cyclopharm

cyclomedica
technegas
ultralute

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

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

CYCLOPHARM LODGES
NEW DRUG APPLICATION FOR TECHNEGAS® WITH THE USFDA

Cyclopharm Limited (ASX: CYC) is pleased to announce that the Company, through its wholly owned subsidiary Cyclomedica Australia, has lodged its New Drug Application (NDA) for Technegas®, a nuclear medicine functional lung ventilation imaging agent, with the United States Food and Drug Administration (USFDA).

Commenting on the 505(b)2 USFDA New Drug Application (NDA), Managing Director and CEO Mr James McBrayer stated, "This is a tremendous milestone and achievement for the Company. I have been working towards this submission since joining Cyclopharm in 2008. I want to thank my team in Australia and in the United States, our Clinical Research Organisation along with our Regulatory Legal consultants, for their outstanding contributions that enabled this application to be submitted. Finally, I want to express my deep gratitude to the Directors both past and present, along with our dedicated shareholders, for supporting Technegas®, our life saving innovative Australian technology, to be available in 59 countries throughout the world and soon to be the United States".

Mr McBrayer went on to say, "Over the coming months there is still a great deal of work to do in preparing the Company for USA commercialization; however, the lodgment of our New Drug Application is the single largest step the Company has ever made toward attaining USFDA approval. We are confident of securing approval within the next twelve months. I look forward to updating our shareholders as each milestone along the way is achieved".

The United States is the largest nuclear medicine market in the world. Cyclopharm estimates the size of the US market for Technegas® in diagnosing the presence of Pulmonary Embolism (PE) to be US$90 million in sales per annum. We expect to gain a 50% share of this market in the first 2 to 3 years, rising to 80% over 5 to 7 years.

The Company believes the extension of Technegas® into new applications such as the diagnosis and monitoring of COPD, asthma and other respiratory disease states will create opportunities to exponentially expand the market for Technegas® beyond its traditional PE market. Cyclopharm's strategy to expand Beyond PE is being delivered by targeting new applications through clinical studies; educating clinicians; and engaging directly with respiratory medicine referrers.

Technegas New Drug Application – Potential for Priority Review and Fee Waiver

Technegas® is designated by the FDA Office of Combination Products as a drug-device combination product with the Center for Drug Evaluation and Research (CDER) assigned as the lead Center for review and regulation. In 2018 the FDA provided further confirmation that the Technegas® Generator, including its associated accessories to include the carbon crucible, an essential active ingredient precursor to Technegas®, are regulated as a Diagnostic Radiopharmaceutical, pursuant to 21 CFR 315.2.

Along with the evidence to support the safe and efficacious use of Technegas, the NDA submission also includes a priority review application. If successful in attaining a priority review designation, the PDUFA[1] review date will reduce, following from the 60-day initial submission review period required for an 'Approval to File' designation, from 10 months to 6 months.

[1] PDUFA - Prescription Drug User Fee Act, authorizes the FDA to collect fees from drug manufacturers to fund the drug approval process and establishes deadlines by which the FDA must review new drug applications.

A fee waiver request prior to the NDA lodgment has also been submitted. We remain confident, given the size of the company and attributes of Technegas®, that we will qualify for either a significant fee reduction or a complete waiver to the US$2.9m application fee.

The following table compares the priority versus standard review pathway along with the milestones our shareholders can expect over the coming 12 months:

Milestones (Represented in Calendar Quarters)	Priority Review Pathway	Standard Review Pathway	**Status**
FDA Submission	Q1 2020	Q1 2020	✓ Lodged
Fee Waiver / Reduction Determination	Q2 2020	Q2 2020	Submitted Q1 2020 - Pending Determination
FDA Approval to File Determination	Q2 2020	Q2 2020	Review Underway – Timeline for determination is 60 days from submission followed by an anticipated Approval to File
Priority Review Determination (6 vs. 10 Month Pathway)	Q2 2020	Q2 2020	Priority reviews = 6 months from Approval to File Standard reviews = 10 months from Approval to File
Manufacturing Site Inspection	Q4 2020	Q1 2021	Site inspection can occur anytime during NDA review
Initiate Inventory Increase	Q2 2020	Q3 2020	Critical suppliers on notice – Targeting 200 Generators
Target NDA Approval	Q4 2020	Q2 2021	

Target dates presented are best estimates based on legislated [1]PDUFA response time guidelines. Questions posed by the USFDA may vary milestone timelines.

Cyclopharm is well funded to begin the launch of Technegas® in the US market. The Company has a strong balance sheet following the completion of a $9.775 million capital raising in December 2019, via an Institutional share placement at an 11.7% premium to the Cyclopharm's share price at the time. This balance sheet strength will also support delivery of Cyclopharm's other strategic priorities, including expanding the use of Technegas® beyond pulmonary embolism and product and system enhancements.

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

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 2,700º 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.