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NARMAFOTINIB ADOPTED AS NONPROPRIETARY DRUG NAME IN USA

HIGHLIGHTS

- *The United States Adopted Names (USAN) Council has approved the name narmafotinib as the nonproprietary drug name for Amplia Therapeutics' lead FAK inhibitor*
- *The timing coincides with the imminent initiation of a clinical trial in pancreatic cancer of narmafotinib combined with the chemotherapy FOLFIRINOX to be conducted in Australia and the USA*

Melbourne, Australia: Amplia Therapeutics Limited (ASX: ATX) ("Amplia" or the "Company") is pleased to announce that the United States Adopted Names (USAN) Council has adopted the name narmafotinib as the generic drug name for the Company's lead FAK inhibitor currently undergoing clinical studies in pancreatic cancer.

Amplia has previously reported that the World Health Organization (WHO) approved narmafotinib as the International Non-Proprietary Name (INN) for global use[1]. The USAN council's adoption of the name narmafotinib is a separate process that formalises the nonproprietary name for the molecule in the United States.

Dr Chris Burns, Amplia's CEO and Managing Director commented: "We are delighted that the USAN council have adopted the name narmafotinib. Obtaining a USAN is an essential step for any drug molecule intended for the US market, and it represents an important step in the drug's commercial development as we begin our trial of narmafotinib in the USA."

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

[1] ASX Announcement 21 June 2023.

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, one (1) complete response and one (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 therapies[2]. 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.

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