cyclopharm

29 November 2022

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Highlights

- **A$1.64 million R&D Tax Incentive payment received from the ATO**
- **USFDA approval process remains on track for target of mid-2023**

Cyclopharm Limited (ASX:CYC) is pleased to provide the following business update.

Cyclopharm Receives A$1.64 million AusIndustry Research and Development Refund

Cyclopharm confirms it has completed its Research and Development Tax incentive claim for the 2022 financial year and has this month received its expected cash of A$1.64 million from the ATO (vs 2021 A$2.3 million). Research and Development tax incentives remain subject to the nature, timing and value of R&D activities undertaken each year.

USFDA Approval Process

Cyclopharm continues to progress toward attaining US Food and Drug Administration (USFDA) approval for the sale of Technegas™ in the US market in mid-2023, consistent with previous expectations.

Cyclopharm is finalising its reply to a USFDA Complete Response Letter (CLR), which contains a definitive list of items and recommendations to be satisfied prior to granting approval for commercial sales of Technegas™ in the US market. As previously advised, the final stages of the process has been slightly disrupted by the current global shortages of the isotope used to produce Technegas™, and the company remains confident of an early 2023 FDA submission, followed by the FDA's stated six-month formal submission review process.

"Beyond PE"

Over the past year several papers utilizing Technegas™ in Beyond PE applications, to include COVID and Long COVID, have been published independently of the company. These publications underscore the global clinical acceptance of this innovative product in the 64 countries where Technegas™ is used.

The Asthma, COPD, Long Covid and Lung Cancer markets represent significant opportunities to grow sales of Technegas™ and drive shareholder value. Cyclopharm estimates the global COPD market alone to be approximately 30 times the size of the PE market, with over 500 million patients suffering with COPD and Asthma with the potential to benefit from the use of Technegas™ in their chronic disease management.

Cyclopharm is now sponsoring 6 clinical trials, in different jurisdictions globally, investigating the use of Technegas™ to improve the diagnosis and management of patients suffering from a broader range of respiratory diseases. Despite COVID-related disruptions to patient recruitment during FY2021, these trials remain on track, and the Company expects to see publications of trial results in the first half of calendar year 2023 in disease states covering Asthma, COPD, Long Covid and Lung Cancer.

Cyclopharm Managing Director and Chief Executive Officer James McBrayer said, "Cyclopharm is an established and growing medical technology company. Our proprietary product Technegas™ is used clinically in 64 countries around the world and is on track for FDA approval mid- 2023. In addition, the exciting work we are doing with the aim of expanding into the much larger markets for disease states including COPD, Asthma, Long Covid and Lung cancer, represent a signific growth trajectory for the company. This month's A$1.64 million AusIndustry R&D Refund, underscores the development work we doing to support our Beyond PE clinical trials."

Bell Potter Healthcare Conference

Cyclopharm participated in the recent annual Bell Potter Healthcare Conference. To view the full company update presentation, please refer to the following link:

https://www.cyclopharm.com/cyclopharm-asxcyc-bell-potter-healthcare-conference-2022/

[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 surgery.