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Cyclopharm's Technegas May Facilitate Earlier Diagnosis of Chronic Obstructive Pulmonary Disease (COPD)

- **Canadian study concludes Cyclopharm's Technegas may be used for earlier detection of lung disease, often caused by cigarette smoking, including chronic bronchitis and emphysema**
- **500 patient pilot trial initiated by Cyclopharm is now underway with initial results expected late 2013**
- **Potential for Technegas to be used in both diagnosis and management of COPD**

The Directors of Cyclopharm Limited (ASX: CYC), Australia's leading nuclear medicine company, are pleased to advise that new research has demonstrated our unique proprietary patented technology, Technegas, may be effective in detecting early changes to the lungs, often caused by cigarette smoke, in advance of traditional CT scans.

In an article published last month in the North American Journal of Nuclear Medicine¹, Canadian researchers from McMaster University and the Firestone Institute for Respiratory Health at St. Joseph's Healthcare in Ontario, Canada demonstrated that Technegas detected changes in lung ventilation and perfusion before structural changes in the lungs were detected by CT scans.

Cyclopharm's Managing Director and CEO Mr James McBrayer commented "Whilst Technegas has until now primarily been used to diagnose pulmonary embolism, clinicians have utilised our technology in several other indications. This research in relation to COPD underscores the validity of the work we have been doing in expanding our life-saving technology.

According to the Lung Foundation Australia, COPD is a condition that affects about 1 in 5 Australians over 40 years old and often causes breathlessness.

We are very excited to see the results of this latest research show that our Technegas technology may assist earlier detection and treatment of people facing chronic bronchitis and emphysema."

The study concluded "Lung ventilation and perfusion imaging (utilising Technegas) can detect early changes to the lung caused by cigarette smoke exposure and thus provides a non-invasive method of longitudinally studying lung dysfunction in preclinical models. In the

¹ "Detection of Lung Dysfunction Using Ventilation and Perfusion SPECT in a Mouse Model of Chronic Cigarette Smoke Exposure", North American Journal of Nuclear Medicine, April 2013



future, these measures could be applied clinically to study and diagnose the early stages of chronic obstructive pulmonary disease.”

Cyclopharm recently initiated a pilot clinical trial targeting the use of Technegas in COPD. The 500 patient pilot trial will be conducted at five locations throughout China and is expected to conclude in mid 2014. However, Cyclopharm anticipates receiving initial results from the trial in late 2013, which will provide an indication of the effectiveness of Technegas in COPD diagnosis, and consequently the potential market size to Cyclopharm.

Dr Michael Guo of the Woolcock Institute said, “The Technegas pilot study is designed to evaluate lung imaging in terms of morphological and functional changes in assessing COPD severity and developing a more effective algorithm to identify other diseases associated with COPD.”

Dr Guo went on to state that “This study could declare a revolutionary method in assessing COPD.”

According to a study published in the Lancet in 2008, it is predicted that China will see 65 million deaths from COPD and 18 million deaths from lung cancer between 2003 and 2033 from driven in a large part from smoking and biomass burning at home.

“China is a very important market for Cyclopharm. In 2012, we have seen significant growth with Technegas sales and the upward trajectory is continuing into 2013. In China, respiratory diseases including COPD are among the leading causes of death. About half of Chinese men smoke. In more than 70% of homes, Chinese people cook and heat their homes with wood and coal,” Mr McBrayer said.

While there is no cure for COPD, there is strong medical evidence to show that early diagnosis, combined with disease management programs at the early stages of the disease could reduce the burden of COPD, improving quality of life, slowing disease progression, reducing mortality and keeping people out of hospital.

If the Technegas clinical trial results demonstrate the ability to detect COPD earlier than existing methods, Technegas could be used as a key element in not only diagnosis but in the management of COPD.

Further details on COPD are included in the attached fact sheet.

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Background

Cyclopharm Limited

Cyclopharm is a 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 through the provision of radiopharmaceutical products, Technegas (for lung imaging) and Molecular Imaging / PET radiopharmaceuticals (used in cancer, brain and cardiac imaging). Our customers are nuclear medicine departments located within hospitals and clinics.

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 2,700°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 the superior diagnosis of pulmonary emboli (blood clots in the lungs).

Positron Emission Tomography (PET)

PET radiopharmaceuticals target specific tissues / organs, concentrate there, and the attached radioisotope emits radiation, which is then detected by a PET or PET / CT gamma (collectively PET camera). These imaging modalities help physicians improve their ability to detect and determine the location, extent and stage of cancer, neurological disorders and cardiac disease at a metabolic level. By improving diagnosis, PET scans aid physicians in selecting better courses of treatment, as well as assessing whether treatment is effective or should be changed at a much earlier stage.

Chronic Obstructive Pulmonary Disease

According to the Lung Foundation of Australia:

COPD: The statistics

- COPD is a lung disease that affects almost 13% or one in seven Australians 40 or over.¹
- 7.5% of Australians 40 or over have COPD that has progressed sufficiently to where symptoms may already be present and affecting daily life. Half of these people will not know they have it.¹
- COPD is the second leading cause of avoidable hospital admissions.²
- Despite falling death rates, COPD is still a leading cause of death and disease burden after heart disease, stroke and cancer.³
- Australia has one of the highest rates of COPD deaths in the developed world – Australian mortality rates place Australia in the worst third of the 34 OECD countries.³
- While there is no cure for COPD, there are things people can do to breathe easier, keep out of hospital and improve their quality of life.⁴
- COPD is preventable and treatable.⁴



What is COPD?

