

ASX RELEASE

31 January 2025

COMPLETION OF RECRUITMENT OF ACCENT TRIAL

HIGHLIGHTS

- *The company has completed planned enrolment of the ACCENT Phase 2a clinical trial*
- *The ACCENT trial explores the activity of narmafotinib in advanced pancreatic cancer patients when dosed in combination with standard-of-care chemotherapy*
- *Full recruitment has been achieved 2 months ahead of schedule with top-line data now planned for release mid-Q3*
- *An additional confirmed partial response (PR) from the initial 26 patient cohort, bringing the total to 10 PRs, has also been recorded*
- *Median duration on trial for the first 26 patient cohort is currently 197 days, representing a 68% improvement over the historical data.*

Melbourne, Australia: Amplia Therapeutics Limited (ASX: ATX), (“Amplia” or the “Company”), is pleased to announce that the [ACCENT trial](#) in advanced pancreatic cancer is now fully enrolled. The two-stage ACCENT trial explores the use of the Company’s best-in-class FAK inhibitor narmafotinib in combination with standard-of-care chemotherapy in first-line patients with advanced pancreatic cancer.

The first stage of the trial - the Phase 1b stage – was completed in November 2023 and identified a safe and well tolerated daily oral dose of narmafotinib. The second stage of the trial – the Phase 2a study – is exploring the efficacy of this dose of drug in 50 advanced pancreatic cancer patients. The Company has now enrolled 53 patients since opening recruitment in January 2024. The three additional patients have been added to the trial to replace patients who came off study prior to any assessment of drug efficacy having been undertaken (so-called non-evaluable patients).

Preliminary safety, tolerability and efficacy data has been previously reported for the initial 26 patients in the Phase 2a stage of the trial. In September 2024, we announced that 6 patients had recorded a confirmed partial response (PR)¹, triggering recruitment of the remaining 24 patients of the 50 patient study. In December 2024 we reported that an additional 3 patients, of the initial 26, had recorded a confirmed PR. We now can report that a further patient has recorded a confirmed PR bringing the total to 10 which represents an objective response rate of 38.5%, significantly better than the 23% reported for the historical trial² being used as the benchmark for this study. Importantly, the drug continues to be well tolerated by patients, and for the first 26 patient group, the median duration on trial is 197 days which is a 68% improvement over the historical data of 117 days.

As of this date the total number of patients remaining on study is 35.

¹ A confirmed PR is recorded when there is at least a 30% decrease in the overall size of tumour lesions sustained for two or more months, with no new tumour lesions apparent.

² *New Engl. J. Med.* 2013, vol 369, 1691-1703.

Amplia CEO and MD Dr Chris Burns commented: “To complete recruitment of the ACCENT trial well ahead of schedule is a direct result of the focused and diligent effort of the Amplia team and our clinical partners. Safety and efficacy data for the patients on study continues to be collected and trial updates will be reported in due course. We now anticipate top-line data from the study to be available mid-Q3 2025. As always, we thank the patients and their loved ones for their involvement with the trial.”

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