

6 October 2021

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

Complete Response Letter received from FDA

Requirement to address approvability issues identified by FDA ahead of NDA resubmission

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 Company has received a Complete Response Letter ("CRL") from the U.S. Food and Drug Administration ("FDA") for the New Drug Application ("NDA") for their drug-device combination product. The FDA has determined it is unable to approve the NDA in its present form and has provided a list of issues to be addressed by the Company. These issues are mostly technical or manufacturing-related in nature and centre around the Xenon hyperpolariser system. Polarean will work to address the issues identified by the FDA with a view to resubmitting the NDA and securing FDA approval as quickly as possible. Following resubmission of the NDA, it is expected that the FDA review period will take 2-6 months.

Whilst the Company believes that the issues to address in the CRL are attainable, Polarean is disappointed by this unexpected response. The Company will seek additional discussions with the FDA as a matter of urgency and further update the market when material information is received. In the meantime, the Company will continue to collaborate with their current and future research investigators in continued exploration of potential clinical applications of this technology, as they have done to date.

Polarean's net cash balance of \$38.2m as of 30 June 2021 allows the Company to fund operations comfortably through the anticipated Company response and FDA review periods.

Richard Hullihen, Chief Executive Officer of Polarean said, *"We are obviously disappointed that we have not received FDA approval within this review cycle, and we will continue to work diligently with the FDA to understand their recommendations to address the issues that have led to the CRL being issued. We remain confident in the safety and efficacy profile of hyperpolarised noble gas imaging and Polarean's ability to accomplish its goals."*

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

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About Polarean (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 (^{129}Xe) as an imaging agent to visualise ventilation. ^{129}Xe gas is currently being studied for visualisation of gas exchange regionally in the smallest airways of the lungs, across the alveolar tissue barrier, and into the pulmonary bloodstream.

In October 2020, the Group submitted a New Drug Application ("**NDA**") to the FDA for hyperpolarised ^{129}Xe used to evaluate pulmonary function and to visualise the lung using MRI. The Group received a complete response letter on 5 October 2021.

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. The annual economic burden of pulmonary disease in the US is estimated to be over US \$150 billion.