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AMPLIA RECEIVES US ETHICS CLEARANCE FOR PANCREATIC CANCER TRIAL

HIGHLIGHTS

- *Institutional Review Board (ethics) approval received to initiate Phase 2 clinical trial of narmafotinib in the US*
- *The trial will explore narmafotinib in combination with the chemotherapy FOLFIRINOX in advanced pancreatic cancer patients*
- *The trial will be undertaken at selected sites in the US and Australia*

Amplia Therapeutics Limited (ASX: ATX) ("Amplia" or the "Company") is pleased to announce that it has received US ethics approval of the protocol for the forthcoming Phase 2 clinical trial of narmafotinib in combination with the chemotherapy FOLFIRINOX.

The ethics approval was received from the central US Institutional Review Board (IRB). The Principal Investigators for each selected US site will now submit to their local authorities for final approval to commence the trial at their site. The Company is working with its contracted clinical trials organisation to identify up to six (6) trial sites in the US. A separate ethics approval for two (2) clinical trial sites in Australia is also being sought.

The open-label Phase 2a clinical trial will explore the combination of the Company's FAK inhibitor narmafotinib with the chemotherapy FOLFIRINOX in first-line patients with advanced pancreatic cancer. This trial differs from the ACCENT trial currently underway in Australia and Korea where narmafotinib is combined with the chemotherapies gemcitabine and Abraxane. FOLFIRINOX is a chemotherapy cocktail of four drugs used in the treatment of advanced pancreatic cancer, and in the US is the preferred treatment for newly diagnosed patients.

The focus of the new trial is identification of the optimal dose of daily, orally-dosed narmafotinib when combined with FOLFIRINOX which is administered intravenously every two (2) weeks. It is anticipated the trial will recruit 60-70 patients, depending on the number of dose-levels explored.

Dr Chris Burns, Amplia's CEO and Managing Director commented: "Receiving the protocol approval from the IRB is a critical step in initiating the US trial of narmafotinib in combination with FOLFIRINOX. Importantly, results from this trial will complement the existing positive data emerging from our current ACCENT trial, aiming to establish narmafotinib as the optimal combination partner for chemotherapy in this challenging disease."

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. Narmafotinib is currently undergoing a clinical trial (the ACCENT trial) where it is dosed in combination with the chemotherapies gemcitabine and Abraxane in first-line patients with advanced pancreatic cancer. The trial has already achieved its desired outcome in achieving a response rate superior to chemotherapy alone. In particular, 2 complete responses have been recorded in this study.

About the FOLFIRINOX Trial

Narmafotinib, in combination with the modified FOLFIRINOX chemotherapy regimen, will explore the safety, tolerability, efficacy and pharmacokinetics of the combination in newly-diagnosed patients with advanced (metastatic) pancreatic cancer. The trial is entitled '*A Phase 1b/2a, Multicenter, Open Label Study of the Safety, Efficacy and Pharmacokinetics of narmafotinib in Combination with modified FOLFIRINOX in Pancreatic Cancer Patients*' and is being conducted under an open IND from the US FDA.

Designed as a single-arm, open-label study, the trial will proceed in two parts, incorporating the principles of the FDA's *Project Optimus* guidance for developing new oncology therapies[1]. Part A will explore a range of doses of narmafotinib (AMP945), taken once daily in combination with modified FOLFIRINOX administered every 14 days, for safety, tolerability, and pharmacokinetics.

Part B of the trial is designed to identify the optimal daily dose of narmafotinib for future studies, by comparing two (2) doses identified from Part A, for safety, tolerability and efficacy.

The trial is being conducted initially at sites in the US and Australia.

The Company has previously presented data from preclinical studies demonstrating that the addition of narmafotinib to FOLFIRINOX improves survival in animal models of pancreatic cancer compared to animals treated with FOLFIRINOX alone.

The Company will provide further updates on the trial as activity progresses.

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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.

[1] https://www.fda.gov/about-fda/oncology-center-excellence/project-optimus