ABN 16 165 160 841

ASX RELEASE **13 January 2022**

AMPLIA COMPLETES MANUFACTURE OF AMP945 FOR PLANNED TRIALS

- Manufacturing batch scale of AMP945 has been doubled and the manufacturing method improved.
- Additional drug substance available to supply planned clinical trials and preclinical studies.
- Long-term storage of AMP945 supported by stability testing data.

Melbourne, Australia: Amplia Therapeutics Limited (ASX: ATX) ("Amplia", the "Company") is pleased to announce a GMP* manufacturing run of its clinical-stage drug candidate AMP945 has been successfully completed. This provides additional drug substance to support toxicology studies and Phase 2 clinical trials in pancreatic cancer and lung fibrosis which are scheduled to start during 2022.

Amplia's contract manufacturing organisation (CMO) has successfully completed the manufacture of a 2 kg GMP batch of AMP945 within budget and on time. Previously, the maximum batch size of AMP945 that had been manufactured was 1 kg, meaning that the Company has now demonstrated a doubling of the scale at which AMP945 can be manufactured under GMP conditions. During the recently completed manufacturing run, the Company also implemented improvements to the manufacturing process for AMP945 that will support its future clinical and commercial development. Of note, long-term stability testing data has shown that AMP945 can be stored for periods of more than 24 months without detectable deterioration, an outcome that further supports commercial development of AMP945.

Amplia's CEO, Dr John Lambert commented that "The successful doubling of our manufacturing capacity for clinical-grade AMP945 and the implementation of manufacturing improvements are outstanding outcomes which have exceeded our initial expectations. As well as providing material for our near-term development programs, these improvements lay a strong foundation for the AMP945 data package that will be required for future regulatory applications and its commercial development."

The Phase 2 clinical trial of AMP945 in patients with pancreatic cancer remains on track to commence during the current quarter. In addition, the extended (3-month) toxicology studies required to support the Phase 2 clinical trial of AMP945 in patients with fibrotic lung disease are on schedule to commence in February 2022 as previously advised.

* GMP: Good Manufacturing Practice

This ASX announcement was approved and authorised for release by the CEO of Amplia Therapeutics.

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For Further Information

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About Amplia Therapeutics Limited

Amplia Therapeutics Limited is an Australian pharmaceutical company advancing a pipeline of Focal Adhesion Kinase (FAK) inhibitors for cancer and fibrosis. FAK is an increasingly important target in the field of cancer immunology and Amplia has a particular development focus in pancreatic and ovarian cancer. FAK also plays a significant role in a number of chronic diseases, such as idiopathic pulmonary fibrosis (IPF).

About Pancreatic Cancer

Approximately 60,000 people in the US, and nearly 4,000 people in Australia, are diagnosed with pancreatic cancer each year. It is one of the most deadly cancers with a 5-year survival rate of only 5%-10%. The only potential cure available for pancreatic cancer is surgical excision. However, only 20% of patients are eligible for surgery with the remainder of patients having either localised, non-resectable (40%) or metastatic (40%) disease. The standard first-line therapy for these patients is chemotherapy with either gemcitabine/Abraxane® or FOLFIRINOX. Only 40%-50% of first-line patients are able to receive a second line therapy, and there is no standard treatment for second line pancreatic cancer patients.

About Idiopathic Pulmonary Fibrosis (IPF)

IPF affects as many as 14-43 people per 100,000 worldwide. The causes of IPF are unknown, but risk factors may include smoking, respiratory viral infections, lung injury and family history. Patients with IPF may experience breathlessness during activity, persistent cough and chest discomfort. IPF is a debilitating and fatal lung disease with high mortality. It causes permanent and progressive scarring of the lungs, difficulty breathing and decreases the amount of oxygen the lungs to supply to the major organs of the body.