cyclopharm

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cyclomedica
technegas

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CYCLOPHARM BUSINESS UPDATE

Cyclopharm (ASX:CYC) provides update shareholders on the latest milestones related to:

- **USA expansion progress following United States Food and Drug Administration (USFDA) approval of Technegas on 29 September 2023 and**
- **Clinical trial outcome to expand use of Technegas**

UNITED STATES UPDATE

Coding Determination for Technegas has been received from the Center for Medicare Medicaid Services (CMS), which means users of Technegas will no longer have to rely on a miscellaneous reimbursement code, and from July 1, 2024 will have a unique identifier which streamlines their reimbursement process.

As previously advised, diagnostic functional ventilation procedures in the United States are reimbursed through CMS as a complete procedure. As a new product, which is replacing existing agents, Technegas is currently being used by nuclear medicine departments via a miscellaneous product code available to newly introduced radiopharmaceuticals.

Driven by the investment required for approval and ongoing compliance, Technegas pricing in the US is at a premium cost to existing products. To enable clinicians to introduce Technegas without a financial impact, CYC has also applied for Pass-Through Status through CMS to allow each site to be fully reimbursed for the use of Technegas for a period of up to three years. As part of CMS's assessment and information gathering process, CYC will present at a CMS virtual public meeting to be held later this month, with a Pass-Through decision expected on or before October 1, 2024. While CYC's submission has been timely, this longer than expected Pass-Through determination outcome (originally anticipated by 1 April 2024), has impacted the company's initial rollout target and resulted in either a slower implementation of Technegas or a deferral of implementation until a Pass-Through decision is made.

With revenue generation from installation and ongoing consumables now underway at each installed site and a strong sales pipeline in the USA, CYC has now issued 136 Proposals and Contracts representing over 400+ locations. Work continues to convert demand into executed contracts through various approval phases at medical institutions across the USA. While the timing of take-up in 2024 has been impacted by sign-off processes (which vary between each medical institution) as well as the timing of the Pass-Through decision through CMS, levels of clinical demand remain exceptionally strong throughout the US nuclear medicine community.

With a focus on initial roll-out to high volume US medical institutions, 5 Technegas systems have been installed and are currently bringing in revenue from institutions across the USA, with a further 7 sites under contract and scheduling installations. An additional 40 sites are linked to these first 12

locations. In addition to these committed sites, the pipeline for the further rollout by category currently stands at:

- 10 contracts active in the Review Stage representing 15 installations with a further 23 sites linked to these organisations;
- 6 Contracts in Committee Stage representing 9 initial installations with a potential 28 additional sites;
- 103 Issued proposals and contracts are in Early Discussion Stage connected to an estimated additional 50 affiliated sites;
- 12 proposals have been provided to the Veterans Administration Healthcare system and 3 to the Military Hospital System (MHS). There are a total of 120 nuclear medicine departments within the VA healthcare system and 35 US based hospitals run by the MHS;
- 18 other opportunities representing approximately 22 locations are pending the outcome of Pass-Through Status from CMS.

CYC continues to prioritise US opportunities through a focused engagement strategy including:

1. US Clinical trial sites involved in Technegas' New Drug Application (NDA)
2. Key Opinion Leaders involved in the NDA process
3. Advocates that have supported Technegas during the NDA process
4. Large Government and Large Private Health Care Groups
5. Large University affiliated Teaching hospitals

The company is also working with facilities that fall outside the CMS reimbursement system which include the 120 nuclear medicine departments in Veterans Administration Hospitals and the 35 US based hospitals run by the Military Hospital Systems. While the decision to implement any new technology is left to each military linked government facility, progress is being made in this sector at a national level. VA will this week host a lecture featuring clinical applications using Technegas. This briefing will be presented to all nuclear medicine clinicians across the entire VA healthcare system.

In addition to the company's sales and rollout initiatives, the upcoming annual US Society of Nuclear Medicine and Molecular Imaging (SNMMI) conference (to be held 8 -11 June, 2024 in Toronto, Canada) represents a major opportunity to further expand the sales pipeline. Based on the recent approval of Technegas, the SNMMI will host its own session, "*Lung Scintigraphy in the Current Era, Sponsored by the General Clinical Nuclear Medicine Counci*l". In addition to a company-sponsored booth, CYC will be hosting a satellite symposium for clinicians during the conference which is expected to once again be one of the one highest attended sessions of the conference.

Cyclopharm CEO James McBrayer said, "We are pleased to receive this positive notification from CMS which will provide our USA customers a more streamlined reimbursement process. There are clear and temporary reasons for a slower than anticipated rate of installations during the first few months since our landmark USFDA approval. The company's view of the total market potential for Technegas therefore remains unaltered.

"We continue to be encouraged by excellent clinical support and interest received as we progress our rollout across a range of fronts throughout the US. We expect that a favorable CMS Pass-Through determination will accelerate the conversion from clinical demand to executed contracts." Mr McBrayer said.

EXPANDING INDICATIONS FOR TECHNEGAS *BEYOND PE*

Cyclopharm continues to play an active role in the clinical shift towards precision medicine in pulmonary care by sponsoring initiatives like the clinical trial conducted with the University of Newcastle and the Hunter Medical Research Institute. The first paper titled, "*Ventilation*

Heterogeneity is a Treatable Trait in Severe Asthma" was recently published in the Journal of Allergy and Clinical Immunology: In Practice[1]. The study concludes that in a population of severe asthmatics that Ventilation Heterogeneity, as diagnosed using Ventilation SPECT with Technegas, is "*clinically significant, measurable, and treatable, which establishes Ventilation Heterogeneity as a treatable trait in severe asthma*".

Professor Peter Gibson the Principal Investigator and author of the publication commented about the findings from this imaging technique using Technegas, "This is a safe, fast and cost-effective way of ensuring that personalised treatments are working. Previously, we have had to rely on symptom surveys from patients. This test provides very accurate, objective and detailed information to support patient accounts of their symptoms".

Cyclopharm CEO James McBrayer commented, "We are thrilled to see the culmination of this research start to transition into real-world benefits for asthma patients. Outcomes like this underscore our commitment to making a meaningful difference in healthcare and improving the lives of those affected by asthma and other respiratory conditions".

- ENDS -

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

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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, Long COVID and certain interventional applications to include lobectomies in lung cancer and lung volume reduction surgery.

[1] Gibson PG, et al. Ventilation heterogeneity is a treatable trait in severe asthma. The Journal of Allergy and Clinical Immunology: In Practice. **2024**; 12(4): 929-935.