22 January 2021

The Manager
Company Announcements Office
Australian Securities Exchange Limited
20 Bridge Street
Sydney NSW 2000

technegas
ultralute

Cyclopharm Ltd
ABN 74 116 931 250
Unit 4, 1 The Crescent
Kingsgrove NSW 2208 Australia
T 61 2 9541 0411
F 61 2 9543 0960
www.cyclopharm.com.au

Support for accelerated USFDA approval of Technegas™ to lower risk of Covid-19 spread within frontline US healthcare workers

Cyclopharm Limited (ASX: CYC) ("Cyclopharm" or "the Company") notes the publication by the US based Society of Nuclear Medicine and Molecular Imaging (SNMMI) of a letter to the US Food and Drug Administration, dated 18 January 2021 and published on their website on 21 January 2021.

With over 16,000 members, the SNMMI is the peak scientific and professional organization located in the United States that promotes the science, technology and practical application of nuclear medicine and molecular imaging. The letter requests a fast tracked (expedited) approval of Technegas™ for use in the USA, in order to reduce the risk of SARS-CoV-2 transmission from patients to frontline healthcare workers.

A copy of this letter is attached.

This letter follows the Company's announcement dated 15 September 2020 that its clinical trial of Technegas™ for the purpose of supporting its New Drug Application with the USFDA had successfully met it primary endpoint. As a result of this announcement, the Company was in a position to move to final approval for sales of Technegas™ into the US market, subject to any final information requests and site inspections required by the USFDA.

The letter, authored by Alan Packard, SNMMI President and Tina Buehner, SNMMI-TS President, notes that when compared to currently available radioactive xenon and radioactive aerosolized particles, Technegas™ is safer to utilize by nuclear medicine and molecular imaging technologists during the COVID-19 pandemic.

In response to this letter, and consistent with announcements it has previously made, Cyclopharm confirms the Company has received a USFDA's Approval to File Determination that includes the standard review period. Further, the USFDA has confirmed they will conduct an onsite pre-approval audit of the Company's manufacturing facility during the week commencing 29 March 2021.

Cyclopharm Managing Director and CEO Mr. James McBrayer said "The Company remains in active and co-operative dialogue with the USFDA regarding its approval processes and we are grateful for the support we have received from the US nuclear medicine and molecular imaging community as we work towards approval to bring Technegas™ to the US market. We

understand the urgency behind the SNMMI's request for an expedited approval of the use of Technegas™ in the USA and will continue to work proactively with the USFDA."

Should circumstances arise that allow for an accelerated entry of Technegas™ into the USA market the Company will inform the market in accordance with its disclosure obligations.

Notwithstanding, Cyclopharm believes the SNMMI letter supports its expectation that Technegas™ will be rapidly adopted within the USA market following its approval to enter that market.

[ENDS]

This ASX announcement was approved and authorised for release by James McBrayer, Managing Director, CEO and Company Secretary.

For more information, please refer to our website at www.cyclopharm.com or contact:
Mr James McBrayer
Managing Director, CEO and Company Secretary
Cyclopharm Limited
T: +61 (02) 9541 0411

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.

SOCIETY OF NUCLEAR MEDICINE AND MOLECULAR IMAGING

TECHNOLOGIST SECTION

January 18, 2021

Libero L. Marzella, MD, PhD
Director, Division of Medical Imaging Products
Department of Health and Human Services
U.S. Food and Drug Administration (FDA)
Silver Spring, MD 20993

Re: Technegas™ "Fast Track" approval by the FDA

Dear Dr. Marzella,

The Society of Nuclear Medicine and Molecular Imaging (SNMMI), headquartered in Reston, Va., is a nonprofit scientific and professional organization that promotes the science, technology and practical application of nuclear medicine and molecular imaging. SNMMI strives to be a leader in unifying, advancing and optimizing molecular imaging, with an ultimate goal of improving human health. With 16,000 members worldwide, SNMMI represents nuclear and molecular imaging professionals, all of whom are committed to the advancement of the field.

