

ASX RELEASE

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AMPLIA REPORTS FIRST PATIENT DOSING IN PHASE 2a ACCENT TRIAL

HIGHLIGHTS

- *The Phase 2a ACCENT trial in patients with advanced pancreatic cancer has commenced.*
- *The first patient in the trial has begun dosing with narmafotinib*
- *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 the first patient in the Phase 2a portion of [the ACCENT trial](#) has begun dosing. The ACCENT trial is examining the combination of Amplia’s best-in-class FAK inhibitor narmafotinib in combination with standard-of-care chemotherapy in first-line patients with advanced pancreatic cancer.

In November 2023, the Company announced completion of the Phase 1b stage of the ACCENT trial where ascending doses of narmafotinib, in combination with the standard-of-care chemotherapy regime of gemcitabine and Abraxane[®], were dosed to first-line patients with advanced pancreatic cancer. This dose-escalation stage identified a safe and well-tolerated dose of narmafotinib that provides sufficient circulating drug levels to significantly block the activity of the FAK enzyme.

Importantly, there were promising preliminary signs of efficacy from the collected Phase 1b data. The identified dose of narmafotinib is now being tested in patients, in combination with gemcitabine and Abraxane, in a Phase 2a trial.

The Phase 2a trial is being conducted at six trial sites open in Melbourne, Sydney and Brisbane and the five additional sites which have been opened in Korea. The trial will initially enrol 26 patients over the coming months and an interim analysis of efficacy will then be conducted in mid-2024. An efficacy assessment showing six or more partial or complete responses out of the 26 patients will be considered statistically significant to continue the trial. An additional 24 patients will then be enrolled to give a total of 50 patients for this trial.

Amplia CEO and MD Dr Chris Burns commented: “Initiation of the Phase 2a stage of the trial is a significant milestone for Amplia. We are excited to be moving ahead with the next stage of the ACCENT trial with a safe and well-tolerated dose of narmafotinib. The trial in advanced pancreatic patients will determine whether narmafotinib, in combination with gemcitabine and Abraxane, provides improved efficacy for the treatment of this devastating cancer. Patients and clinicians are desperate for improved treatment options given the current five-year survival for newly diagnosed patients is only 12%.”

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 a single-arm open label study conducted in two stages. The first stage (Phase 1b) determined an optimal dose of AMP945 by assessing the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary efficacy of AMP945 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](#).