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ACCENT TRIAL DATA DEMONSTRATES THAT NARMAFOTINIB + CHEMOTHERAPY COMBINATION SUPERIOR TO CHEMOTHERAPY ALONE

HIGHLIGHTS

- *Key milestone achieved, with 15 confirmed responses recorded in the ongoing Phase 1b/2a ACCENT trial*
- *Sufficient confirmed responses have now been recorded to demonstrate that narmafotinib combined with chemotherapy is superior to chemotherapy alone.*
- *The ACCENT trial is evaluating narmafotinib in combination with the chemotherapies gemcitabine and Abraxane® in patients with advanced pancreatic cancer*
- *Narmafotinib is a highly potent and selective FAK inhibitor discovered at the Melbourne-based Cooperative Research Centre for Cancer Therapeutics.*
- *Phase 2a ACCENT trial is fully recruited with top-line data expected in mid Q3 2025*

Melbourne, Australia: Amplia Therapeutics Limited (ASX: ATX), ("Amplia" or the "Company"), is pleased to announce important new data from our ongoing ACCENT clinical trial in pancreatic cancer. The trial is investigating the Company's best-in-class FAK inhibitor narmafotinib in combination with standard-of-care chemotherapies gemcitabine and Abraxane. Fifteen (15) confirmed partial responses (PRs) have now been recorded in the trial, a level of response sufficient to demonstrate that the combination of narmafotinib and chemotherapy is superior to chemotherapy alone.

A confirmed partial response is a formal designation of response where tumour shrinkage >30% is recorded and sustained for two (2) or more months and where no new cancerous lesions have been detected. As pancreatic cancer is highly aggressive it is extremely rare for patients to achieve a complete response (CR).

The ACCENT trial is an open-label study meaning that all patients on the study receive narmafotinib in combination with the standard-of-care therapy. The data obtained in this trial is compared to historical data for the combination of gemcitabine and Abraxane in pancreatic cancer, and specifically data from the MPACT study, upon which we have closely modelled our trial[1].

At the outset of the study a statistical analysis was performed which identified that a patient cohort of 50 patients would be sufficient to allow the efficacy of our combination to be ascertained with reasonable confidence if 15 or more responders (confirmed PR or CR) were recorded. A total of 55 advanced pancreatic patients have enrolled in the study since January 2024, with 21 patients still on study at this time.

[1] *New England Journal of Medicine* 2013; 369: 1691 – 703

As noted in our recent press release[2], the drug continues to be well tolerated by patients with the rate and type of adverse events for the narmafotinib combination being similar to that reported for chemotherapy alone.

Amplia CEO and MD Dr Chris Burns commented: "We are extremely excited to have now recorded 15 confirmed partial responses in the ACCENT trial, demonstrating the benefit of adding narmafotinib to standard-of-care chemotherapy. With over 20 patients still on study we are hopeful that further PR's will be observed"

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) and LinkedIn.

[2] ASX Release 28 April 2025