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BETTER DEFINING AIRWAYS DISEASE WITH TECHNEGAS

Cyclopharm Limited (ASX: CYC) is pleased to announce its core product, Technegas, is the focus of a new clinical trial seeking to develop better tools to diagnose and manage patients suffering from Asthma and Chronic Obstructive Pulmonary Disease (COPD).

Cyclopharm will be working with the Woolcock Institute for Medical Research on the three-year, 100 patient study utilizing nuclear medicine imaging, in collaboration with The University of Sydney and the Northern Sydney Local Health District.

The $387,000 cost of the clinical study, led by Professor Greg King, will be funded by Cyclopharm. James McBrayer, CEO and Managing Director, said, "There are still significant challenges in managing both asthma and COPD. Not all subjects respond to standard treatments. To develop personalised treatments, clinicians need to have better diagnostic tools, such as using Technegas in the measurement of respiratory functionality and heterogeneity."

Professor King commented, "Respiratory function is predominantly measured by spirometry which has limitations that are universally recognised. Despite its wide acceptance as the gold standard, spirometry is neither sensitive nor specific in diagnosing airways disease and is insensitive to treatment responses. Spirometry is an overall measure of lung function but it fails to measure the underlying complexity of pathophysiology in disease."

"A recent Lancet Commission report identified the need for innovative ways to study asthma[1] and calls for better characterisation of the highly-varied group of diseases collectively called asthma. VSPECT[A] ventilation imaging, using Technegas as the imaging agent, could fulfill the criteria of a novel and effective measurement tool. By having better research tools, particularly in lung imaging, we can probe what is happening in the lungs of asthma patients. This is desperately needed if, as suggested in the Lancet Commission report, we are to make any significant advances in the study of asthma, which has hit a 'road-block'."

Professor King said, "The Airway Physiology and Imaging Group at Woolcock has a long history of clinical research using VSPECT with Technegas. I first used Technegas imaging in the mid 1990's to study ventilation patterns in healthy and asthmatic subjects[2&3]. Twenty years later, with modern imaging methods and technologies, I believe Technegas VSPECT imaging has the potential for many more applications."

[A] VSPECT- Ventilation Single Photon Emission Computed Tomography

Professor King also noted, "The outcomes of this study will advance the understanding of treatment responses and make a strong case for Technegas VSPECT imaging to be used as an important tool in development of new Asthma and COPD treatment regimes, disease characterisation in routine practice and to monitor the success and progress of treatment."

The specifics of the study are as follows:

In patients with Asthma the study is seeking to:

1. Determine immediate response to therapy as measured by regional VSPECT ventilation distribution following administration of reliever medications and also after 2 months treatment with high-dose combination therapy.
2. Determine the relationships between changes in VSPECT with treatment and; patient characteristics (e.g. symptoms, age, disease duration), and markers of allergic inflammation.

In patients with COPD the study is seeking to:

1. Determine and describe ventilation distribution in mild and moderate COPD
2. Evaluate the relationships between VSPECT and other diagnostic techniques to include spirometry, forced oscillation impedance and multiple breath nitrogen.
3. Determine the relationship between the short-term response to long acting bronchodilators, as measured by spirometry and forced oscillation impedance, and ventilation distribution.
4. Determine the relationship between ventilation distribution and symptoms in mild and moderate COPD.

Professor Carol Armour, the Executive Director of The Woolcock Institute of Medical Research, stated "The Woolcock Institute is committed to developing targeted, more effective treatment in airways diseases. Collaboration with industry is one of the ways we do this. We are very excited to embark on this work with Cyclopharm using 3-Dimensional imaging of ventilation in airways disease as it could lead to greater understanding of these conditions and from there to more effective treatments."

James McBrayer stated that, "We are thrilled to be working with collaboration led by Professor King and the Woolcock Institute of Medical Research. This initiative is another example of our strategic priority of expanding the use of Technegas. The global incidence of lung disease is increasing rapidly every year. The World Health Organisation rates COPD as the 4th leading cause of death globally and is expected to rise to the 3rd leading cause of death by 2030. We believe functional lung imaging using Technegas will offer new clinical insights in both the diagnosis and management in these chronic and deadly diseases for millions of patients."

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About Asthma

Prevalence for asthma ranges between 235 million to 339 million people globally[4,5&6] . It is estimated that the number of people with asthma will grow by more than 100 million by 2030[7].

Globally, incidence has been estimated to be 75 million new cases of asthma each year[8].

