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UNITED STATES SOCIETY OF NUCLEAR MEDICINE AND MOLECULAR IMAGING ANNOUNCEMENT REGARDING FDA APPROVAL OF TECHNEGAS®

Cyclopharm Limited (ASX: CYC) notes that following confirmation yesterday of the United States Food and Drug Administration (FDA) approval of its functional lung imaging product Technegas, the below announcement¹ made in the US overnight by the Society of Nuclear Medicine and Molecular Imaging (SNMMI). SNMMI is the approximate 20,000-member leading US nuclear medicine peak body.

FDA Approves Widely Used Imaging Agent for Respiratory Disease

September 29, 2023

Reston, VA—The U.S. Food and Drug Administration (FDA) has approved the imaging agent Technegas for use in ventilation–perfusion studies to diagnose pulmonary embolism and other respiratory pathologies. A carbon-based nanoparticle developed in Australia nearly 40 years ago, Technegas has been recognized as a standard for ventilation studies and is widely used in clinics around the world.

Benefits of Technegas include high diagnostic accuracy, low radiation burden to patients, and easy administration. It offers advantages for scanning of COVID-19 patients, as the procedure is quick and the apparatus is single use, without recirculation. In 2021, SNMMI urged FDA to begin a fast-track review of the agent.

"We applaud the FDA for the long-awaited approval of Technegas," said SNMMI president Helen Nadel, MD, FRCPC, FSNMMI. "Technegas will offer advantages in diagnostic accuracy, workflow, and patient comfort for departments that adopt the technology and will have a large impact on those undergoing imaging for pulmonary disease."

Pulmonary embolism affects approximately 900,000 Americans per year, and more than 34 million Americans live with chronic lung disease, according to the American Lung Association.

Technegas is manufactured by Cyclomedica and is currently distributed to 54 countries worldwide.

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

¹ https://www.snmmi.org/NewsPublications/NewsDetail.aspx?ItemNumber=45004

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, Long COVID and certain interventional applications to include lobectomies in lung cancer and lung volume reduction surgery.