cyclopharm

26 September 2017

The Manager
Company Announcements Office
Australian Securities Exchange Limited
20 Bridge Street
Sydney NSW 2000

cyclomedica
technegas
ultralute

Cyclopharm Ltd
ABN 74 116 931 250
Unit 4, 1 The Crescent
Kingsgrove NSW 2208 Australia
T 61 2 9541 0411
F 61 2 9543 0960
www.cyclopharm.com.au

CYCLOPHARM'S USFDA TECHNEGAS CLINICAL TRIAL - PATIENT ENROLMENT UNDERWAY

Cyclopharm is pleased to announce that the first two patients have been enrolled today in the Company's United States Food & Drug Administration (USFDA) Phase 3 clinical trial for its proprietary lung imaging technology, Technegas.

These patients are the first recruits in a 240-patient non-inferiority structural ventilation trial that will compare Technegas with Xe133. The full study will be conducted at up to 15 clinical sites throughout the USA and is the second stage of a two-part study (CYC-010 and CYC-009). CYC-010 established the inter- and intra-reader variability for Xe133 and was completed last year. CYC-009 is the current patient trial reference number and has received USFDA's Special Protocol Assessment (SPA) approval. An SPA approval significantly de-risks the USFDA clinical trial program and expedites the review process once submitted for approval.

Results from the initial CYC-009 40-patient review are expected to be provided to the USFDA by 1H 2018 with the results of the full study due to be submitted to the USFDA by the end of 2H 2018 for final review. The USFDA trial process is expected to cost US$7 million.

Cyclopharm CEO & Managing Director, James McBrayer, stated "While Technegas is already sold in 56 countries and has been the subject of 3.7 million patient studies since 1987, the United States, with 50% of the world's nuclear medicine departments, offers the greatest immediate opportunity to Cyclopharm."

Currently in the United States nuclear medicine ventilation imaging is performed either with the radiopharmaceutical Xe-133 or Tc99m-DTPA. As Tc99m-DTPA is not officially approved for use in lung imaging, the only approved agent for Technegas comparison purposes is Xe-133. The existing combined United States market for Xe-133 and Tc99m-DTPA is estimated at 600,000 patients and valued at approximately $US 90 million p.a.

"Canada is our largest single country market. With 14 years of sales, Canada represents an excellent indicator of ultimate acceptance in the United States. Based on our experience there, we believe that we will be able to covert 80% of the total US market to Technegas," Mr McBrayer said.

Technegas has primarily been used historically in the diagnosis of pulmonary embolism (PE). Technegas, together with advancements in the complementary technologies of 3D acquisition, multimodality imaging and analytical software, is starting to be used in other disease states. These disease states include chronic obstructive pulmonary disease (COPD), asthma, pulmonary hypertension and certain interventional applications such as lobectomies in lung cancer and lung volume reduction interventions.

Mr McBrayer went on to say that "There is recognition within the global respiratory community that the old methodologies for diagnosing and managing patients with respiratory diseases need to be improved. On 21 September, 2017 The Lancet[1] published a commissioned report that *'proposes a revolution in thinking about asthma that is generalizable to all airways diseases*.' The report cites the use of diagnostic imaging as part of this strategy."

Mr McBrayer added that "Given the unique functional ventilation imaging information Technegas can provide clinicians, we believe that our technology can be part of this revolution. The clinical trial collaboration with Newcastle University, HMRI and Cyclopharm that we announced last month is designed to reflect this new innovative thinking in respiratory disease management."

Mr McBrayer concluded by saying "With the advancements that are occurring globally in the field of respiratory medicine and the progress we are making in gaining USFDA approval, it is an exciting time for Cyclopharm. The first patients recruited today mark a significant milestone in the company's history. With additional sites beginning in the next several weeks, we are looking forward to building patient recruitment momentum going into the Northern Hemisphere winter."

Additional facts:

- Technegas was first commercialised in 1987
- Technegas is sold in 56 countries
- Europe is currently the largest regional market
- Canada is the largest single country market
- Preliminary trials in China indicate that Technegas can be an effective tool to diagnose and monitor COPD
- Clinical trials underway applying Technegas technology in Asthma, Lung Reduction & COPD.
- More than 210,000 patient studies were undertaken in 2016 with more than 3.7 million since 1986
- To date, more than 1500 Technegas generators have been sold globally
- Technegas is composed of carbon nanoparticles dispersed in high purity argon gas

For more information, please contact:

Mr James McBrayer
Managing Director, CEO and Company Secretary
Cyclopharm Limited
T: +61 (02) 9541 0411

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^{o} 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.

[1] After Asthma: redefining airways disease, The Lancet Commissioned Report, September 2017