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Polarean, Inc.
("Polarean" or the "Company")

FDA grants New Chemical Entity designation for XENOVIEW™ (xenon Xe 129 hyperpolarized)

Polarean Inc, (AIM: POLX), the medical imaging technology company, announces that the U.S. Food and Drug Administration ("FDA") has granted New Chemical Entity ("NCE") designation for its drug product, XENOVIEW, prepared from the Xenon Xe 129 Gas Blend. XENOVIEW 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. It has designated a five-year market exclusivity period.

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 the risk of exposing patients to ionizing radiation. 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 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 designation of New Chemical Entity represents an achievement of a major milestone for the Company's technology. As the first ever inhaled hyperpolarized contrast agent approved, this designation provides the important first mover protection envisioned under the Hatch Waxman legislation."*

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.

About Polarean (www.polarean.com)

Polarean Plc and its wholly owned subsidiary, Polarean, Inc. (together "Polarean") 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). ¹²⁹Xe 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.

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