ABN 16 165 160 841

ASX RELEASE **21 August 2024**

FIVE PATIENTS RECORDING A SUSTAINED REDUCTION IN TUMOUR SIZE IN ACCENT TRIAL

HIGHLIGHTS

- *A fifth patient in the Company's ACCENT trial in pancreatic cancer has recorded a confirmed response*
- *Only one additional confirmed response is now required to trigger the interim analysis for the first cohort in the trial*
- *The ACCENT trial protocol requires that six (6) of the 26 patients enrolled in the first cohort achieve this response level for the trial to continue with enrolment of an additional 24 patients*
- *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 a fifth patient enrolled in the Company's Phase 2a clinical trial in pancreatic cancer (the ACCENT trial) has recorded a confirmed partial response (PR), meaning a 30% or greater decrease in the overall size of tumour lesions maintained over a two-month period, and with no new tumour lesions.

In addition, six (6) patients have shown stable disease (SD) at their 2 month and 4 month assessment time points. By the standard RECIST 1.1 criteria,[1] SD is reported when tumour lesions have reduced in size by less than 30% (i.e. not sufficient to be classified as a PR) or have shown either no growth or minimal growth (<20%), and no new lesions.

A total of 50 patients are planned for the Phase 2a ACCENT trial which is investigating the company's lead asset narmafotinib in the treatment of advanced pancreatic cancer. Initially, a cohort of 26 patients have been recruited and response to the therapy is monitored every two months. A minimum of six (6) patients who record a confirmed partial or complete response are required before recruitment of the second cohort of 24 patients is initiated. We have previously reported[2] that four (4) confirmed PRs have already been observed and this latest patient response means that only one more confirmed response (partial or complete) is required before recruitment of the additional 24 patients can begin. Importantly, the fifth PR has been observed from a total of 13 patients imaged at the four-month time point, representing an initial response rate of 38%.

Amplia CEO and MD Dr Chris Burns commented: "The continued positive data from the trial is extremely gratifying and at this rate we remain confident we will reopen recruitment in early October."

The Company will provide further updates on the trial as it proceeds.

This ASX announcement was approved and authorised for release by the Board of Amplia Therapeutics.

[1] European Journal of Cancer 2009, vol. 45, pg 228–247.
[2] ASX Release 06 August 2024

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.