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

FDA submission to expand minimum age for XENOVIEW™

Polarean Imaging plc (AIM: POLX), a commercial-stage medical device leader in advanced Magnetic Resonance Imaging ("MRI") of lung function, announces that it has submitted a New Drug Application ("NDA") supplement to the US Food and Drug Administration ("FDA"), to allow the administration of XENOVIEW™ to paediatric patients aged six years and older. This supplement includes updates to the HPX Polarisation Measurement Station and new XENOVIEW™ Dose Delivery Bag sizes.

Currently XENOVIEW™, prepared from the Xenon Xe 129 Gas Blend, is a hyperpolarised contrast agent indicated for use with magnetic resonance imaging (MRI) for evaluation of lung ventilation in adults and paediatric patients aged 12 years and older.

Christopher von Jako, Ph.D, Chief Executive Officer of Polarean, said: *"I am pleased to have submitted our NDA supplement to the FDA to expand the minimum age of XENOVIEW™ to paediatric patients six years and older. If granted, this will allow our technology to help even more children with chronic lung conditions and their clinicians, allowing for better management of their disease. I look forward to further updating the market in due course."*

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About Polarean

Polarean is a revenue-generating medical imaging technology company revolutionising 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.

Please see full prescribing information at www.XENOVIEW.net

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