

ASX RELEASE

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First Patient Recruited to ACCENT Trial in Pancreatic Cancer

Amplia Therapeutics Limited (ASX: **ATX**) (**Amplia** or **the Company**) is pleased to advise that the first patient has been dosed in the Company's Phase 1b/2a ACCENT clinical trial of focal adhesion kinase inhibitor AMP945. AMP945 targets focal adhesion kinase (FAK) and its use in the ACCENT trial is intended to enhance the efficacy of gemcitabine/nab-paclitaxel chemotherapy for people with advanced pancreatic cancer undergoing first-line treatment. Patients in the trial will receive AMP945 in addition to a standard treatment regimen with gemcitabine/nab-paclitaxel.

In a prior Phase 1 clinical trial of AMP945, conducted in healthy volunteers and completed in 2021, once daily oral doses of AMP945 showed excellent safety, tolerability and pharmacokinetic properties. AMP945 was also shown to inhibit FAK in skin samples provided by the healthy volunteers.

Dr John Lambert, Amplia's CEO and Managing Director commented that "This is another exciting milestone marking the achievements and growth of our Company and we're very proud of our team's efforts in starting up the ACCENT trial. The work we have done to date with AMP945 both in the clinic and in preclinical models of pancreatic cancer tells us that AMP945 deserves to be clinically tested in this dangerous type of cancer. We are also grateful to our first patient and their family for consenting to join the trial. It is our sincere hope that addition of AMP945 to a standard of care in pancreatic cancer improves outcomes for all patients."

About the ACCENT Trial

The protocol for 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 to be conducted in two stages. The first, Phase 1b stage of the trial, is a single-arm open-label study to select an optimal dose of AMP945 by assessing the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary efficacy of AMP945 when dosed in combination with gemcitabine and nab-paclitaxel (Abraxane®) in first-line patients with advanced pancreatic cancer. Approximately 12 patients will be recruited across 4-5 sites in Australia where ascending oral doses of AMP945 will be given together with a fixed dose combination of gemcitabine and nab-paclitaxel. It is expected that for each dose level of AMP945, three patients will be recruited. After each group of three patients has completed their first 28-day treatment cycle, the Company and an independent data monitoring committee will review the data before authorising progression to the next dose level of AMP945. The Company assumes that up to four dose levels of AMP945 will be assessed and that, assuming all four dose levels are required, the Phase 1b stage of the trial will take approximately 9 months to complete.

The second, Phase 2a, stage of the trial is also a single-arm open-label study and is designed to perform an assessment of the optimal dose of AMP945 (selected in the Phase 1b part of the trial) in combination with gemcitabine and nab-paclitaxel. The primary endpoint of the Phase 2a trial is the Objective Response Rate (ORR) of patients to treatment. Further endpoints will assess efficacy by other means as well as safety and tolerability. To determine whether addition of AMP945 to gemcitabine/nab-paclitaxel improves the ORR in this patient population, data from the ACCENT trial will be compared to a historical control of 23% ORR which was established in the original pivotal trial of gemcitabine/nab-paclitaxel. The Phase 2a trial uses a Simon 2-Stage design in which approximately 26 patients with advanced pancreatic cancer will be recruited across sites in Australia and South

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Korea before an interim efficacy analysis is performed. Assuming the interim analysis concludes that adding AMP945 to gemcitabine/nab paclitaxel may be beneficial, the trial will continue to recruit a further 24 patients across Australian, South Korean and US sites.

More information about the ACCENT trial, including a list of participating sites, can be found at ClinicalTrials.gov [NCT05355298](https://clinicaltrials.gov/ct2/show/study/NCT05355298). The Company will provide further updates on the trial as recruitment proceeds.

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

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 cancer. FAK also plays a significant role in a number of chronic diseases, such as idiopathic pulmonary fibrosis (IPF).