

ASX RELEASE

16 October 2024

RECRUITMENT RESTARTS IN ACCENT PANCREATIC CANCER TRIAL

HIGHLIGHTS

- *Recruitment of the final cohort of patients in the ACCENT clinical trial has begun with the first patient having started on trial this week*
- *The final cohort of 24 patients adds to the 26 patients already enrolled on the trial*
- *The ACCENT trial explores the activity of narmafotinib, in combination with standard-of-care chemotherapy, in advanced pancreatic cancer patients*

Melbourne, Australia: Amplia Therapeutics Limited (ASX: ATX), (“Amplia” or the “Company”), is pleased to announce that recruitment of the final cohort of patients in the Company’s Phase 2a clinical trial has begun. The first patient of the 24 patients in this cohort began dosing this week. The ACCENT clinical trial is investigating the Company’s best-in-class FAK inhibitor narmafotinib in combination with standard-of-care chemotherapy for the treatment of advanced pancreatic cancer. The trial has restarted recruitment after the Company recently announced that six (6) patients from the initial cohort of 26 have recorded confirmed partial responses (PRs) indicating that the combination of narmafotinib with the chemotherapies gemcitabine and Abraxane® is sufficiently active to support continuation of the trial.

A total of 50 patients are planned for the Phase 2a ACCENT trial. Recruitment of this final cohort of 24 patients is open at the existing trial sites in Australia and South Korea, including the Calvary Mater Hospital in Newcastle that became an active trial site this week. Recruitment of this cohort is expected to be completed by end of Q1 2025.

Amplia CEO and MD Dr Chris Burns commented: “We are very pleased to begin recruitment of the remaining 24 patients for the ACCENT trial. We plan to complete recruitment by the end of March 2025, and to increase the opportunities for patients to join the trial we have this week also opened recruitment at the Calvary Mater Hospital in Newcastle.”

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 and other cancers, 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. The drug has successfully completed a healthy volunteer study, and is currently in an open-label Phase 2a trial in pancreatic cancer where a combination of narmafotinib and the chemotherapies gemcitabine and Abraxane® is being assessed for safety, tolerability and efficacy.

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 ACCENT trial explores the use of narmafotinib in combination with standard-of-care chemotherapy of gemcitabine and Abraxane® in first-line patients with advanced pancreatic cancer. The trial is a single-arm open label study conducted in two stages. The first stage (Phase 1b), completed in November 2023, identified a 400 mg oral daily dose of narmafotinib, given in the days preceding regular chemotherapy infusion, as safe and well tolerated.

This second stage (Phase 2a), of the trial is designed to assess drug 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.

More information about the ACCENT trial, including a list of participating sites, can be found via the Amplia Therapeutics [website](#) and at ClinicalTrials.gov under the identifier [NCT05355298](#).

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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), [Threads](#) (@ampliatx) and [LinkedIn](#).