cyclopharm
Nuclear Medicine

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molecularimaging
technegas

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Cyclopharm Receives Approval from United States FDA to Commence Technegas Clinical Trials

The Directors of Cyclopharm (ASX: CYC) are pleased to announce that the company has received approval from the United States Food and Drug Administration (FDA) to commence Phase 3 clinical trials with Technegas.

The FDA approval is based on the successful review of Cyclopharm's Investigational New Drug application for Technegas submitted to the FDA last month.

Technegas is a lung ventilation imaging agent used primarily to detect pulmonary embolism. The product is distributed in over 50 countries. The United States represents the largest nuclear medicine market in the world. Based on Technegas' success in the Canadian market, we expect to see the company more than double its current size within 3 to 5 years of attaining United States marketing authorisation approval.

Cyclopharm announced earlier in the year that it had reached clinical protocol agreement with the FDA through the Special Protocol Assessment process. A Special Protocol Assessment is a mechanism through which the FDA and sponsor reach agreement on the design, size, clinical endpoints, and data analysis of a clinical trial that is intended to support an efficacy claim in a New Drug Application for regulatory approval. The Special Protocol Assessment ensures that the agreed clinical trial design meets the FDA's expectations for a pivotal study

750 patients will be imaged during the trial period at several leading clinical sites across the United States. The trial is expected to cost up to USD $4m to complete. Subject to patient recruitment frequency we expect that marketing approval could be granted by 2014.

With the FDA endorsement in hand we have commenced site qualification, product installation and user training procedures in initial clinical sites. We expect that the first United States patients to have access to our life saving technology will occur by the end of January.

With this significant milestone achieved Cyclopharm has made an enormous step forward in gaining marketing approval for Technegas in the USA. The speculation is now over. Cyclopharm is now about to enter into a phase that will allow the company to actually demonstrate the benefits of Technegas to the clinical community in the United States.

Regards,

James McBrayer
Managing Director and Company Secretary

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Background

Cyclopharm Limited

Cyclopharm is a radiopharmaceutical company servicing the medical global medical community. The Company's mission is to enable nuclear medicine and other clinicians with the ability to improve patient care outcomes.

Cyclopharm achieves this objective through the provision of radiopharmaceutical products, Technegas (for lung imaging) and Molecular Imaging / PET radiopharmaceuticals (used in cancer, brain and cardiac imaging). Our customers are nuclear medicine departments located within hospitals and clinics.

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 gaseous 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 the superior diagnosis of pulmonary emboli (blood clots in the lungs).

Positron Emission Tomography (PET)

PET radiopharmaceuticals target specific tissues / organs, concentrate there, and the attached radioisotope emits radiation, which is then detected by a PET or PET / CT gamma (collectively PET camera). These imaging modalities help physicians improve their ability to detect and determine the location, extent and stage of cancer, neurological disorders and cardiac disease. By improving diagnosis, PET scans aid physicians in selecting better courses of treatment, as well as assessing whether treatment is effective or should be changed.

Macquarie University Hospital and the Macquarie University School of Advanced Medicine

Macquarie University Hospital is a major medical precinct within the Macquarie University Research Park to complement the Allied Health teaching services offered by Macquarie University.

The Macquarie University Hospital together with the Macquarie University School of Advanced Medicine is a state of the art facility that delivers health education and research on site.

Macquarie Medical Imaging

Cyclopharm formed a joint venture with Alfred Health Solutions to provide all imaging services on-site at the hospital. The new venture named Macquarie Medical Imaging ("MMI") represents a rare strategic opportunity to provide a fully aligned and integrated diagnostic, therapeutic and research platform. MMI offers a range of diagnostic radiology, interventional radiology, nuclear medicine and molecular imaging services for inpatient and outpatients.

The combination of state of the art imaging equipment, a GE cyclotron located on the grounds of MUH, leading surgeons, clinicians and academics will ensure that MMI will become the leading centre of imaging excellence.