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TUMOUR RESPONSE IN SIXTH PATIENT TRIGGERS ADDITIONAL RECRUITMENT IN PANCREATIC CANCER TRIAL

HIGHLIGHTS

- *Six (6) patients in the Company's ACCENT trial in pancreatic cancer have now achieved the required reduction in tumour size with no detection of new lesions*
- *The ACCENT trial can now proceed to recruit the next cohort of 24 patients, giving a total of 50 patients on study*
- *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 Company's Phase 2a clinical trial investigating narmafotinib in the treatment of advanced pancreatic cancer (the ACCENT trial) has achieved the required response rate to support continued enrolment in the study. Six (6) patients have now recorded confirmed partial responses (PRs) out of 16 assessed at the four-month timepoint, indicating that the combination of narmafotinib with the chemotherapies gemcitabine and Abraxane® is sufficiently active to support continuation of the trial.

The formal term 'confirmed partial response' means in these patients there is at least a 30% decrease in the overall size of tumour lesions, with no new tumour lesions, sustained over a two-month period.

A total of 50 patients are planned for the Phase 2a ACCENT trial. With the six (6) confirmed PRs now obtained, recruitment of the remaining 24 patients in the trial will begin at the existing open trial sites in Australia and South Korea. Recruitment of the second cohort of patients is expected to be completed by end of Q1 2025.

A detailed interim analysis of the Phase 2a trial data obtained to date will be reported in the coming weeks; however, key points are noted below:

- Narmafotinib continues to be generally well tolerated by patients with no safety trends identified or dose reductions recorded to date
- In addition to 6 confirmed PRs, there have been 7 patients who have recorded stable disease over 2 or more months, including one patient whose stable disease has improved to achieve a partial response at their 4-month assessment

Amplia CEO and MD Dr Chris Burns commented: "Having now confirmed our sixth PR, we will move forward with recruiting the remaining 24 patients for the trial. We are actively working with our clinical sites to ensure seamless reopening of enrolment with the goal of completing recruitment by the end of March 2025. As always, we thank the patients and their loved ones for being involved with this 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 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 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.