cyclopharm

12 March 2021

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CONFIRMATION OF TECHNEGAS™ USFDA TIMETABLE

Cyclopharm Limited's (ASX: CYC) provides the following update of the US Food & Drug Administration's (USFDA) timetable in respect of approval of the Company's New Drug Application (NDA) for Technegas[tm].

As previously advised, the USFDA is scheduled to commence its pre-approval audit of Cyclopharm's manufacturing facility during the week commencing 29 March 2021. The Company has been actively assisting the USFDA in preparation for this audit, and has provided them with further information to assist with their NDA assessment process. Cyclopharm notes such audits outside of the United States are presently rare given the current difficulties associated with international travel. Furthermore, the Company believes the USFDA's continued and active commitment to complete the audit, as scheduled, demonstrates the importance of Technegas™ for the US market.

The USFDA has advised that, following completion of the pre-approval audit and review of requested supporting documentation received to date, it expects to provide the Company with proposed labelling requirements for Technegas™ by early May 2021. Upon receipt of these requirements, Cyclopharm intends to finalise the packaging and labelling of Technegas™Generators and Patient Administration Sets for the US market.

The USFDA has also advised the goal date for completion of its full review of the NDA is 26 June 2021. Cyclopharm is targeting a rapid rollout of Technegas™ in the US market to meet the Company's expectations for a strong initial sales demand following receipt of the final NDA approval.

This confirmed timetable is broadly in line with Cyclopharm's expectations and reaffirms the Company's anticipation of commencing sales into the US market early in the second half of 2021.

ENDS

This ASX announcement was approved and authorised for release by James McBrayer, Managing Director, CEO and Company Secretary.

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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.