



**FDA expands XENOVIEW® indication to include children from six years of age**  
*Increases number of eligible patients by approximately one million*

**DURHAM, NC and LONDON, June 2, 2025 (GLOBE NEWSWIRE) –**

Polarean Imaging plc (AIM: POLX) ("Polarean" or the "Company"), a commercial-stage medical imaging technology leader in functional Magnetic Resonance Imaging ("MRI") of the lungs, announces that the US Food and Drug Administration ("FDA") has approved the Company's Supplemental New Drug Application ("NDA") to expand the indication of XENOVIEW®. This approval immediately lowers the minimum patient age from 12 to six years old, significantly broadening access to this technology and expanding Polarean's total addressable market.

The approval means that XENOVIEW can now be used with MRI for evaluation of lung ventilation in adults and pediatric patients aged six years and older, representing an increase in the number of eligible patients by approximately one million. The FDA supplement approval also includes the introduction of new XENOVIEW Dose Delivery Bag sizes tailored for smaller lungs of younger patients and corresponding updates to the HPX Polarization Measurement Station to measure various bag sizes. This approval reinforces Polarean's dedication to advancing functional lung imaging and increasing access to its technology, enabling enhanced care for a broader patient population.

**Christopher von Jako, Ph.D., Chief Executive Officer of Polarean, said:** "We are delighted that the FDA has approved our Supplemental NDA, allowing XENOVIEW to be used in younger pediatric patients, increasing the number of patients eligible to use our technology by approximately one million. This expanded indication further enhances our technology's clinical utility, offering clinicians an advanced tool to assess the lungs in children with chronic respiratory conditions, and strengthens its return on investment for hospitals. We look forward to launching a controlled US market release of the pediatric Dose Delivery Bags later this year, starting with Cincinnati Children's."

**Erik Hysinger, MD, Pediatric Pulmonologist from Cincinnati Children's, said:** "This approval is an exciting step for children with chronic lung diseases, such as cystic fibrosis, asthma, bronchopulmonary dysplasia, and inflammation following bone-marrow transplant. For years, I've studied Xenon MRI in children ages 6 to 12, and expanding access to younger patients offers clinicians a powerful tool to characterize disease progression, monitor response to therapy, and guide interventions like airway dilation or tissue removal. This imaging platform enhances our ability to deliver more personalized, precise care for children with complex respiratory conditions."

For more information, visit [www.xenoview.net](http://www.xenoview.net).

## **About Polarean**

Polarean is a revenue-generating medical imaging technology company revolutionizing pulmonary medicine through direct visualization 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 optimize 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 hyperpolarization science and has successfully developed the first and only hyperpolarized Xenon MRI inhaled contrast agent, XENOVIEW®, which is now FDA-approved in the United States. Polarean is dedicated to researching, developing, and commercializing 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 hyperpolarization 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](http://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 6 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 SpO<sub>2</sub>% and transient increase in heart rate was reported following hyperpolarized xenon Xe 129 administration.

Please see full prescribing information at [www.xenoview.net](http://www.xenoview.net).

**Contact Information:**

Polarean:

Chuck Osborne

Chief Financial Officer

+1 (919) 206-7900, ext. 117

[cosborne@polarean.com](mailto:cosborne@polarean.com)

Polarean Investors:

Anna Dunphy / Phillip Marriage

+44 (0)20 7933 8780

[polarean@wallbrookpr.com](mailto:polarean@wallbrookpr.com)

Polarean Media Contact:

Alexis Opp

+1 (919) 206-7900, ext. 145

[aopp@polarean.com](mailto:aopp@polarean.com)

General inquiries: [info@polarean.com](mailto:info@polarean.com)

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**POL-PR-2503**