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TECHNEGAS™ – USFDA NEW DRUG APPLICATION APPROVAL – NEXT MILESTONE IN APPROVAL PROCESS SUCCESSFULLY ACHIEVED

- **APPROVAL TO FILE NOTIFICATION RECEIVED**
- **TECHNEGAS APPROVAL EXPECTED IN Q2 2021**
- **TARGET SHARE OF USA NUCLEAR MEDICINE PE MARKET AFFIRMED – 80%**
- **EXPANSION BEYOND PE CREATING NEW GROWH OPPORTUNITIES**

Cyclopharm Limited (ASX: CYC) is pleased to announce that the Company, through its wholly owned subsidiary Cyclomedica Australia, has been granted Approval to File status for its New Drug Application (NDA) for Technegas™. Following this approval Cyclopharm will now proceed to the next stage of the USFDA approval process – Review.

The following table outlines the pathway, along with the milestones shareholders can expect over the coming 12 months, as the Company seeks United States Food and Drug Administration (USFDA) approval for Technegas™.

Milestones (Represented in Calendar Quarters)	**USA Approval Pathway**	**Status**
FDA Submission	Q1 2020	✓ Lodged
Fee Waiver / Reduction Determination	Q2 2020	✓ Approved - $2.9m USD Refund Received
FDA Approval to File Determination	Q2 2020	✓ **Approved**
Review Period Confirmed[1]	Q2 2020	✓ **10-month Review Period Determined**
Manufacturing Site Inspection	Q1 2021	Site inspection can occur anytime during NDA review
Initiate Inventory Increase	Q3 2020	Critical suppliers engaged – Targeting 200 Generator Launch
Target NDA Approval	Q2 2021	

Commenting on this announcement, Managing Director and CEO Mr James McBrayer stated, "We are absolutely thrilled with the progress we are making in completing the steps to gain approval to market Technegas™ in the USA. This Approval to File follows our successful lodgment in March and a full USD $2.9m Fee Waiver designation in April. Today's notification confirms that we are on track for Technegas™ to be approved early next year".

[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.

"The Approval to File designation was given following a 60-day quantitative review of Cyclopharm's New Drug Application (NDA) submitted to the USFDA. The NDA will now move to the next phase of the review process outlined in the PDUFA[1] guidelines, a 10-month qualitative review where the USFDA will look at the safety and efficacy of Technegas™ as a nuclear medicine functional lung ventilation imaging agent."

"The United States is the largest nuclear medicine market in the world. We estimate the size of the US market for Technegas™ in diagnosing the presence of Pulmonary Embolism (PE) is approximately US$90 million in sales per annum. Following USFDA approval to sell into that market, we will be targeting 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.

ENDS

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 surgsaery.