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cyclomedica technegas ultralute

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COMPANY UPDATE

- A\$1.9 million received from the Research & Development Tax Incentive Program
- 100th Patient enrolled in USFDA Phase 3 Technegas Clinical Trial
- A\$335,000 received from German Litigation

Cyclopharm Limited (ASX: CYC) is pleased to provide the following update on key developments:

Research & Development Tax Incentive - A\$1.9 million received

As previously advised, AusIndustry approved Cyclopharm's inclusion of certain expensed costs associated with its overseas research and domestic development activitites as part of its application for a research and development tax incentive.

Cyclopharm confirms it has completed its Research and Development Tax incentive claim for the 2018 financial year and has received a payment of \$1.9 million.

Cyclopharm expects to receive an R&D tax incentive of a similar amount through to at least FY2020. The exact amount of any future R&D tax incentive will be subject to the nature, timing and value of R&D activities undertaken each year, some elements of which will be outside the company's control.

USFDA Phase 3 Trial – 100th patient enrolled

Cyclopharm advises that, on 2 January 2019, the Company enrolled its 100th patent in its current Phase 3 Trial in support of its proposed application to the USFDA to obtain approval to sell Technegas into the US market.

As previously announced, Cyclopharm is also pursuing an alternate pathway for the approval of US Technegas sales, known as a '505(b)2' pathway. This pathway will allow the use of existing clinical data on the performance of Technegas compared to competing products and technologies, in addition to data obtained from the current Phase 3 Trial.

Cyclopharm submitted its 505(b)2 literature review protocol to the USFDA on 27 December 2018 and are awaiting comments. If the 505(b)2 New Drug Application is successful, the Company will be in a position to conclude patient recruitment for the current Phase 3 Clinical Trial ahead of previous expectations.

German Litigation – A\$335,000 received

The successful conclusion of the first civil case brought by Cyclopharm against its former employee in the German market, Mr Bjorn Altmann and Almedis Altmann GmbH ("Almedis") has resulted in the company's subsidiary, Cyclomedica Germany, being awarded and receiving a payment of approximately A\$335,000 from Almedis, representing 100% of its claim.

In its 2017 financial accounts, Cyclopharm recorded bad debt provisions of approximately A\$540,000 in relation to these matters and, while delighted with the outcome of this first civil case, the company will continue with its efforts to recover the remainder of this bad debt provision.

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.