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SUSTAINED REDUCTION IN TUMOUR SIZE SEEN IN PATIENTS IN PANCREATIC CANCER TRIAL

HIGHLIGHTS

- *50% of the required patient responses in the initial enrolment stage of the Company's Phase 2a ACCENT trial have now been confirmed*
- *The ACCENT trial explores the activity of narmafotinib, in combination with standard-of-care chemotherapy, in advanced pancreatic cancer patients*
- *The ACCENT trial protocol requires that at least six (6) of the first 26 patients enrolled achieve this level of response*
- *A further three confirmed partial responses are required to initiate the complete enrolment of the trial*

Melbourne, Australia: Amplia Therapeutics Limited (ASX: ATX), ("Amplia" or the "Company"), is pleased to announce that three (3) patients enrolled in the Company's Phase 2a clinical trial investigating narmafotinib in the treatment of advanced pancreatic cancer (the ACCENT trial) have recorded a confirmed partial response. The formal term 'confirmed partial response' means there is at least a 30% decrease in the overall size of tumour lesions, and no new tumour lesions, in these patients sustained over a two month period.

Of the six (6) patients currently assessed at the four month time point, in addition to the three (3) confirmed partial responses, two (2) additional patients have recorded sustained stable disease.

Amplia CEO and MD Dr Chris Burns commented: "To be reporting that three confirmed partial responses have been observed so early in this stage of the trial is extremely encouraging. We are well on track to reach the efficacy threshold of six confirmed partial or complete responses by the end of this quarter, which will then allow us to restart the trial to recruit the full cohort of fifty patients."

The Company recently announced completion of enrolment of the first 26 patients in the trial as part of the industry-standard Simon's Two-Stage Trial design. Once six (6) confirmed partial or complete responses are obtained then an additional 24 patients will be enrolled, giving a total of 50 patients for the trial.

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.

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.