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technegas

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FIRST US CLINICAL PAPER HIGHLIGHTS TECHNEGAS' CLINICAL EFFECTIVENESS FOR LUNG TRANSPLANT EVALUATION

9 December 2024 – Cyclopharm Limited (ASX: CYC) today announced publication of the first US-based study which highlights the clinical utility and operational benefits of its proprietary Technegas technology - compared to current US ventilation imaging radiopharmaceuticals used in lung transplant evaluation.

The study, which follows last year's United States Food and Drug Administration (FDA) approval of Technegas, was written independently by leading clinicians at Washington University's Mallinckrodt Institute of Radiology in St. Louis, Missouri. It highlights Technegas' clinical efficacy compared to 133-Xenon (Xenon), the current US ventilation imaging standard used in lung transplant evaluation.

Technegas is already recognised as the global nuclear medicine standard of care[1] for functional ventilation imaging in diagnosing Pulmonary Embolism (PE)'. Indications for Technegas continue to evolve as it is being successfully combined with advancements in imaging technology and AI in nuclear medicine departments around the world.

This study further underscores the potential for its adoption across a broader range of respiratory conditions in the US healthcare market and beyond.

About the Study:
Titled *Comparability of Quantifying Relative Lung Ventilation with Inhaled 99mTc-Technegas and 133Xe in Patients Undergoing Pre-lung Transplant Evaluation*, the peer reviewed study published in the US Journal of Nuclear Medicine, analysed 74 patients and confirmed Technegas' effectiveness and efficiency in surgical planning for lung transplant patients.[2]

The Study Highlights:

- **Demonstrated Comparability with Standard Imaging**: The study directly compared Technegas with Xenon in a population of lung transplant patients. Key findings include:
  - **Strong Correlation**: Technegas achieved a high correlation with Xenon in quantifying relative lung ventilation.
  - **High Agreement**: The study confirmed clinical equivalence.
  - **Enhanced Performance in Challenging Cases**: Technegas outperformed Xenon in cases involving obstructive lung diseases, due to its superior peripheral deposition and image quality.
- **Operational Advantages**: Technegas, compared to Xenon, provides a safer, more accessible solution for hospitals and imaging centres and avoids the logistical complexities of radioactive gas handling associated with Xenon.

[1] https://pubmed.ncbi.nlm.nih.gov/39086050/
[2] https://jnm.snmjournals.org/content/early/2024/12/05/jnumed.124.268801

- **Clinical Advantages**: Technegas can be used with advanced imaging techniques like SPECT and SPECT-CT[3] where Xenon is limited to Planar imaging.
- **Broader Implications**: The study positions Technegas as a pivotal tool for preoperative planning in lung transplantation and other thoracic surgeries, improving patient outcomes through accurate lung function assessments.
    - The study also reinforces the existing broad FDA approved indications for use for Technegas in the US market.[4]

Financial Implications for Investors:

- **Expanding U.S. Market Opportunity**: With FDA approval and reimbursement secured, Cyclopharm remains well-positioned to displace competing nuclear medicine products and other much larger imaging technologies like CTPA scans (Computed Tomography Pulmonary Angiogram) to a market estimated at USD $180 million for pulmonary embolism (PE) alone and over USD$1 billion in applications Beyond PE.
- **Cost-Effective Market Entry**: As a proven technology in 66 countries globally, Technegas is demonstrating to be a cost-efficient implementation strategy for US healthcare providers
- **Global Growth Synergies**: This milestone, marking the first independent research initiative in the US, is expected to generate additional global interest in other Beyond PE applications for Technegas.

James McBrayer, Managing Director and CEO of Cyclopharm, remarked: "This groundbreaking study, wholly driven by clinicians, clearly illustrates the transformative potential of Technegas across the US healthcare market. By validating its clinical equivalence to Xenon and highlighting its operational benefits, this independent research paves the way for broad adoption of Technegas across a range of respiratory conditions in the world's largest healthcare market. We are committed to delivering innovative, life-changing diagnostic solutions while driving long-term shareholder value."

"The results also emphasise how Technegas can not only replace existing radiopharmaceuticals but also challenge higher-radiation alternatives like CTPA, enhancing patient safety, care and clinical outcomes."

ENDS

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

[3] SPECT-CT: Single Photon Emission Computed Tomography with co-registered Computed Tomography imaging. When combined, both function and anatomy can be analysed together.
[4] https://www.cyclomedica.com/wp-content/uploads/2023/08/MNL-0030-Rev-01-USPI-Manual-30-Oct-23.pdf

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.

In the United States the Technegas approved indication for use for use is:
TECHNEGAS, when used with sodium pertechnetate Tc 99m in the Technegas Plus System, provides technetium Tc 99m-labeled carbon inhalation aerosol (Technegas Aerosol), a radioactive diagnostic agent for use in adults and pediatric patients aged 6 years and older is for the visualization of pulmonary ventilation and the evaluation of pulmonary embolism when paired with perfusion imaging.