

ASX RELEASE

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AUSTRALIAN TRIAL SITES OPEN FOR NEW NARMAFOTINIB COMBINATION TRIAL

HIGHLIGHTS

- *Two clinical trial sites in Australia (Melbourne and Sydney) are now recruiting patients for the Company's new pancreatic cancer study*
- *The trial will investigate the combination of Amplia's FAK inhibitor, narmafotinib, with the chemotherapy FOLFIRINOX in patients with newly diagnosed metastatic pancreatic cancer*
- *The trial is being 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 two (2) trial sites are now open in Australia for the Company's new clinical trial in pancreatic cancer. This new trial explores the combination of the Company's best-in-class FAK inhibitor narmafotinib with the chemotherapy FOLFIRINOX in newly diagnosed metastatic pancreatic cancer patients.

Patient recruitment at the trial sites in Melbourne and Sydney has now begun, and dosing of the first patient in the trial will be reported in due course. Clinical trial sites in the US have already been identified and will be open for patient recruitment in the coming weeks.

Dr Chris Burns, Amplia's CEO and Managing Director commented: "We are excited to have the first clinical trial sites for this new pancreatic cancer trial now open in Australia. Based on the promising data from the existing ACCENT trial, and our preclinical studies, we believe that the combination of narmafotinib and FOLFIRINOX has potential to improve patient outcomes in this challenging disease."

This ASX announcement was approved and authorised for release by the CEO 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 of 31%, superior to chemotherapy alone. In particular, 1 complete response and 1 pathological complete response 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 therapies¹. Part A will explore a range of oral daily doses of narmafotinib (AMP945) 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 Australia and the US. 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>