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The Manager
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USFDA GRANTS CYCLOPHARM
USD $2.9M FEE WAIVER FOR TECHNEGAS APPLICATION

Cyclopharm Limited (ASX: CYC) is pleased to announce that the United States Food and Drug Administration (USFDA) has granted the Company a full application fee waiver of USD $2.9m related to its recently submitted New Drug Application (NDA) for Technegas®, a nuclear medicine functional lung ventilation imaging agent.

The USFDA can waive the application fee for the first human drug application that a small business or its affiliate submits for review[1]. A small business is defined as a business that has fewer than 500 employees, including employees of affiliates.

Commenting on USFDA granting the fee waiver for the Technegas® NDA, Managing Director and CEO Mr James McBrayer stated, "Whilst we were confident that we were eligible for a fee waiver, we are very grateful to the USFDA in their support of small business and the speed at which our application was granted. What normally takes three to four months to review, our request was granted in two months."

Mr McBrayer went on to comment about the substance of the application, "Our approval was based on our small business status; however, to de-risk the process, the Company also submitted additional waiver applications under the categories of public health and a barrier-to-innovation. The additional fee waiver applications contained supporting elements to include:

- Technegas® protects the public health because it has the potential to be a significant improvement compared to other marketed products;
- Technegas® is intended for the diagnosis of a life-threatening condition; and
- Technegas® as a diagnostic is innovative in seeking to expand its use beyond diagnosing PE."

Mr McBrayer concluded by saying, "Having recently submitted our Technegas New Drug Application to the USFDA, and now obtaining the full fee waiver, the next important step in the process is concluding the USFDA sixty-day review of our NDA submission for completeness and the subsequent granting of an Approval to File. During this sixty-day period the USFDA will also determine if our application for Priority Review will be granted. The request for a Priority Review, as opposed to the Standard Review, will reduce our timeline to market by four months. Both Approval to File and the review period determination is expected to be decided by 27 May 2020."

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.

[1] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/user-fee-waivers-reductions-and-refunds-drug-and-biological-products

Technegas New Drug Application Milestones– Potential for Priority Review

The following table, updated with the Fee Waiver Determination announced today, 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 - 27 March 2020
Fee Waiver / Reduction Determination	Q2 2020	Q2 2020	✓ Granted - 10 April 2020
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 - submitted 27 March 2020)	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	TBD Based on Priority vs Standard

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

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:

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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° 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.

[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.