

ASX RELEASE

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COMPLETION OF RECRUITMENT OF FIRST 26 PATIENTS IN PHASE 2A ACCENT TRIAL

HIGHLIGHTS

- *The ACCENT trial explores the activity of narmafotinib, in combination with standard-of-care chemotherapy, in advanced pancreatic cancer patients*
- *The company has completed enrolment of the 26 patients required for an interim analysis for the Phase 2a portion of the trial*

Melbourne, Australia: Amplia Therapeutics Limited (ASX: ATX), (“Amplia” or the “Company”), is pleased to announce that it has now recruited 26 patients in the Phase 2a stage of its clinical trial investigating narmafotinib in the treatment of advanced pancreatic cancer. 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 Phase 1b stage of the trial, 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 dosing regimen is being employed in the Phase 2a trial where drug efficacy is being assessed.

The Phase 2a trial is being conducted using the industry-standard Simon’s Two-Stage Trial design, wherein an interim analysis of efficacy is determined at a statistically defined number of patients. In the ACCENT trial this is 26 patients. An efficacy assessment showing six or more partial or complete responses out of the 26 patients will be sufficient to continue the trial, when an additional 24 patients will be enrolled, giving a total of 50 patients.

Amplia CEO and MD Dr Chris Burns commented: “The recruitment of our 26th patient is an important milestone for the Company. With 26 patients enrolled, and based on experience to date, we believe that the outcome from the interim analysis will be reported around the beginning of Q4 2024. Imaging data for the first patients from this cohort is now being collated and efficacy signals to date mirror the positive data previously reported from the Phase 1b stage of the trial.”

The ACCENT trial is currently being conducted at 6 sites in Australia and 5 sites in South Korea.

Dr Burns added: “We are grateful for the dedicated work of our study clinicians and clinical trial sites to reach this recruitment milestone, and as always thank the patients and their loved ones for being involved in the trial.”

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.

This 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.

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](#).

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.

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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](#).