



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

FDA clears XENOVIEW® 3T Chest Coil in GE HealthCare MRI Systems
Expands accessibility for institutions utilising GE HealthCare MRI systems

Polarean Imaging plc (AIM: POLX), a commercial-stage medical imaging technology leader in advanced Magnetic Resonance Imaging ("MRI") of lung function, announces that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the Company's specialised MRI Chest Coil to now include GE HealthCare 3 Tesla (3T) MRI scanners for the visualisation 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 hyperpolarised Xenon-129 for oral inhalation for the evaluation of lung ventilation in adults and paediatric 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."

Click [here](#) to view an interview with Christopher von Jako on the 510(k) clearance and other recent Company milestones.

Enquiries:

Polarean Imaging plc
Christopher von Jako, Ph.D., Chief Executive Officer
Charles Osborne, Chief Financial Officer

www.polarean.com / www.polarean-ir.com
Via Walbrook PR

Stifel (NOMAD and Sole Corporate Broker)
Nicholas Moore / Nick Harland / Ben Good

+44 (0)20 7710 7600

Walbrook PR
Anna Dunphy / Phillip Marriage

Tel: +44 (0)20 7933 8780 or polarean@walbrookpr.com
Mob: +44 (0)7876 741 001 / +44 (0)7867 984 082

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

Risk of decreased image quality from supplemental oxygen: supplemental oxygen administered simultaneously with XENOVUE inhalation can cause degradation of image quality. For patients on supplemental oxygen, withhold oxygen inhalation for two breaths prior to XENOVUE inhalation, and resume oxygen inhalation immediately following the imaging breath hold.

Risk of Transient Hypoxia: Inhalation of an anoxic gas such as XENOVUE 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. XENOVUE is not approved for use in pediatric patients less than 12 years of age.

Please see full prescribing information at www.XENOVUE.net

This information is provided by RNS, the news service of the London Stock Exchange. RNS is approved by the Financial Conduct Authority to act as a Primary Information Provider in the United Kingdom. Terms and conditions relating to the use and distribution of this information may apply. For further information, please contact ms@lse.com or visit www.ms.com.

RNS may use your IP address to confirm compliance with the terms and conditions, to analyse how you engage with the information contained in this communication, and to share such analysis on an anonymised basis with others as part of our commercial services. For further information about how RNS and the London Stock Exchange use the personal data you provide us, please see our [Privacy Policy](#).

END

MSCBMBRTMTTBTI