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CYCLOPHARM ACHIEVES USFDA AGREEMENT FOR TECHNEGAS TRIAL DESIGN

Australian radiopharmaceutical company, Cyclopharm Limited (ASX: CYC) is delighted to announce that today it received Special Protocol Assessment (SPA) agreement[1] from the United States Food and Drug Administration (USFDA) for patient trials of its Technegas product, to be known as CYC-009.

Cyclopharm Managing Director and CEO, James McBrayer, said the company's proposed clinical protocol was agreed without request for clarification or variation and was announced earlier than expected.

The SPA agreement means the USFDA has reviewed specific critical elements of the company's overall protocol design (including entry criteria, dose selection, endpoints, and planned analyses) and concurred that the proposed parameters for the trial are acceptable. This agreement also confirms that the trial protocols will support a future application for regulatory approval of Technegas sales into the United States market.

The CYC-009 trial will be a Phase 3 non-inferiority structural ventilation protocol comparing Xenon-133 with Technegas in 240 patients. The trial will proceed on an 'all-comers' basis, which means that the trial participant selection criteria is very broad and will ultimately allow a more efficient and expeditious completion of the trial.

Mr McBrayer said, "I believe the SPA agreement confirms that our pathway and strategy for ultimate USFDA approval for Technegas is well and truly on track. The rapid receipt of the SPA agreement confirms our USFDA trial and approval process remains on track for completion by mid-2018 at a cost of less than $7 million USD."

"The selection of the ten to fifteen locations for the trial is already underway. With some of the already advanced locations we will commence patient enrolment into the CYC-009 trial in early 2017. Given the low barrier for recruitment, we expect that we will be able finalise the patient numbers during 2017 with a target to submit our New Drug Application to the FDA by early 2018."

"Half of all the nuclear medicine departments in the world are located in the US – thus, this is a very exciting and significant development for the continued growth of Technegas which is already sold in 55 countries," Mr McBrayer concluded.

[1] An SPA agreement indicates concurrence by FDA with the adequacy and acceptability of specific critical elements of overall protocol design (e.g., entry criteria, dose selection, endpoints, and planned analyses). These elements are critical to ensuring that the trial conducted under the protocol has the potential to support a future submitted application's ability to meet regulatory requirements for approval. Feedback on these issues provides the greatest benefit to sponsors planning late-phase development strategy.

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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 2,700o 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 UltraluteTM 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.