmit-receive (T/R) RF coil tuned to 129Xe frequency on a 3.0T MRI magnetic field of a compatible MRI scanner. The Polarean XENOVIEW 3.0T Chest Coil is indicated to be used in conjunction with compatible 3.0T MRI scanners and approved xenon Xe 129 hyperpolarized for oral inhalation for evaluation of lung ventilation in adults and pediatric patients aged 12 years and older. The Chest Coil is intended to be worn by a patient who inhales hyperpolarized 129Xe gas (XENOVIEW) to obtain an MR image of the regional distribution of hyperpolarized 129Xe in the lungs.

About XENOVIEW

Clinical Trial Results: FDA approval of XENOVIEW was based on clinical trial results from two prospective, multi-center, randomized, open-label, cross-over clinical trials that compared XENOVIEW MRI to xenon Xe 133 scintigraphy in adult patients with pulmonary disorders. The mean XENOVIEW dose used in these trials was 99 mL Dose Equivalent ("DE") of hyperpolarized xenon Xe 129 at the time of measurement within 5 minutes of administration. Both trials met their primary endpoints.

Study 1 compared XENOVIEW and xenon Xe 133 imaging in patients being evaluated for possible lung resection surgery. Patients had a medical history of respiratory disorders such as pulmonary mass (44%) and COPD (35%). Additional concomitant respiratory disorders were reported, including; cough (15%), sleep apnea syndrome (12%), and asthma (12%). In the primary analysis of 31 patients, the mean within-patient difference in the predicted postoperative percentage of remaining lung ventilation between XENOVIEW and xenon Xe 133 imaging was within a pre-specified equivalence interval with an observed estimate of 1.4% (95% confidence interval: -0.8%, 3.6%).

Study 2 compared XENOVIEW and xenon Xe 133 imaging in patients being evaluated for possible lung transplant surgery. Patients had a medical history of respiratory disorders, including; interstitial lung disease (49%), idiopathic pulmonary fibrosis (29%), COPD (22%), and other pulmonary fibrotic disorders (14%). In the primary analysis of the 49 patients who completed both scans, the mean within-patient difference in the percentage of overall lung ventilation contributed by the right lung between XENOVIEW and xenon Xe 133 imaging was within a pre-specified equivalence interval with an observed estimate of 1.6% (95% confidence interval: -3.7%, 0.5%).

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 www.xenoview.net

US Customer support
Polarean offers support for customers who need assistance with; placing an order, reimbursement support, service request, and general inquiries. You may reach the Customer Care Center at 1-844-XENOVIE(W) or (1-844-936-6843) or via e-mail at info@polarean.com.

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) 596/2014.

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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 function, diagnose disease, characterize 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 hyperpolarization science and has successfully developed the first and only hyperpolarized MRI contrast

agent to be approved in the United States. On December 23, 2022, the FDA granted approval for Polarean's first drug device combination product, XENOVIEW™ (xenon Xe 129 hyperpolarized). ^{129}Xe 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™ is a trademark of Polarean, Inc. *POL-PR-2201*