



February 2023

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

Company Update

Company to focus on commercial sales of XENOVIEW™ (xenon Xe 129 hyperpolarized), the first and only FDA approved hyperpolarized MRI contrast agent, and pursue corporate partnering opportunities to drive shareholder value

Polarean Imaging plc (AIM: POLX), the medical imaging technology company, announces that following the approval by the U.S. Food and Drug Administration ("FDA") for its drug device combination product, XENOVIEW, it intends to pursue a dual strategy of using its current cash resources to maximize commercial sales of XENOVIEW, while also pursuing collaborations with pharmaceutical companies, magnetic resonance imaging ("MRI") companies, Contract Research Organizations ("CRO") and other strategic partners to fund the future commercial applications of the Company's technology.

Financial Update

The Company finished 2022 with approximately \$16M in cash, which is expected to fund the company until May 2024.

Commercial Strategy

The Company will focus primarily on securing new installations in leading Centers of Excellence in academic medicine institutions specializing in Pulmonary and Radiology diagnostics and therapeutics distributed across North America. A key part of this strategy is to leverage its existing enthusiastic user base of Key Opinion Leaders and institutions expanding exposure and education in the use of Hyperpolarised noble gas imaging in medicine and research. The Company anticipates converting 9 research sites to FDA approved configuration and clinical use, selling 75 to 100 Xenoview Gas Blend cylinders and 15 to 20 Polarizer systems over the next 24 months. In addition, the Company will continue to develop a plan for seeking regulatory approval of the next indications for the Xenoview technology.

Future Financing

Based on the current cash balance, the Company will need additional cash resources to achieve the 24 month commercial targets and to pursue the development of the next indications and their approvals, and advanced R&D for future products. The Company is exploring a broad range of options to provide further financing, including, but not limited to, equity raises and strategic partnering.

Corporate Partnering

The Company will focus Business Development activities with respiratory drug and radiology contrast agent manufacturers, pulmonary drug clinical trial CROs, and MRI system manufacturers to monetize their use of our technology to leverage their commercial activities. In addition, the Company will continue in its dialog with the FDA to finalize its plans for seeking regulatory approval for the next indications of its Xenoview technology.

Richard Hullihen, Chief Executive Officer of Polarean said: *“Having achieved regulatory approval for our first indication, we now need to demonstrate the establishment of commercial traction and clinical adoption beyond our existing global research base according to our consistently stated objectives. We will do that within our existing resources, and strategic sources of non-dilutive financing, and return to markets for future financing to expand clinical indications and geographic territories on an ROI basis if and when appropriate.”*

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). 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.

ABOUT XENOVIEW

Indication

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

Limitations of Use

Xenoview has not been evaluated for use with lung perfusion imaging.

IMPORTANT SAFETY INFORMATION

Contradictions

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 saturation 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 Patients: In published literature in paediatric patients aged 6 to 18 years, the following transient adverse reactions were reported: blood oxygen desaturation, heart rate elevation, numbness, tingling, dizziness, and euphoria. In at least one published study of paediatric patients aged 6 to 18 years, transient decrease in SpO₂% and transient increase in heart rate were reported following hyperpolarised xenon Xe 129 administration. XENOVIEW is not approved for use in paediatric patients less than 12 years of age.

See full U.S. Prescribing Information at www.xenoview.net

XENOVIEW has received marketing approval in the United States and not in other countries.

XENOVIEW™ is a trademark of Polarean, Inc.

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