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FIRST 40 PATIENT MILESTONE REACHED IN USFDA PHASE 3 TECHNEGAS STUDY

Cyclopharm Limited (ASX:CYC) is delighted to announce it has completed recruitment and imaging of the first 40 patients in its Phase 3 clinical trial required to gain US Food and Drug Administration ('USFDA') approval to market and sell Technegas in the US market.

Commenting on the announcement, Cyclopharm Managing Director, Mr James McBrayer said, "Achievement of this significant milestone, in line with our previously announced timeline, demonstrates that we remain on track to submit our first 40 patient interim study to the USFDA in the current half year."

"This first 40 patient interim study was agreed to by the USFDA to establish the trial's effectiveness. It will also provide Cyclopharm the opportunity to engage with the USFDA to review, refine and improve the trial's protocol which may accelerate the overall rate of recruitment."

In November 2016, Cyclopharm announced that it received Special Protocol Assessment agreement from the USFDA for its proposed clinical trial design for Technegas. Specifically, the trial is a non-inferiority, structural indication comparing Technegas with Xenon-133 in a total of 240 patients.

The study is expected to be conducted at between ten to fifteen locations. Cyclopharm anticipates the rate of patient recruitment will increase as an additional two locations, making a total of five sites, commence recruitment in the coming weeks. The study will be funded from existing cash reserves with regulatory approval expected to be received in the first half of 2019.

Concurrently, Cyclopharm is accelerating programs that relate to satisfying the USFDA Center for Drug Evaluation and Research (CDER) by:

- providing the Administration, a pediatric plan for Technegas; and
- expanding the existing Supporting Clinical Information package to include a comprehensive literature review.

In addition, Cyclopharm is undertaking a development program to ensure its quality systems and manufacturing processes are USFDA compliant and that the Technegas Generator passes the design and performance requirements expected from the Center for Device and Radiological Health (CDRH).

"The results from the first 40 patient interim study will form an important contribution in our New Drug Application for Technegas and provide valuable clinical feedback. Based on the progress to date, including advancing the CDER and CDHR matters, we remain on track to receive the anticipated approvals to commence marketing and sales of Technegas in the US market in 2019," said Mr McBrayer.

For more information, please contact:

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

Ultralute™

Cyclopharm's patented nuclear medicine technology Ultralute™ 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.