

ASX RELEASE

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## UPDATE ON AMPLIA'S ACCENT TRIAL IN PANCREATIC CANCER

### HIGHLIGHTS

- *The ACCENT trial explores the activity of narmafotinib, in combination with standard-of-care chemotherapy, in advanced pancreatic cancer patients*
- *Response rates from the Phase 1b portion of the trial continue to be substantially better in terms of clinical response and duration on trial, when compared to treatment with chemotherapy alone*
- *There are now 11 patients enrolled in the Phase 2a portion of the trial*

**Melbourne, Australia:** Amplia Therapeutics Limited (ASX: ATX), (“Amplia” or the “Company”), is pleased to provide an update on our Phase 1b/2a trial ([the ACCENT trial](#)) of narmafotinib in combination with standard-of-care chemotherapy gemcitabine and Abraxane® in first-line patients with advanced pancreatic cancer. Narmafotinib is the company’s best-in-class inhibitor of the protein FAK, a drug target gaining increasing attention in the treatment of solid tumours.

Completion of the Phase 1b stage of the trial was announced in November 2023.

- Fourteen (14) patients were dosed over three dose levels,
- A safe and well-tolerated dose of 400 mg narmafotinib once-a-day was identified that provided the drug levels to significantly inhibit FAK.
- Of these fourteen patients seven (7) patients remained on trial for >6 months, with two (2) patients being on trial for more than 10 months. By contrast, the median progression free survival for advanced pancreatic cancer patients treated with gemcitabine and Abraxane alone is 5.5 months.
- Six (6) patients have now recorded a partial response as best response, with the remaining eight (8) recording stable disease.
- These response rates are substantially higher than predicted from historical studies of gemcitabine and Abraxane treatment alone.
- Three (3) patients remain on trial from the Phase 1b cohort.

The Phase 2a trial will initially enrol 26 patients over the coming months. Recruitment into this next stage of the trial is progressing well recruiting patients through six trial sites in Australia and five trial sites in South Korea.

- Currently eleven patients have now been recruited.
- Seven patients in Australia and four patients in Korea.

An interim analysis of efficacy will then be conducted around Q3 2024. An efficacy assessment showing six or more partial or complete responses out of the 26 patients will be sufficient to continue the trial. An additional 24 patients will then be enrolled to give a total of 50 patients.

Amplia CEO and MD Dr Chris Burns commented: “The clinical responses we are seeing in patients from the Phase 1b stage is very promising. The duration on trial, given the aggressiveness of the disease in

these patients, is also extremely encouraging. As reported at the end of our Phase 1b trial, the drug safety and tolerability also appears to be very acceptable for this patient group. We look forward to reporting on further data from the trial as the Phase 2a patients are assessed.”

### **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](http://www.ampliatx.com) and follow Amplia on [Twitter](#) (@ampliatx), [Threads](#) (@ampliatx) and [LinkedIn](#).