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AMPLIA RECEIVES AUSTRALIAN ETHICS CLEARANCE FOR PANCREATIC CANCER TRIAL

HIGHLIGHTS

- *Australian Human Research Ethics Committee approval received to initiate a Phase 2 clinical trial of narmafotinib in pancreatic cancer patients*
- *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 Australia and the USA.*

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

The ethics approval received covers two (2) clinical trial sites in Australia and follows US ethics approval received last month.

The open-label Phase 2a clinical trial will explore the combination of the Company's FAK inhibitor narmafotinib with the chemotherapy FOLFIRINOX in newly diagnosed patients with advanced pancreatic cancer. Commonly employed in the USA for advanced pancreatic cancer, FOLFIRINOX chemotherapy is also utilized in Australia, particularly for younger patients.

The focus of the new trial is identification of the optimal daily dose of narmafotinib when combined with FOLFIRINOX which is administered intravenously every two (2) weeks. The trial will be run in two stages: the first being a dose exploration stage involving up to 27 patients, and the second comparing two doses of narmafotinib across 40 patients.

Dr Chris Burns, Amplia's CEO and Managing Director commented: "With ethics approval now obtained in both Australia and the US, we look forward to initiating recruitment of the 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 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. More information about the trial can be found at the Amplia Therapeutics website and at ClinicalTrials.gov under the identifier NCT07026279.

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