



Polarean Imaging plc Announces Positive Results From Pivotal Phase III Clinical Trials

Both trials met their primary endpoint, showing pre-defined equivalence of hyperpolarized ¹²⁹Xenon Gas MRI to an approved comparator, ¹³³Xenon Scintigraphy

Company plans for NDA submission to FDA in Q3 2020

Polarean's technology could offer clinicians a powerful tool to visualize lung function, overcoming limitations of existing methods of diagnosis and monitoring treatment

Durham, N.C. – January 29, 2020 – Polarean Imaging plc (AIM: POLX), a clinical stage medical imaging technology company developing a proprietary magnetic resonance imaging (MRI) drug-device combination, today announced positive top-line results from two pivotal Phase III clinical trials of the Company's drug-device combination, which uses hyperpolarized ¹²⁹Xenon gas MRI to visualize and quantify regional lung function.

The drug, ¹²⁹Xenon, when polarized in Polarean's proprietary system, permits functional, regional and quantitative imaging of the lungs using MRI, without the use of ionizing radiation. ¹²⁹Xenon is administered as an inhaled gas that is given to patients in a 10-second breath-hold procedure. For patients who participated in the clinical trials, the ventilation in zones of interest was quantified and compared to images, similarly quantified, derived from a different imaging modality.

Phase III Clinical Trials Demonstrate Effective Measurement of Regional Lung Ventilation

The two clinical trials were multi-center, randomized, open-label studies that compared MRI with ¹²⁹Xenon gas, polarized in Polarean's system, to ¹³³Xenon scintigraphy. These tests were used to measure regional pulmonary function in patients being evaluated for possible lung resection surgery and possible lung transplant surgery, respectively.

Both clinical trials met their primary endpoints within the prospectively defined equivalence margin (+/- 14.7%) when compared to the FDA-approved reference standard, ¹³³Xenon scintigraphy imaging.

Lung Resection Trial

The surgical resection trial of 32 patients required investigators to specify lung zones that would likely be resected if the patient received resection surgery. This trial compared each imaging modality's prediction of the proportion of lung function that would remain if the zone(s) were removed, expressed as a percentage of remaining function. The intra-patient mean difference between ¹²⁹Xenon MRI-predicted remaining function and ¹³³Xenon scintigraphy-predicted remaining function was 1.4% with a 95% confidence interval of (-0.75%, 3.60%).

Lung Transplant Trial

In the lung transplant trial of 48 patients, the intra-patient mean difference between the imaging modalities' measurement of the contribution of right lung to total lung function (percentage function) was -1.59% with a 95% confidence interval of (-3.69%, 0.50%).

Hyperpolarized ¹²⁹Xenon gas inhalation and the 10-second breath-hold procedure were well tolerated. Data from these clinical trials are being submitted for presentation at an upcoming scientific conference.

In addition, data from the clinical trials will form the basis of a Pre-New Drug Application (NDA) Meeting with the U.S. Food and Drug Administration (FDA). Following the Pre-NDA Meeting and incorporation of the conclusions of the Clinical Trials into the NDA submission, Polarean plans to submit an NDA for the drug-device combination to the FDA, which is now estimated for Q3 2020.

More information on these studies can be found on www.clinicaltrials.gov under the identifiers NCT03417687 (lung resection) and NCT03418090 (lung transplant).

“The positive results of these clinical trials validate our belief that Polarean’s technology allows clinicians to visualize aspects of lung function, which have never before been visible by MRI, both safely and quantitatively,” said Richard Hullahen, Chief Executive Officer of Polarean. “More than 30 million Americans suffer from a chronic lung disease, and the financial burden of lung disease now exceeds \$150 billion annually. Given the limitations of existing methods to diagnose and monitor lung disease, we see a significant unmet need for non-invasive, quantitative and cost-effective image-based diagnosis technology without exposing patients to ionizing radiation. We believe that our technology has the potential to overcome these limitations and we look forward to using data from the clinical trials to support our New Drug Application.”

“The use of conventional, anatomical MRI has, historically, not played a role in addressing the substantial unmet need in working up difficult-to-diagnose pulmonary diseases,” said Y. Michael Shim, MD, Director of Pulmonary Rehabilitation and Director of the Pulmonary Function Testing Lab at the University of Virginia, and an investigator on the trials. “The innovative approach we have taken with the use of hyperpolarized ¹²⁹Xenon gas opens up a whole new window into how physicians diagnose, stage and monitor responses to treatment in a broad range of lung diseases with this high resolution, non-ionizing MRI method. Based on what has been demonstrated in these clinical trials, we are excited about the prospect of having the technology available as an additional tool to make a potentially clinically significant impact in the future.”

About Polarean’s Technology

Polarean's technology produces hyperpolarized inert Xenon gas, used in conjunction with standard MRI to create high-resolution three-dimensional functional maps of the human lung. This technique provides a unique and sensitive way to monitor changes in lung structure and function; it is currently used in basic and clinical research to study lung physiology and to monitor the efficacy of new drugs.

The central equipment required for hyperpolarized gas MRI is a polarizer. Using circularly polarized laser light, the polarizer transforms the inert, stable noble gas isotope ¹²⁹Xenon into its hyperpolarized state. This process leaves the gas chemically unchanged, while only the nucleus is magnetically aligned. The resulting MRI signal is enhanced by a factor of 100,000, making direct imaging of gas atoms possible.

About Polarean (www.polarean.com)

Polarean Imaging plc and its wholly owned subsidiary, Polarean, Inc. (together the "Group") are revenue-generating, medical drug-device combination companies operating in the high-resolution medical imaging market.

The Group develops equipment that enables existing MRI systems to achieve an improved level of pulmonary function imaging and specializes in the use of hyperpolarized Xenon gas (¹²⁹Xe) as an imaging agent to visualize ventilation. ¹²⁹Xe gas is currently being studied for visualization of gas exchange regionally in the smallest airways of the lungs, the tissue barrier between the lung, and the bloodstream and in the

pulmonary vasculature. Xenon gas exhibits solubility and signal properties that enable it to be imaged within other tissues and organs.

The Group also develops and manufactures high performance MRI radiofrequency (RF) coils which are a required component for imaging ^{129}Xe in the MRI system. The development of these coils by the Group facilitates the adoption of the Xenon technology by providing application-specific RF coils which optimize the imaging of ^{129}Xe in MRI equipment for use as a medical diagnostic as well as a method of monitoring the efficacy of therapeutic intervention.

Contacts:

For Media:

Lindsey Bailys

Tel: +1 786-252-1702 or lindsey.bailys@gcihealth.com

Polarean Imaging plc

Richard Hullihen, Chief Executive Officer

Richard Morgan, Chairman

www.polarean.com / www.polarean-ir.com

Via Walbrook PR

SP Angel Corporate Finance LLP

David Hignell / Soltan Tagiev (Corporate Finance)

Vadim Alexandre / Rob Rees (Corporate Broking)

Tel: +44 (0)20 3470 0470

Walbrook PR

Paul McManus / Anna Dunphy

Tel: +44 (0)20 7933 8780 or polarean@walbrookpr.com

Mob: +44 (0)7980 541 893 / +44 (0)7879 741 001