15 November 2023

cyclomedica
technegas

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TECHNEGAS® - USA COMMERCIALISATION UPDATE

Highlights

- **Strong pre-existing demand driving momentum for USA wide rollout**
- **Customer engagement with medical facilities across the USA progressing well**
- **First 20 Technegas Plus Systems built and first commercial batch of consumables being readied for shipment**
- **Interviews underway for key US based talent**

On 2 October 2023 Cyclopharm Limited (ASX: CYC) announced that the company received United States Food and Drug Administration (USFDA) approval to commence commercial sales of Technegas in the US market. The approval opens for Cyclopharm the single largest market for Technegas globally, and one which the company estimates to be initially worth approximately US$180 million annually for the diagnosis and management of Pulmonary Embolism (PE).

Customer Engagement Update

Prior to USFDA approval, CYC had logged over 420 individual expressions of interest and the company is now prioritising this strong demand for Technegas in US medical facilities in the following order:

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 estimates that the target market for Technegas in the USA is equal to 2,000 facilities. Since approval, the company has specifically engaged with approximately 200 sites nationwide with a substantial number progressing through their internal approval processes.

This internal process for implementing Technegas is generally first driven by a recommendation from the nuclear medicine department, followed by an interdepartmental review conducted which includes an analysis of commercial terms. Contract execution then progresses to installation and training. Based on this process and engagement to date, Cyclopharm expects first installations to commence in Q1 2024.

Manufacturing Update

The first 20 Technegas Plus Systems destined for the United States are manufactured and, following some external container labelling clarifications pending from the USFDA, will be shipped by air to our contracted third-party logistics partner. Additionally, the first commercial production batch of Technegas patient consumables will be completed within the next few weeks.

As previously advised, the company is targeting 200 US installations by the end of 2024. There are an additional 180 Technegas Systems currently manufactured to subassembly level in inventory. Following the release of the first 20 Technegas Systems, production of these additional units is now underway.

To ensure ongoing capacity for both Technegas and CYC's growing third-party distribution business, CYC has secured additional manufacturing and storage space directly adjacent to its current production facility located at Kingsgrove NSW.

The USA Ground Game Underway

Leveraging CYC's experience in commercialising Technegas across the world, the company is currently securing wholesale pharmaceutical state licenses in Georgia and Tennessee that will allow CYC to avoid a distributor model and serve customers directly.

Responses to US based employment advertisement have been overwhelming with interviews of exceptional candidates already taking place.

Contracts for all supporting third party providers to include customer service, technical support, logistics, invoicing, accounting, and human resources are being finalised.

Existing global technical and educational resources will be utilised for both customer fulfillment training new employees and business partners are ready for deployment for first installations.

Reimbursement Update

Diagnostic functional ventilation procedures in the United States are reimbursed through the Centers for Medicare (CMS) as a complete procedure. As a new product, replacing existing competitive agents, Technegas can be used immediately by the nuclear medicine department by using a miscellaneous product code. CYC has applied through the CMS for its own unique identifier that will be used as a reference in hospital formularies. Furthermore, because Technegas will be introduced at a premium cost to existing competitive products at $225 per patient consumable, the company is also applying for Pass-Through Status through CMS that will allow the site to be fully reimbursed separately from the current procedure code for a period of three years.

Cyclopharm's Managing Director James McBrayer said, "I am very pleased by the outpouring of support and enthusiasm from the US nuclear medicine community following the USFDA approval of Technegas. We already had a strong foundation of clinical support to launch from and, on a daily basis, we continue to receive incoming requests for our technology. I look forward to updating shareholders as we continue to execute our plans in the USA."

- ENDS -

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

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