



24 March 2020

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

cyclo**medica**
techneg**as**
ultra**lute**

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

CYCLOPHARM COMPANY UPDATE

- **COVID-19 Virus likely to increase use of Technegas®**
- **US FDA New Drug Application for Technegas – Application ready to submit to FDA**
- **Litigation – Statement of Claim Lodged with the NSW Supreme Court**

Covid-19 Impact to CYC

- Technegas® is primarily used to diagnose the life-threatening condition Pulmonary Embolism (PE). Dyspnea or shortness of breath is a key symptom exhibited in both COVID-19 and PE.
- Currently, the primary diagnostic method for determining the presence of the COVID-19 virus is a laboratory test. We are receiving reports of an increase in the use of Technegas® to differentiate between Covid-19 and Pulmonary Embolism where laboratory tests results cannot be attained quickly.
- In many markets around the world, non-essential or outpatient imaging procedures are temporarily being delayed. We believe that any delays in the use of Technegas® in noncritical procedures are short term and are expected to rebound once gathering restrictions begin to lift.
- Technetium-99m is the isotope used in the manufacture of Technegas®. Tc-99m is produced from the decay of Molybdenum-99 (Mo-99). According to the latest reports, the supply chain for Mo-99 continues without interruption.
- Research and Development activities pertaining to our Beyond PE initiatives are expected to be impacted as the rate of patient recruitment for trials is expected to slow or in some cases placed on hold during the outbreak.
- CYC Employees that are able to perform their duties from home are encouraged to do so. However, under the NSW *Essential Services Act 1988 No 41*, organisations involved in the manufacture of pharmaceuticals are designated to be an essential service. Based on this designation, Cyclopharm will continue to manufacture.

USFDA Submission

- The Company is now ready to file its New Drug Application (NDA) for Technegas® with the United States Food and Drug Administration (USFDA). Submission is expected in the coming days.
- Our USFDA NDA submission includes a priority review application. If successful in attaining a priority review designation, the PDUFA¹ date will reduce, beginning from the 60-day initial submission review period, from 10 months to 6 months.
- A fee waiver request has also been submitted. We remain confident, given the size 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.

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 United States is the largest nuclear medicine market in the world. We estimate the size of the US market for Technegas 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.

Cyclopharm is well funded to begin our 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.

Litigation Update

- Cyclopharm (CYC) has lodged a Statement of Claim with the NSW Supreme Court to vigorously protect its valuable Intellectual Property and seek damages from the defendants named in the matter.
- In January 2019, Cyclopharm successfully brought an initial civil case against Altmann and Almedis in Germany which resulted in the Company, being awarded and receiving a payment of approximately A\$339,000, which represents 100% of this claim. The company is continuing with its efforts to recover the remainder of this bad debt provision along with other claims in Germany.
- In September 2019 Cyclopharm initiated additional legal proceedings in Australia against individuals based in Australia and linked with Altmann.
- Based on evidence secured through NSW Supreme Court Anton Piller search orders executed in October 2019, CYC is now seeking to join additional defendants to the Australian proceedings.
- CYC is seeking a range of relief to include defendants pay equitable compensation, damages, exemplary damages and/or compensation under the *Corporations Act* in respect of their respective breaches of their duties to CYC along with the costs associated with the proceedings.

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

For more information, please 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 2,700° 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.