31 March 2022

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

New Drug Application Resubmission
NDA submission for Polarean's hyperpolarised ^{129}Xenon gas drug-device combination product

Polarean Imaging plc (AIM: POLX), the medical-imaging technology company, with an investigational drug-device combination product using hyperpolarised ^{129}Xenon gas to enhance magnetic resonance imaging (MRI) in pulmonary medicine, announces that the Company has filed the resubmission of its New Drug Application ("NDA") with the US Food and Drug Administration ("FDA").

The filing follows the Company's receipt of a Complete Response Letter ("CRL") from the FDA on 6 October 2021. Following detailed discussion in the Type A meeting with the FDA, these issues have now been addressed by Polarean in the resubmission.

It is currently expected that the FDA review period will take six months. The Company is making full use of this time with regards to commercialisation and launch preparation and will further update the market once material information is received.

Richard Hullihen, CEO of Polarean, said: *"We have resubmitted the NDA for our ^{129}Xenon drug-device combination product, following extensive discussions with the FDA regarding the issues that were raised in the CRL. The entire Polarean team has worked diligently to ensure that all the points raised in the CRL were comprehensively addressed".*

"We look forward to completing the FDA review and approval processes necessary to bring our unique technology to market addressing the significant unmet need for our non-invasive, quantitative and cost-effective functional lung imaging."

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 membrane, 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 6 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.