cyclopharm

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TECHNEGAS™ RECEIVES 'COMPLETE RESPONSE LETTER' FROM THE USFDA - REQUIREMENT TO ADDRESS OUTSTANDING TECHNICAL ELEMENTS

Cyclopharm Limited (ASX: CYC) announces that the US Food and Drug Administration (USFDA) has provided a Complete Response Letter (CRL) for the New Drug Application (NDA) for Technegas™. The USFDA has determined it is unable to approve the NDA for Technegas™ in its present form and has provided a definitive list of items and recommendations for outstanding elements to be addressed within a 12-month period. Cyclopharm expects to resolve all these elements with a view to securing approval for commercial sales of Technegas™ in the US market in 2022.

CYC's Managing Director and CEO, James McBrayer commented; "While the elements in the USFDA's CLR letter are attainable within the required timeframe, we are disappointed with this news of the additional technical information requests. Effectively the CLR has extended the expected approval timeframe by around nine months."

"We have complete confidence that we can address these matters and do what is required to expedite this process. We now have clarity as to what will satisfy the USFDA's expectations and will commence work on the response immediately."

Mr McBrayer added, "Since submitting the NDA, the company has worked closely and constructively with the USFDA on matters relating to Technegas™ and we will continue to do so as we address the outstanding elements."

Once these outstanding issues are completed, Cyclopharm expects commercial sales of Technegas™ in the US to commence in the second half of 2022. The company is committed to delivering Technegas™ to the US market on this revised timeframe. In the meantime, Cyclopharm will continue to service the 60 countries around the globe where Technegas™ has been clinically delivered to over 4.4 million patients, as well as expand its indications for use beyond Pulmonary Embolism.

The majority of the technical issues outlined in the CRL relate to better defining and validating the unique characteristics, production and delivery of the Technegas™ particle. Other remaining issues include specific aspects of crucible manufacturing and dosimetry both in adults and children. Additionally, the letter stated the Company's need to address items identified in the recent pre-approval inspection that occurred at the beginning of April. With respect to the inspection, the Company is awaiting feedback from the USFDA on two formal submissions it has made since the pre-approval inspection.

The company and the USFDA will in the coming weeks be meeting to discuss the contents of the CRL and the further steps required to attain approval. The CRL includes unique elements not raised in other jurisdictions where Technegas™ is delivered.

Given the additional testing that is required and the time the USFDA will need to assess our resubmission, the company is updating its guidance for gaining USFDA approval from H2 2021 to H2 2022. This change in timing does not impact the company's ability to fund the remaining approval process. The US represents a market opportunity for Cyclopharm that is estimated to be worth US$180[1] million annually and is key to Cyclopharm's growth plans.

The Directors note that despite the delay imposed on the process, the USFDA CRL gives all stakeholders clarity on the forward timeline and a definitive list of objectives to meet and address those matters.

Mr McBrayer concluded by saying that "The company is grateful for the US clinical support it has received over the past year and remains committed to delivering Technegas™ to the US market on this revised timeframe".

ENDS

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

For more information, please contact:

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[1] Current addressable PE market of US$90 million plus the projected increase of PE imaging through nuclear medicine from 15% to 30% through the adoption of Technegas™ and Single Photon Emission Tomography (SPECT) 3-D imaging

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.