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POSITIVE USFDA MEETING - TECHNEGAS SALES EXPECTED IN 2019

- **Constructive meeting with USFDA**
- **Alternative USFDA approval pathway identified that should deliver lower cost and reduced risk profile**
- **Commercial sales expected to commence in the USA during 2019**

Cyclopharm Limited (ASX:CYC) is pleased to advise shareholders that the meeting held with the United States Food and Drug Administration ('USFDA') earlier today has opened an alternative pathway for the approval of Technegas. The proposed pathway is likely to allow for a faster market entry and reduced risk profile. As a result, Cyclopharm is likely to be in a position to submit its New Drug Application for Technegas during the First Half of 2019.

As previously announced, the purpose of the Type C meeting today followed its submission of its first 40-patient interim study. The proposed meeting was set to explore opportunities to refine or alter the clinical trial and drug application process for Technegas.

At the meeting, the USFDA provided constructive guidance to Cyclopharm relating to submitting a new drug application (NDA) via a 505 (b)2 pathway. In addition to the positive results from its current USFDA Phase 3 trial, the 505 (b)2 pathway will allow the use of existing clinical data on Technegas' efficacy, safety and performance compared to Technegas' competing products and technologies. In pursuing this new drug application protocol, Cyclopharm will:

- continue to recruit patients under the CYC 009 study;
- file an amendment to the current Special Protocol Assessment that is expected to accelerate the rate of patient recruitment;
- submit a 505 (b)2 New Drug Application to the USFDA in the first half of 2019; and
- target the commence sales of Technegas in the US in late 2019.

Commenting on the announcement, Cyclopharm Managing Director, Mr James McBrayer said, "Being allowed to submit a New Drug Application protocol for Technegas via a 505 (b)2 pathway significantly de-risks the FDA approval process, gives confidence to our timeline target to start sales of Technegas in the US in 2019 and is likely to reduce the anticipated overall costs (USD \$7.5m) of gaining approval USFDA substantially."

"We will redeploy any savings we make from adopting this alternative approval pathway to building the distribution, sales and marketing capabilities needed to initiate US sales in 2019." Mr. McBrayer said.

The USA accounts for around half of the total addressable global market for Technegas. The existing market for nuclear medicine ventilation imaging in the USA is estimated to be approximately US\$90 million annually, representing approximately 600,000 individual procedures. Based on the Group's Canadian experience, Cyclopharm believes that Technegas can achieve a 50% share of the USA market over 2 to 3 years, post market entry, with an 80% share representing around 480,000 procedures per annum achievable over a 7-year period.

Market Update

Cyclopharm is also pleased to re-affirm its operational guidance for 2018, which includes:

- higher sales volume in France and the resumption of sales in China in FY 2018
- continued investment in new indications for Technegas
- continued progress towards resolving the company's litigation in the German market
- progressing commercial production of the exciting Ultralute™ technology
- a resolution on the future of the Molecular Imaging division by the end of calendar year 2018

Overall the company expects to deliver modest sales and earnings growth during FY 2018 and maintain a healthy capital position.

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 furnace 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.