ABN 16 165 160 841

ASX RELEASE **16 June 2025**

PATHOLOGICAL COMPLETE RESPONSE RECORDED IN PATIENT FROM ACCENT CANCER TRIAL

HIGHLIGHTS

- *A confirmed pathological complete response has been recorded in the ACCENT trial*
- *A pathological complete response (pCR) is extremely rare in patients undergoing treatment for advanced pancreatic cancer*
- *A pCR means that there are no signs of cancer in tissue examined by a pathologist following surgical removal*
- *The ACCENT trial is evaluating the Company's best-in-class FAK inhibitor narmafotinib in combination with chemotherapy in advanced pancreatic cancer*

Melbourne, Australia: Amplia Therapeutics Limited (ASX: ATX), ("Amplia" or the "Company"), is pleased to announce important new data from our ongoing ACCENT clinical trial in pancreatic cancer. The trial is investigating the Company's best-in-class FAK inhibitor narmafotinib in combination with standard-of-care chemotherapies gemcitabine and Abraxane® in patients with metastatic pancreatic cancer. A patient from the trial has now recorded a pathological complete response (pCR), an extremely rare observation in this patient population.

During routine assessment of tumour burden for the patient in question, it was noted that there had been a significant reduction in the size and number of hepatic metastases (secondary tumours in the liver) and in the primary tumour in the pancreas. The medical team decided that this enabled them to change the treatment plan for this patient, and surgery was performed to remove both the secondary tumours in the liver and the primary tumour in the pancreas. The surgically removed lesions were subjected to pathological examination and were determined to contain no live tumour tissue. This outcome is classified as a pCR.

A pCR is very rarely reported in patients with advanced pancreatic cancer, where the disease has spread to other organs in the body. In patients with locally advanced (i.e. non-metastatic) pancreatic cancer, however, around 5% of patients do record a pCR in response to treatment with neoadjuvant chemotherapy (chemotherapy before surgery).[1] In these earlier stage patients, a pCR is associated with improvements in overall survival.

Amplia CEO and MD Dr Chris Burns commented: "We are extremely excited to learn that a patient from our study has achieved a pathological complete response. This is wonderful news for the patient and the clinical team involved. We firmly believe this outcome further demonstrates the promising activity narmafotinib, on top of standard-of-care, is showing in the treatment of advanced pancreatic cancer."

[1] JAMA Netw Open 2024;7;(6):e2417625.

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

About Narmafotinib

Narmafotinib (AMP945) is the company's best-in-class inhibitor of the protein FAK, a protein over-expressed in pancreatic cancer and a drug target gaining increasing attention for its role in solid tumours. The drug, which is a highly potent and selective inhibitor of FAK, has shown promising data in a range of preclinical cancer studies.

About the ACCENT Trial

The ACCENT trial is entitled '*A Phase 1b/2a, Multicentre, Open Label Study of the Pharmacokinetics, Safety and Efficacy of AMP945 in Combination with Nab-paclitaxel and Gemcitabine in Pancreatic Cancer Patients*'.

The trial is a single-arm open label study conducted in two stages. The first stage (Phase 1b), completed in November 2023, determined an optimal dose of narmafotinib (AMP945) by assessing the safety, tolerability, pharmacokinetics and preliminary efficacy when dosed in combination with gemcitabine and Abraxane in first-line patients with advanced pancreatic cancer.

The second stage (Phase 2a) of the trial is designed to assess efficacy in combination with gemcitabine and Abraxane. The primary endpoints are Objective Response Rate (ORR) and Duration on Trial (DOT) with secondary endpoints being Progression Free Survival (PFS) and Overall Survival (OS). Safety and tolerability will continue to be assessed.

The trial is being conducted at seven sites in Australia and five sites in South Korea.

More information about the ACCENT trial can be found via the ACCENT trial site, the Amplia Therapeutics website and at ClinicalTrials.gov under the identifier NCT05355298.

The Company will provide further updates on the trial as data is accrued.

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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 and Amplia has a particular development focus in fibrotic cancers such as pancreatic and ovarian cancer. FAK also plays a significant role in a number of chronic diseases, such as idiopathic pulmonary fibrosis (IPF). For more information visit www.ampliatx.com and follow Amplia on Twitter (@ampliatx) and LinkedIn.