About 287,000[1] people die each year from asthma, corresponding to 0.5% of all deaths. Mortality rate for asthma varies significantly between regions, age and economic groups. Projections estimate asthma will take annually more than 428,000 lives by 2030[4]

Epidemiology of Asthma:	Prevalence	Yearly Mortality	Yearly Cost of care
Global	300 million people	287,000 deaths	
USA	25 million people	3,650 deaths	81.9 billion USD
Europe	30 million people	1,400 deaths *(UK only)*	19.3 billion EUR
Australia	2.5 million people	400 deaths	28.0 billion AUD

About COPD

Latest estimates for COPD prevalence is 251 million people globally[9]. Among those, 65 million people has moderate to severe COPD[10].

The global incidence was measured to be 18.7 million new cases of COPD each year[7].

COPD has also an important mortality burden globally. Each year, 2.9 million people die each from COPD which corresponds to 5% of all deaths globally[7]. In 2004, COPD was the fourth-leading cause of death worldwide but will most probably become the third-leading cause by 2030[8]. The World Health Organization estimated that total deaths are expected to increase more than 30% in the next ten years[11].

Epidemiology of COPD:	Prevalence	Yearly Mortality	Yearly Cost of Care (Direct + Indirect)
Global	251 million people	2.9 million deaths	
USA	27 million people	134,000 deaths	460 billion USD
Europe	40 million people	250,000 deaths	141 billion EUR
Australia	1.45 million people	7100 deaths	98.2 billion AUD

The Woolcock

The Woolcock Institute of Medical Research and the Woolcock Clinic has over 200 medical researchers and doctors working to uncover the causes of diseases, find better treatments and provide the best treatment for patients. The Woolcock is a world-class network of specialised researchers and clinicians who deal with the causes, prevention, diagnosis and treatment of respiratory disease and sleep disorders. The Woolcock Institute's approach is holistic, from basic science into the mechanics of disease through to the development of high tech apps and inhalers for the front line. The Institute is determined that their work creates a better life for people living with lung conditions and sleep disorders. Their dedication to improving wellbeing is at the very heart of what they do.

Professor Greg King

Professor King is a medical graduate of Otago University and a clinician-researcher at the Woolcock Institute of Medical Research, The University of Sydney and Royal North Shore Hospital. He is Professor of the Sydney Medical School, The University of Sydney and Medical Director of the Respiratory Investigation Unit. He has a research interest in the mechanics of airways disease in relation to clinical aspects of disease. His expertise includes complex measurements of airway and lung function, including the forced oscillation technique, multiple breath nitrogen washout and 3-dimensional ventilation SPECT imaging and CT imaging. He currently supervises 7 PhD students (6 as primary supervisor) and postdoctoral fellows from science and medical backgrounds. He has a clinical and research interest in asthma, COPD and bronchiolitis in haemopoietic stem cell transplant recipients. Professor King maintains active participation in the activities of the TSANZ and ATS in terms of teaching, professional development and executive committee function.

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^{o} 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.

REFERENCES:

[1] Pavord ID, Beasley R, Agusti A, Anderson GP, Bel E, Brusselle G, et al. After asthma: redefining airways diseases. The Lancet. 2017

2 King GG, Eberl S, Salome CM, Meikle SR, Woolcock AJ. Airway closure measured by a Technegas bolus and SPECT. Am J Respir Crit Care Med. 1997;155(2):682-8

[3] King GG, Eberl S, Salome CM, Young IH, Woolcock AJ. Differences in airway closure between normals and asthmatics measured by SPECT and Technegas. American Journal of Respiratory and Critical Care Medicine. 1998;158(6):1900-8

[4] World Health Organization (WHO) 2008. The Global Burden of Disease (GBD), 2004 update (last accessed 11 April 2018).

[5] The Global Asthma Report 2014. Auckland, New Zealand: Global Asthma Network, 2014. (last accessed 11 April 2018).

[6] Global Burden of Disease Collaborative Network. Global Burden of Disease Study 2016 (GBD 2016) Incidence, Prevalence, and Years Lived with Disability 1990-2016. Seattle, United States: Institute for Health Metrics and Evaluation (IHME), 2017. (last accessed 13 April 2018)

[7] World Health Organization (WHO) 2008. The Global Burden of Disease (GBD), 2004 update (last accessed 11 April 2018).

[8] Global Burden of Disease Collaborative Network. Global Burden of Disease Study 2016 (GBD 2016) Incidence, Prevalence, and Years Lived with Disability 1990-2016. Seattle, United States: Institute for Health Metrics and Evaluation (IHME), 2017. (last accessed 13 April 2018)

[9] Global Burden of Disease Collaborative Network. Global Burden of Disease Study 2016 (GBD 2016) Incidence, Prevalence, and Years Lived with Disability 1990-2016. Seattle, United States: Institute for Health Metrics and Evaluation (IHME), 2017.

[10] World Health Organization. Chronic Respiratory Diseases: Burden of COPD. (last accessed 12 April 2018)

[11] COPD Foundation. COPD Statistics Across America – How common is COPD. (last accessed 12 April 2018)