

7 October 2020

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

**NDA Submission**

*NDA submission for Polarean's hyperpolarised <sup>129</sup>Xenon gas drug-device diagnostic for lung imaging*

Polarean Imaging plc (AIM: POLX), the medical-imaging technology company, with an investigational drug-device combination product for magnetic resonance imaging (MRI), announces its submission of a New Drug Application ("NDA") and request for priority review to the US Food and Drug Administration ("FDA") for hyperpolarised <sup>129</sup>Xenon gas used to evaluate pulmonary function and to visualise the lung using MRI.

The submission of the NDA follows the Company's successful completion of two Phase III clinical trials (the "Clinical Trials") which demonstrated effective measurement of regional lung ventilation. In the Clinical Trials, Polarean's <sup>129</sup>Xenon gas MRI was used to measure regional pulmonary function in patients with a wide variety of underlying lung diseases who were being evaluated for possible lung resection or lung transplant surgery. As detailed in the Company's announcement of 29 January 2020, both Clinical Trials met their primary endpoints, showing pre-defined equivalence of hyperpolarised <sup>129</sup>Xenon Gas MRI to an approved comparator, <sup>133</sup>Xenon Scintigraphy, and displayed a benign safety profile.

<sup>129</sup>Xenon, when polarised in Polarean's proprietary drug-device system, permits functional, regional and quantitative imaging of the lungs using MRI, without the risk of exposing patients to ionising radiation. The polarised <sup>129</sup>Xenon is administered as an inhaled gas that is given to patients in a 10 second breath-hold MRI procedure.

**Commenting on the submission, Richard Hullahen, CEO of Polarean, said:** *"The NDA submission of <sup>129</sup>Xenon gas MRI as a drug-device combination represents another key regulatory milestone for our Company. I am delighted with the performance of Polarean's team, who have worked tirelessly to achieve this important goal, and would also like to thank the institutions, clinicians and patients who took part in the studies that have formed part of this NDA.*

*"More than 30 million Americans suffer from a chronic lung disease and we see a significant unmet need for non-invasive, quantitative and cost-effective image-based diagnostic technology without exposing patients to ionising radiation. We look forward to working with the FDA to address this unmet need."*

*This announcement contains inside information for the purposes of Article 7 of Regulation (EU) 596/2014.*

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*Via Walbrook PR*

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**About Polarean** ([www.polarean.com](http://www.polarean.com))

The Company 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 specialises in the use of hyperpolarised Xenon gas ( $^{129}\text{Xe}$ ) as an imaging agent to visualise ventilation.  $^{129}\text{Xe}$  gas is currently being studied for visualisation 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  $^{129}\text{Xe}$  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  $^{129}\text{Xe}$  in MRI equipment for use as a medical diagnostic as well as a method of monitoring the efficacy of therapeutic intervention.