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### **Positive Meeting with USFDA Regarding Technegas™ Approval Process**

Cyclopharm Limited (ASX: CYC) is pleased to provide a further update regarding the Company's progress towards obtaining approval to commence sales of Technegas™, Cyclopharm's proprietary lung imaging technology, into the US market.

As foreshadowed in our Business Update ASX announcement, dated 24 January 2022, representatives of Cyclopharm have now met with the United States Food and Drug Administration (USFDA) to provide an update on the Company's progress in addressing matters raised in the Preapproval Inspection in early 2021 and items outlined in their Complete Response Letter (26 June 2021).

As a result of the feedback provided during the meeting, the Company expects it will submit its formal and complete response to the USFDA in Q3 2022. Following Cyclopharm's submission, the USFDA has up to 6 months to complete its review. Cyclopharm remains committed to commence sales into the US market at the earliest time following receipt of formal approvals.

Mr McBrayer in commenting on the meeting stated "Cyclopharm is very grateful for the commitment and collegiate interaction extended to the Company by the FDA during the two hour-long meetings. Based on the discussions, Cyclopharm reaffirms its confidence that the actions taken to date and those proposed will fulsomely address the USFDA's outstanding requirements for approval. Once approved, Cyclopharm will be in a position to rapidly commercialise Technegas™ in the United States."

[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](http://www.cyclopharm.com) or 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 and certain interventional applications to include lobectomies in lung cancer and lung volume reduction surgery.