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Cyclopharm Receives Clinical Protocol Approval from United States Food and Drug Administration

The Directors of Cyclopharm (ASX: CYC) are pleased to announce that it has received an approved Special Protocol Assessment (SPA) from the United States Food and Drug Administration (FDA). After a series of proposals and meetings throughout 2010, the FDA has agreed to the Company's Phase 3 clinical trial development program for Technegas in-patients with suspected pulmonary embolism (PE).

A SPA 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 (NDA) for regulatory approval. The SPA ensures that the agreed clinical trial design meets the FDA's expectations for a pivotal study.

Cyclopharm's positive SPA response leaves no clinical issues outstanding, and provides Cyclopharm with confidence that the design of the Phase 3 development program and clinical trial for Technegas is suitable to support regulatory approval for the United States.

The next step toward approval is to finalise negotiations with potential clinical sites and submit an Investigational New Drug (IND) application to the FDA. It is expected that patient recruitment may start by the end of the second quarter.

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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 2,500°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 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.