We are writing to you today to express our support for "fast track" (expedited) approval of Technegas™ by the FDA. Technegas™ is an ultra-fine dispersion of technetium-labeled carbon produced by heating technetium-99m in a carbon crucible for a few seconds – the result being gas-like Technegas™. Technegas™ penetrates to the sub-segmental areas of the lung and is trapped by surfactants in the alveolar walls. Once inhaled, the patient is then imaged. Technegas™ is utilized in the ventilation part of the ventilation/perfusion (V/Q) lung scan.

In an effort to support nuclear medicine and molecular imaging technologists performing V/Q lung studies, on March 19, 2020, SNMMI released a statement responding to concerns regarding V/Q lung scans and, specifically, the inherent risk of spread of COVID-19 to patients and staff related to the ventilation portion of this study. At that time, many institutions opted not to perform the ventilation part of the V/Q study. When lung perfusion images are normal, the perfusion scan alone essentially rules out acute pulmonary embolism, and no further studies are needed. When lung perfusion images show a high-probability appearance in the setting of a normal chest radiograph, this also provides helpful information. However, there are cases in which perfusion-only images are indeterminate and a ventilation study may be felt to be clinically necessary to make a definitive interpretation, with recognition of the need for diagnostic accuracy given the potential risks of anticoagulation in this population. In addition, ventilation images provide important information about airway patency and obstructive lung disease that may help to explain symptoms.

Since the time of the original statement, the COVID-19 pandemic has evolved differently in various regions of the world, and questions have arisen as to the safety of resuming performance of the ventilation study.

There remain unknowns about the transmissibility of COVID-19 using ventilation systems. In some situations, it may remain appropriate not to perform ventilation studies. These situations may include when institutions or practices are in regions where there is a high or increasing number of COVID-19 cases or where there is inadequate access to COVID-19 testing.

SOCIETY OF NUCLEAR MEDICINE AND MOLECULAR IMAGING

TECHNOLOGIST SECTION

However, it is important to recognize that in some regions and in some clinical situations, a ventilation study may be felt to be clinically necessary to help diagnose lung disease, including vascular and airway disease. In addition, symptom overlap has been documented in patients with detected pulmonary embolism who have tested positive for COVID-19[1]. Because the nuclear medicine and molecular imaging technologists are required to be in the room throughout the V/Q study, there is concern that the technical requirements and logistics of administration of the two radiopharmaceuticals currently used in ventilation imaging, radioactive xenon and radioactive aerosolized particles, may increase their risk of exposure to the COVID-19 virus. Technegas™, which doesn't release aerosolized particles during the ventilation scan, is therefore safer to utilize during the COVID-19 pandemic. In addition, Technegas™ provides an alternative to radioactive xenon and radioactive aerosolized particles that is less expensive and available daily[2].

On behalf of the SNMMI, we would like to thank you for your time and consideration of this important topic. If you have questions or need any additional information or data, please let us know.

Sincerely,

Alan Packard, PhD
SNMMI President

Tina Buehner, PhD, CNMT, RT(N), NMTCB(CT)(RS), FSNMMI-TS
SNMMI-TS President

References

1. Zuckier, LS; Moadel, RM; Haramati, LB; Freeman, LM. Diagnostic Evaluation of Pulmonary Embolism During the COVID-19 Pandemic. J Nucl Med. 2020;61;630-631 - http://jnm.snmjournals.org/content/61/5/630.full.pdf+html
2. Hartmann, IJC; Hagen, PJ.; Stokkel, MPM; Hoekstra, OS; ANTELOPE Study Group. Technegas Versus ^{81m}Kr Ventilation–Perfusion Scintigraphy: A Comparative Study in Patients with Suspected Acute Pulmonary Embolism. J Nucl Med. 2001;42;393-400 - http://jnm.snmjournals.org/content/42/3/393.long