

ASX RELEASE

11 December 2024

POSITIVE NEW DATA AND STRONG RECRUITMENT IN PANCREATIC CANCER TRIAL

HIGHLIGHTS

- *Data analysis up to 6 December 2024 from the ongoing ACCENT trial of narmafotinib in combination with chemotherapy has been undertaken*
- *Nine (9) patients have now recorded a confirmed Partial Response*
- *A substantial improvement in patient time on trial, compared to historical data for standard-of-care alone, is apparent*
- *Recruitment for the final cohort of 24 patients is ahead of schedule*

Melbourne, Australia: Amplia Therapeutics Limited (ASX: ATX), (“Amplia” or the “Company”), is pleased to report updated data from Company’s ongoing Phase 2a clinical trial. This trial is investigating the Company’s FAK inhibitor narmafotinib in combination with standard-of-care chemotherapy of gemcitabine and Abraxane® in the treatment of advanced pancreatic cancer (the [ACCENT trial](#)). This latest data analysis was conducted up to 6 December 2024 and expands on the previous interim data release¹ which covered data up to 27 September 2024.

Nine (9) confirmed partial responses (PRs) have now been recorded from the initial 26 patient cohort of the Phase 2a trial. This represents an objective response rate of ~35%, significantly better than the 23% reported for the historical trial² being used as the benchmark for this study. 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.

Importantly, the median duration on trial for the 26 patients is currently 172 days which is a 47% improvement over the historical data of 117 days. The duration on trial is a measure of how effective the treatment is in inhibiting disease progression, as patients with progressive disease must leave the trial. Currently 11 patients from the initial 26 enrolled remain on trial.

Narmafotinib continues to be generally well tolerated by patients and no patients have withdrawn from study due to issues from narmafotinib.

The Company is now recruiting the second cohort of patients for the Phase 2a study to bring the total number of evaluable patients for the trial to 50. At this time 12 new patients have enrolled on the trial since reopening recruitment in October.

Amplia CEO and MD Dr Chris Burns commented: “Adding narmafotinib to the standard-of-care treatment continues to show promise in comparison to the historical data for standard-of-care alone. We’ve recruited over 75% of the trial at this time, and with ongoing positive support from clinicians involved in the study, we are well on track to fully recruit the trial by end of Q1 2025. In addition, we

¹ ASX Release 30 October 2024

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

have been reassured by our clinical team in Korea that the recent political situation in the country is not impacting the trial sites located there in terms of recruitment and ongoing support of patients."

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 ACCENT [website](#), 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](#).