



22 September 2022

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

**Update on New Drug Application**

*FDA request for additional information from Polarean's contract drug manufacturer*

Polarean Imaging plc (AIM: POLX), the medical-imaging technology company, with an investigational drug-device combination product using hyperpolarised xenon-129 gas to enhance magnetic resonance imaging (MRI) in pulmonary medicine, announces that the U.S. Food and Drug Administration ("FDA") has requested additional information from Polarean's xenon-129 gas blend drug manufacturing partner. This request is related to the recent cGMP (Current Good Manufacturing Practice) pre-approval inspection at the partner's production facility. The FDA has suggested that the required information would constitute a major amendment to the New Drug Application ("NDA") that, if timely submitted, would allow for the FDA to grant a 90-day extension to the review timeline. The FDA has proposed frequent meetings to occur during the extended review period to ensure that any questions that arise during the review can be rapidly addressed to provide the best chance at a positive review decision by the extended date.

The Company has received assurances from its drug manufacturing partner that they will address the concerns. Polarean will provide an additional update on the status of its NDA in due course.

Polarean's net cash balance is \$22.7m as of 30 June 2022 which, based on strategic decisions, could finance the Company into 2024.

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

**Enquiries:**

**Polarean Imaging plc**

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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, investigational drug-device combination companies operating in the high-resolution medical imaging research space.

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 (<sup>129</sup>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, across the alveolar tissue membrane, and into the pulmonary bloodstream.

In October 2020, the Group submitted a New Drug Application (“NDA”) to the FDA for hyperpolarised  $^{129}\text{Xe}$  used to evaluate pulmonary function and to visualise the lung using MRI. The Group received a complete response letter on 5 October 2021. On 30 March 2022, the Company filed the resubmission of its NDA with the US FDA and has received a PDUFA date of Sept 30, 2022.

The Group operates in an area of significant unmet medical need and the Group's technology provides a novel investigational diagnostic approach, offering a non-invasive and radiation-free functional imaging platform.