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POSITIVE RESULTS OF CHINA TRIAL SUPPORT THE POTENTIAL USE OF TECHNEGAS IN COPD

- Successful trial in China for COPD confirms potential of Technegas new and significant market opportunity
- Pilot trial to commence in Newcastle targeting use of Technegas in small airways disease
- USFDA trial Number of sites extended from 10 to 15. Enrolment commencing imminently.

Cyclopharm Limited (ASX:CYC) announced today that the final results of its China clinical trial designed to assess the efficacy of Technegas in the diagnosis of Chronic Obstructive Pulmonary Disease (COPD) have been published in the May 2017 issue of the International Journal of Chronic Obstructive Pulmonary Disease¹.

Cyclopharm received positive preliminary results from the COPD trial conducted in early 2016. Interim results indicated that Technegas delivered outcomes superior to existing diagnostic methods.

The positive final results support Cyclopharm's strategy of expanding the use of Technegas beyond the traditional diagnosis of PE into significantly larger applications.

Technegas is currently sold in 56 countries primarily for the diagnosis of patients suspected of having a Pulmonary Embolism (PE). Technegas business had global annual sales of \$14.4 million in FY16.

Cyclopharm Managing Director James McBrayer said that the Company is extremely pleased by the results. The study conclusion states that:

'V/P SPECT, using Technegas as the functional ventilation imaging agent, is a new tool to diagnose COPD and to grade its severity. Additionally, it revealed heterogeneity of COPD caused by pulmonary comorbidities. The characteristics of these comorbidities suggest their significant impact in clarifying symptoms, and also their influence on the prognosis.'

"This trial confirms that Technegas through the provision of early detection and periodic follow-up combined with the identification of other disease states that often accompany this chronic disease, can play an important clinical role in the ongoing management of patients with COPD. This opens up a new and potentially large market for CYC...," Mr McBrayer added.

"The publication of the study is particularly timely in that we intend to promote the results at several upcoming conferences to include the Society of Nuclear Medicine and Molecular

¹ Link: <u>https://www.dovepress.com/international-journal-of-chronic-obstructive-pulmonary-disease-archive6-v1121</u>

Imaging in June, the European Association of Nuclear Medicine in September and the European Respirology Meeting in October," Mr McBrayer said.

COPD is currently the fourth leading cause of death worldwide, and the World Health Organisation predicts it will rise to the third leading cause by 2030².

The China research results come as Cyclopharm prepares to announce commencement of recruitment for both its USFDA trial and another pilot clinical trial based in Newcastle Australia.

The Newcastle trial will be targeting the application of Technegas in small airways disease such as asthma and patient response to therapy. The study, estimated to cost just over \$600k AUD over two years, will be in collaboration with the University of Newcastle, the Hunter Medical Research Institute and John Hunter Hospital.

Cyclopharm's USFDA clinical trial program is currently in the process of installing Technegas units at several nuclear medicine departments across the country. Commencement of patient enrolment is imminent. In order to expedite the patient recruitment process in line with expectations, the company has decided to expand the number of clinical sites from 10 to 15. The additional costs associated with expanding the number of locations is expected to increase the study cost by \$500k USD to a total of \$7.5m USD. As of 30 April 2017, \$2.43m AUD of the total \$7.5m USD has been invested to date.

There are over 600,000 patient ventilation studies conducted in the USA each year. These studies are primarily conducted for the detection of PE. The market potential for ventilation imaging in the USA is estimated to be over of \$90m USD per year.

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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.

² Link: <u>http://www.who.int/respiratory/copd/burden/en/</u>