cyclopharm
Nuclear Medicine

cyclomedica
technegas
ultralute

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13 October 2016

The Manager
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Successful completion of first stage of USFDA trials of Technegas and significant progress on Technegas and Ultralute™ sales strategies

Australian radiopharmaceutical company Cyclopharm Limited (ASX: **CYC**) is pleased to update shareholders on the following developments:

1. Cyclopharm successfully completes the first stage of its United States Food and Drug Administration (**USFDA**) clinical trial program
2. Strategy to expand the use of Technegas progressing, with pilot clinical trial programs initiating in Australia, China and Canada
3. Cyclopharm receives an invitation from the International Atomic Energy Association (**IAEA**) for Ultralute™, our new innovative technology
4. Relocation to new Kingsgrove (Sydney) facility to be completed by mid-November 2016

USFDA Clinical Trial for Technegas

Cyclopharm has now successfully completed the first stage of its USFDA clinical trial program, known as CYC-010. Completion of CYC-010 is in line with the timeline set out in our recent investor presentation.

The CYC-010 trial set out to determine inter-reader and intra-reader variability for Xenon-133, the only existing USFDA approved nuclear medicine ventilation imaging agent in the United States. This step was essential in establishing the number of patients required for the next stage in the clinical trial program.

As a result of the CYC-010 completion, Cyclopharm will next submit to the USFDA by 17 October 2016 a Phase 3 non-inferiority structural ventilation protocol comparing Xenon-133 with Technegas in 240 patients. This stage of our clinical trial program will be designated with the USFDA as CYC-009.

The content for the CYC-009 protocol has been completed and is being formatted for submission under a Special Protocol Assessment (**SPA**) regime. As per USFDA guidelines for SPA submissions, a response from the USFDA is expected to be within 45 days from lodgement.

Based on this timeline, we are confident the CYC-009 trial will commence in line with our expectations during the first half of 2017. The clinical trial program is projected to be completed by mid-2018 at a total cost of less than $7 million USD.

Technegas is sold in 55 countries around the world, excluding the USA. As half the world's nuclear medicine departments are located within the United States, gaining USFDA approval will represent a significant opportunity for Cyclopharm to materially expand its sales and profitability.

The completion of the first stage clinical trial program marks a major milestone in Cyclopharm's progress towards anticipated USFDA approval for Technegas by mid-2018.

Ultralute™ – Invitation by the International Atomic Energy Agency

Earlier this year the International Atomic Energy Agency (**IAEA**) held a scientific summit to review emerging technologies in the production and supply of Molybdenum-99 (**Mo99).**

Mo99 is the precursor to Technetium-99 (**Tc99m**), the isotope used in over 80% of all nuclear medicine studies. During the IAEA sponsored review, Cyclopharm's new technology Ultralute™ was recognised for its optimisation of the isotope Tc99m.

Following a recommendation from summit participants, the IAEA has formally invited Cyclopharm to collaborate in launching a multi--country, multicentre evaluation of Ultralute™ in early 2017.

The invitation from the IAEA represents significant recognition for the technology's potential. In particular, Cyclopharm notes that in its invitation the IAEA referred to Ultralute™ as a "new innovation…that has significant global potential in the nuclear medicine supply chain".

Ultralute™ is scheduled for commercial launch in the first half of calendar year 2017.

Indication Expansion for Technegas

The University of Newcastle and Cyclopharm through the Hunter Medical Research Institute and John Hunter Hospital are partnering to conduct a pilot clinical trial to assess small airway dysfunction using Technegas functional lung ventilation imaging with quantification in order to identify treatable traits related to obstructive airway disease.

The study will seek to test two specific hypotheses:

1. There is ventilation heterogeneity among patients with severe obstructive airway diseases that can be assessed using Technegas functional lung ventilation imaging with quantification and
2. Technegas functional lung ventilation imaging with quantification is responsive to change following intervention in patients with severe obstructive airway diseases

The implication in advancing these hypotheses further could expand the use of Technegas by improving the diagnosis and management of patients with Chronic Obstructive Pulmonary Disease (**COPD**).

COPD is currently the fourth leading cause of death worldwide, and the World Health Organisation (**WHO**) predicts it will rise to the third leading cause by 2030. The Lung Foundation Australia estimates that approximately over 1.45 million Australians[2] have some form of COPD. This represents approximately one in seven Australians over age 40.

[2] Based on ABS census data — CData Online 2006 Census, Australian population over 40

Technegas is primarily used in the diagnosis of pulmonary embolism (**PE**). This partnership with the University of Newcastle represents a significant deliverable in one of Cyclopharm's principal strategies of expanding the use of Technegas. Other efforts related to this strategy are progressing at leading clinical sites in both China and Canada.

Cyclopharm expects the study's protocol will be finished by mid-November 2016 with patient recruitment initiating in early 2017. Total cost for the pilot clinical trial is estimated to be approximately $500,000 AUD. It is expected that the trial will take approximately two years to complete.

Manufacturing Facility Relocation

As previously announced, after nearly 25 years of continuous operations at our Lucas Heights facility, Cyclopharm will be moving next month to a new state-of-the-art manufacturing facility located in Sydney's south-west in the suburb of Kingsgrove.

The new facility has been designed to accommodate the growing demand for our products globally and the anticipated USFDA approval for Technegas in mid-2018.

The fit out and relocation will cost approximately $1.4 million AUD, in line with its projected cost. The facility will be capitalised and amortised over 10 years.

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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 labeled 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.

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

Ultralute

Cyclopharm's patented nuclear medicine technology Ultralute^{TM} extends the useful life of Molybdenum-99 (Mo-99) generators by up to 50%. This technology potentially gives nuclear medicine departments the ability to dramatically improve operating efficiencies and health outcomes for patients.

Mo-99 generators are used in diagnostic imaging to harvest Technetium-99m, or Tc-99m, which is the primary isotope used in diagnostic imaging throughout the world. This isotope accounts for approximately 80% of all nuclear medicine diagnostic imaging procedures.