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technegas

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FIRST PATIENTS IMAGED WITH TECHNEGAS IN FRENCH CLINICAL TRIAL

3 December 2024 Cyclopharm Limited (ASX: CYC) is pleased to announce that first patients have been imaged in a multicentre PRONOSPECT[1] clinical trial across 13 nuclear medicine centres in France. PRONOSPECT is a clinician driven trial integrating Technegas into advanced imaging modalities to set new benchmarks in the diagnosis and management of recurring pulmonary embolism (PE).

The trial is examining the potential of nuclear medicine imaging using Technegas to enable improved detection of residual pulmonary vascular obstruction (**RPVO**) as a predictor of venous thromboembolism (VTE) – which is a clinical area currently dominated by incumbent CT pulmonary angiogram (CTPA) scanning.

Key Highlights:

- **Successful Imaging Initiated**: First 15 of a total of 665 patients have been imaged.
- **Innovative Technegas Technology**: Technegas utilised as the primary ventilation agent used for ventilation/perfusion (V/Q) SPECT/CT[2] imaging to assess RPVO.
- **Study Objectives**: To establish RPVO as a predictor of VTE **recurrence**, improving patient phenotyping and treatment protocols to include clinical guidelines.
- **Potential Global Impact**: Results to redefine diagnostic protocols for managing recurring PE and enhance global adoption of Technegas-supported imaging.
- **Market Growth Potential**: Supporting Cyclopharm's growth strategy, underpinned by the expanding demand for precision pulmonary diagnostics.

Clinical Relevance:

Pulmonary embolism (PE) and venous thromboembolism (VTE) remain significant public health challenges:

- **High Mortality Risk**: Untreated PE is fatal in approximately **10% of cases**, often due to sudden complications. Even with treatment, acute-phase fatality rates are **3-4%**.[3]
- **Recurring Threat**: Patients with unprovoked PE face a **9% recurrence risk in the first year** after stopping anticoagulation, rising to as much as **30% over a decade** without preventive measures.[4,5]
- **Long-term Impacts**: Up to **50% of survivors** experience lasting symptoms, including chronic breathlessness and exercise intolerance.[6]

Clinical Trial Scope:

The PRONOSPECT trial is a prospective multicentre cohort study designed to investigate the clinical utility of ventilation/perfusion (V/Q) SPECT/CT imaging, specifically the role of residual pulmonary vascular obstruction (RPVO) in predicting venous thromboembolism (VTE) recurrence. To date 13 nuclear medicine centres in France have been enrolled in the study. The trial involves over 665 patients diagnosed with PE, regardless if they were diagnosed by CTPA or nuclear medicine SPECT imaging, who have completed 3–6 months of anticoagulation treatment.

The study aims to establish whether RPVO, as identified via V/Q SPECT/CT imaging, is an independent predictor of VTE recurrence. It also seeks to refine diagnostic protocols and identify patients at high risk of recurrent VTE, thereby guiding individualised treatment decisions.

Clinical Potential:

The PRONOSPECT trial has the potential to redefine standards in PE management, bridging critical gaps in clinical knowledge and practice. Current management strategies lack robust predictive tools to identify patients at intermediate risk of recurrence. Technegas, through its integration into advanced imaging modalities, provides:

1. **Enhanced Accuracy**: A 3D nuclear medicine (SPECT) imaging platform enabling improved detection of RPVO over CTPA.[7]
2. **Reduced Radiation Exposure**: Conventional CPTA imaging delivers up to 20 times the radiation dose compared to nuclear medicine imaging using Technegas.[8]
3. **Reduced Patient Risk associated with CTPA Contrast Media**: An estimated **5-15% of patients** requiring imaging for suspected pulmonary embolism are unsuitable for CTPA due to contraindications like contrast media allergy while nuclear medicine with Technegas has no contraindications.[9]
4. **Improved Patient Outcomes**: By identifying individuals at higher recurrence risk, clinicians can make more informed treatment decisions including suspension of anticoagulants.

Professor Pierre-Yves Le Roux, Principal Investigator of the PRONOSPECT trial based at Brest University Hospital, stated: “The initiation of patient imaging in the PRONOSPECT trial marks an exciting step forward in advancing our understanding of pulmonary embolism. Nuclear Medicine using Technegas, with its precision and safety, is an invaluable tool for assessing residual pulmonary vascular obstruction, a critical factor in predicting recurrence risk. This study holds the potential to reshape clinical protocols and improve outcomes for patients worldwide. We are proud to be leading this pivotal research effort and grateful for Cyclopharm’s support in making this innovation possible.”

Commercial Potential:

Technegas’ central role in this clinician driven initiative underscores its broad market applicability and accessibility. With growing adoption of nuclear medicine V/Q SPECT/CT imaging globally, Technegas stands to significantly expand its commercial footprint through:

- **Global Market Expansion:** Already utilised in over 65 countries, Technegas is poised for deeper penetration as the nuclear medicine ventilation imaging agent of choice in diagnosing PE.
- **Increased Procedure Volumes**: The eventual adoption of advanced imaging in routine clinical practice is anticipated to drive an increase in Technegas-supported diagnostics.
- **Recurring Revenue Streams**: As a consumable product, Technegas offers a sustainable revenue model aligned with increased utilization rates.

Cyclopharm anticipates the results of the PRONOSPECT trial will further validate Technegas' clinical and economic value, providing a platform for continued growth and long-term shareholder value creation.

Mr James McBrayer CEO of Cyclopharm, commented: "The imaging of the first patients using Technegas in the PRONOSPECT trial marks another milestone in our strategy to expand the use of Technegas. This study validates Technegas' capabilities in advanced pulmonary diagnostics and aligns with our commitment to improving global healthcare outcomes. We look forward to sharing the trial results, which we believe will have implications for patient care and our commercial strategy."

Cyclopharm remains steadfast in its commitment to innovation and excellence in pulmonary diagnostics. The progress in the PRONOSPECT trial reinforces Technegas’ position as a market-leading technology with transformative clinical and financial potential.

We will provide updates as the study progresses and as additional milestones are achieved.
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.

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.

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[1] https://classic.clinicaltrials.gov/ct2/show/NCT06372730

[2] SPECT/CT – Single Photon Emission Computerised Tomography co-registered with low dose, non-contrast Computerised Tomography

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