- Chronic Obstructive Pulmonary Disease (COPD) is a deadly long-term disease of the lungs which causes shortness of breath. While COPD has no cure, there are things that people can do to breathe easier, keep out of hospital and improve their quality of life.⁴
- COPD is an umbrella term that includes emphysema, chronic bronchitis and chronic asthma.
- COPD is usually characterised by:
- Shortness of breath
- A repetitive cough with phlegm / mucus most days
- History of cigarette smoking or exposure to other environmental pollutants (smokes and fumes) or industrial dust

How does a person with COPD feel?

Symptoms for an individual with COPD tend to creep up gradually. Breathlessness may lead those with the condition to cut back on physical activities. This gradual decline continues until simple daily activities like showering, dressing or making a cup of tea, become almost impossible. Depression and anxiety often affect those with COPD.

What Causes COPD?

- In the western world, cigarette smoking is the single largest cause of COPD.⁴ However, despite being the highest risk group for COPD, regular smokers are less likely than the rest of the population to consider themselves at risk of developing COPD.⁵
- Some 20% of COPD occurs in never smokers⁶.
- Other known risk factors are passive smoking, especially during infancy when the lungs are still developing, exposure to environmental agents, including indoor and outdoor air pollutants and occupational dusts and chemicals.⁴
- Women may be at greater risk than men of COPD from exposures at work and are more susceptible to COPD due to smaller lungs and airways and more sensitive airways.⁷
- Chronic asthma may evolve into COPD in later life, especially in those who have smoked and when appropriate medications have not been taken properly.⁴

Prevalence of COPD

- The Australian Lung Foundation estimates that approximately 1.2 million Australians have some form of COPD.⁸ This represents approximately one in seven Australians over 40.¹
- Of those with COPD currently, The Australian Lung Foundation estimates that over 680,000 Australians^{1,8} have COPD that has progressed to a stage at which symptoms, such as breathlessness may already be present and affecting their daily lives. Half of these people do not have a doctor's diagnosis of COPD and are therefore not taking the important steps to slow down the progression of the disease.¹
- Nearly 520,000 Australians^{1,8} have a mild form of COPD where symptoms may not yet be present. Many of these will go on to develop more severe COPD.
- People who unknowingly have COPD may mistake their symptoms as signs of ageing, lack of fitness or asthma – a simple lung function test from a GP can diagnose COPD.

The Burden of COPD

- In Australia, despite falling death rates, COPD is still a leading cause of death and disease burden after heart disease, stroke and cancer³.
- COPD is a significant cause of death in Australia. Estimates range from 12,000 persons per year⁹ where COPD was a contributing factor (or 9.5% of all deaths in 2005) to 16,000¹⁰ deaths a year as a result of COPD.



- Australia has one of the highest rates of COPD deaths in the developed world – Australian mortality rates place Australia in the bottom third of the 34 OECD countries³.
- COPD is the second leading cause of avoidable hospital admissions in Australia.²
- In 2008-09 the median length of hospital stay for COPD was 5 days among people aged 55-69 years, rising to 6 days for those aged 85 years and over.¹⁹
- In 2008, the total economic impact of COPD was estimated to be \$98.2 billion of which \$8.8 billion was attributed to financial costs and \$89.4 billion to the loss of wellbeing.¹⁰
- Of the financial costs (\$8.8 billion), a large proportion is due to the loss of productivity due to COPD, ie lower employment, absenteeism and the workplace impact of premature death of Australians with COPD.¹⁰
- The direct cost to the Australian health care system is estimated to be \$900 million with hospital use contributing the largest share of health spending (\$473 million).¹⁰
- In addition to the above costs on the public and private sector purse, there are the costs that are harder to quantify – those of lost wellbeing as a result of COPD. These are estimated to be some \$90 billion.¹⁰
- In terms of overall costs, COPD is more costly per case than cardiovascular disease, osteoporosis or arthritis.¹⁰

COPD diagnosis and treatment

- COPD is preventable and treatable⁴.
- While there is no cure for COPD, there is strong medical evidence to show that early diagnosis, combined with disease management programs at the early stages of the disease could reduce the burden of COPD, improving quality of life, slowing disease progression, reducing mortality and keeping people out of hospital.⁴
- Lower costs and burden of disease can result if diagnosis is achieved early and optimally assessed, especially as treatment can reduce exacerbations.¹³⁻¹⁸

Treatment

The key aims of COPD treatment are to reduce symptoms, improve quality of life, increase the capacity for exercise and ultimately, keep people well and out of hospital. There are a number of steps people with COPD can take to breathe easier and improve their quality of life.

- Stop smoking – helps improve symptoms and slow down the rate the disease progresses.^{4,14}
- Inhaled medications – reduce symptoms, improve quality of life, reduce activity limitation and prevent exacerbations associated with hospital admissions.⁴
- Pulmonary rehabilitation –reduces breathlessness, fatigue, anxiety and depression, improves exercise capacity, emotional function and health-related quality of life and enhances patients' sense of control over their condition. Pulmonary rehabilitation reduces hospitalisation and has been shown to be cost-effective.⁴
- Regular vaccinations against influenza and pneumonia.⁴
- Support groups/services – as COPD worsens and patients feel less able to carry on their normal activities, patients become increasingly isolated. Support groups/services can help meet the emotional and social needs of people with the condition, helping them realise that they are not alone.
- Oxygen therapy – helps those people with advanced lung disease who are unable to absorb sufficient oxygen to supply their vital organs.⁴
- People over 40 with a history of cigarette smoking should speak with their GP if they do any of the following:
- Cough several times most days



- Bring up phlegm or mucous most days
- Are short of breath compared with others their age

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