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technegas
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Cyclopharm Ltd
ABN 74 116 931 250
Unit 4, 1 The Crescent
Kingsgrove NSW 2208 Australia
T 61 2 9541 0411
F 61 2 9543 0960
www.cyclopharm.com.au

The Manager
Company Announcements Office
Australian Securities Exchange Limited
20 Bridge Street
Sydney NSW 2000

Cyclopharm Confirms USFDA Scheduled Inspection Date

Cyclopharm Limited (ASX: CYC) today advises that the United States Food and Drug Administration (USFDA) has notified the company that an inspection of the Company's Kingsgrove, New South Wales facility will be conducted between 24 July through 4 August 2023.

The inspection notification follows last month's confirmation by the USFDA of a six-month review period, ending 29 September, 2023, for Cyclopharm's New Drug Application for its proprietary lung ventilation imaging agent, Technegas. The Company also advised on April 24, 2023 that active dialogue with the USFDA, and a USFDA site visit were expected during the review timeline.

Cyclopharm Chief Executive Officer James McBrayer said he was particularly pleased that the inspection is scheduled to fall well within the USFDA's goal review period.

As previously advised, Cyclopharm comfirms its expectation that USFDA approval will create an initial addressable market in the USA of US$180 million per annum in the diagnosis of Pulmonary Embolism (PE). This estimate does not include the exponentially larger potential for Technegas' application for *Beyond PE* indications, including the diagnosis and management of Chronic Obstructive Pulmonary Disease, lung cancer, asthma and Long COVID.

[ENDS]
This ASX announcement was approved and authorised for release by James McBrayer, Managing Director and CEO

For more information, please refer to our website at www.cyclopharm.com or contact:
Mr James McBrayer
Managing Director, CEO and Company Secretary
Cyclopharm Limited
T: +61 (02) 9541 0411

Cyclopharm Limited
Cyclopharm is an ASX Listed radiopharmaceutical company servicing the global medical community. The Company's mission is to provide nuclear medicine and other clinicians with the ability to improve patient care outcomes. Cyclopharm achieves this objective primarily through the provision of its core radiopharmaceutical product, Technegas used in functional lung ventilation imaging.

Technegas
The Technegas technology is a structured ultra-fine dispersion of radioactive labelled carbon, produced by using dried Technetium-99m in a carbon crucible, micro furnaced for a few seconds at around 2,700^{o} C. The resultant gas like substance

is inhaled by the patient (lung ventilation) via a breathing apparatus, which then allows multiple views and tomography imaging under a gamma or single photon emission computed tomography (SPECT) camera for evaluating functional ventilation imaging. Historically used in the diagnosis of pulmonary embolism, Technegas, together with advancements in complementary technology to multimodality imaging and analytical software, is being used in other disease states to include COPD, asthma, pulmonary hypertension and certain interventional applications to include lobectomies in lung cancer and lung volume reduction surgery.