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CYCLOPHARM TO PROCEED INDEPENDENTLY WITH FDA TRIALS FOR APPROVAL OF TECHNEGAS IN US MARKET

- CYC not to proceed to binding agreement with Jubilant DraxImage
- CYC to fund remainder of USFDA trials from cash on the balance sheet and strong ongoing Technegas revenues
- Trial program remains on track - targeting USFDA approval in mid-2018
- Company reconfirms corporate strategy and dividend policy

In September 2015 Jubiliant DraxImage (JDI) and, Cyclopharm (ASX: CYC) announced its intention to enter into a licensing agreement with JDI for the registration and distribution of Cyclopharmôs patented lung imaging technology Technegas in the United States. Despite several months of negotiations the two companies have not been able to reach agreement on the final terms. As a result, Cyclopharm has notified JDI of its decision to move forward independently with its USFDA clinical trial program at this time. The two companies have agreed to continue to discuss potential commercial opportunities once USFDA approval for Technegas is achieved.

Cyclopharm Managing Director James McBrayer said that in determining the best pathway to enter the US market the company would always ensure shareholder value would be maximised. In assessing commercial and operational elements of the final license negotiations, the Cyclopharm Board determined shareholders would be better rewarded by Cyclopharm funding the remainder of the trial program itself.

ñCyclopharm is in a strong financial position, given its existing cash balance, and is producing sustainable profits,òMr McBrayer said. ñThis enables us to fund the cost of the US trials while continuing to prosecute our corporate strategy, progress our research and development activities and grow distributions to shareholders.ò

USFDA approval remains a key pillar of Cyclopharmôs strategy for growing shareholder value. Technegas is a superior alternative to CTPA scans, producing more detailed imaging of the lungs at much lower radiation levels.

The technology is already used by hospitals and nuclear medicine clinics in 55 countries across Asia, Europe, North and South America, but the United States has the potential to be its largest single market. Half of the worldôs nuclear medicine departments are located in the United States and the potential market for Technegas in diagnosing pulmonary embolism is as high as 480,000 patients per annum.

Cyclopharm expects to finalise the US clinical trial program design in the second half of calendar 2016, with the FDA trial program completed by the second half of 2017. The company is targeting USFDA approval for mid-2018. The total cost to Cyclopharm is expected to be less than US$7 million, fully funded from existing cash reserves and ongoing profits from Technegas sales.

Technegas sales underpinned record group revenues of $12.6 million and record net profit after tax of $4.8 million in 2015. Cyclopharmôs strong and growing operational cash flow supported the directorsô decision to reward shareholders with maiden dividends. The Board confirmed today that the decision to fully fund the USFDA trial program would not impact the companyôs dividend policy.

Cyclopharm is also working to expand the clinical uses of Technegas beyond its primary purpose of diagnosing pulmonary embolism. The company recently received positive early clinical trial results from China, where Technegas is being tested for its efficacy in diagnosing and managing chronic obstructive pulmonary disease (COPD), a leading cause of death worldwide.

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Cyclopharm Limited

Cyclopharm is an ASX Listed radiopharmaceutical company servicing the global medical community. The Companyôs 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 (for lung imaging).

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^{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 the superior diagnosis of pulmonary emboli (blood clots in the lungs).