cyclopharm

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technegas
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USFDA Completes Pre-approval Site Inspection

Cyclopharm Limited (ASX: CYC) today advises that the United States Food and Drug Administration (USFDA) has completed the site inspection of the company's manufacturing facility at Kingsgrove, New South Wales, which was undertaken between 31 July and 8 August, 2023.

Cyclopharm CEO James McBrayer said "Technegas will be regulated in the United States as combination product. The inspection covered both the drug and device elements of Technegas."

"While the inspection report will require further internal FDA review before it is final, we are pleased with the process and are confident that our USFDA's goal review date of 29 September 2023 remains on track," Mr McBrayer said.

As previously advised, Cyclopharm confirms 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:
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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.