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TYPE D MEETING OUTCOME WITH US FOOD AND DRUG ADMINISTRATION

Melbourne, Australia: Amplia Therapeutics Limited (ASX: ATX), ("Amplia" or the "Company"), is pleased to provide a regulatory update on its planned US clinical trial following its Type D meeting with the United States Food and Drug Administration (FDA).

The Company has previously disclosed plans for a clinical trial in the US of its best-in-class FAK inhibitor narmafotinib, in combination with the chemotherapy regime FOLFIRINOX, in advanced pancreatic cancer patients. FOLFIRINOX, which is a mixture of four different drugs, is the preferred first-line treatment option for advanced pancreatic cancer in the US. The Company has previously reported[1] that narmafotinib enhances the activity of FOLFIRINOX in preclinical models of pancreatic cancer.

A Type D meeting is an opportunity for a company to seek feedback from the FDA for specific questions regarding clinical development activities. The Company sought the FDA's feedback regarding modifications to the clinical trial protocol previously submitted as part of the Investigational New Drug application cleared by the FDA in January 2024[2]. Specifically, the Company was seeking commentary regarding changes to the dose-escalation and dose-optimization phase of the study and concerning removal of a pharmacokinetic assessment of FOLFIRINOX in the trial. In the written response received by the Company, the FDA noted that the proposed changes 'appear reasonable' clearing the way for the Company to finalise the study protocol and initiate the final stages of trial planning prior to commencing the study.

Amplia CEO and MD Dr Chris Burns commented: "We are grateful for the thoughtful input from the FDA regarding the modifications to our clinical trial protocol. These changes will allow the Company to progress the trial in a more time-efficient and capital-efficient manner, and we are now in the final planning stages to start the trial in the coming months."

Dr Burns continued: "Positive data from this clinical study, combined with promising data from the current ACCENT trial - where narmafotinib is combined with gemcitabine and Abraxane® - will position narmafotinib as the preferred drug to combine with the two main chemotherapy regimes used for the treatment of pancreatic cancer across the globe."

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

[1] ASX Release 29 Sep 2023
[2] ASX Release 18 Jan 2024

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. The drug successfully completed a Phase 1 study in healthy volunteers and is currently being trialled in advanced pancreatic cancer in the ACCENT trial.

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.