cyclopharm

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technegas
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USFDA Confirms Six Month Review Period

Cyclopharm Limited (ASX: CYC) today advises that the United States Food and Drug Administration (USFDA) has formally acknowledged receipt of the Company's 30 March 2023 reply to the USFDA's Complete Response Letter (CRL). The acknowledgement relates to Cyclopharm's New Drug Application for its proprietary functional lung ventilation imaging agent, Technegas.

The USFDA states that the Company's submission reply is "complete" and eligible for review. The USFDA also confirmed a review "goal date" of 29 September, 2023, which is consistent with the Company's expected six-month review guidance. Based on this timetable, the Company remains confident of the commencement of commercial sales of Technegas in the United States shortly after the goal date in late 2023.

As previously advised, during the six-month review period, it is expected that Cyclopharm will maintain an active dialogue with the USFDA, including the provision of additional information upon request. During the period the USFDA may also require a follow up from its April 2021 inspection of the Company's manufacturing facility in Sydney.

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:
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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.