

ASX RELEASE

20 September 2024

## FDA FAST TRACK DESIGNATION FOR NARMAFOTINIB IN ADVANCED PANCREATIC CANCER

### HIGHLIGHTS

- *The US FDA has granted Fast Track Designation to Amplia's lead drug narmafotinib in advanced pancreatic cancer*
- *Fast Track Designation facilitates the development of investigational drugs and allows for expedited review*

**Melbourne, Australia:** Amplia Therapeutics Limited (ASX: ATX), ("Amplia" or the "Company"), is pleased to announce that the United States Food and Drug Administration (FDA) has granted Fast Track Designation to Amplia's Focal Adhesion Kinase inhibitor, narmafotinib, for the treatment of advanced pancreatic cancer.

Fast Track Designation is available to drugs that may provide an advantage over current therapies in the treatment of serious conditions. It is designed to speed the development of these drugs to enable patients to receive them sooner. This Designation will grant the Company access to more frequent meetings, and written communication, with the FDA. In future, narmafotinib may be eligible for Accelerated Approval and Priority Review. The Company has previously received Orphan Drug Designation from the FDA for narmafotinib in pancreatic cancer.

The Company's CEO and Managing Director, Dr Chris Burns, commented, "Fast Track Designation for narmafotinib is a significant milestone for the Company. With this designation, we can work more closely with the FDA to accelerate our clinical program and gather the most compelling evidence for regulatory approval in this devastating disease."

Amplia's clinical trial in advanced pancreatic cancer, the [ACCENT](#) trial, is ongoing in Australia and South Korea. Earlier this year, the Company announced that the US FDA had cleared its IND<sup>1</sup> application for a trial of narmafotinib in pancreatic cancer in the US. This trial is in advanced planning stages.

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 and other cancers, 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 has successfully completed a healthy volunteer study and is currently in an open-label Phase 2a trial in pancreatic cancer where a combination of narmafotinib and the chemotherapies gemcitabine and Abraxane® is being assessed for safety, tolerability and efficacy.

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<sup>1</sup> Investigational New Drug

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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](http://www.ampliatx.com) and follow Amplia on [Twitter](#) (@ampliatx), [Threads](#) (@ampliatx) and [LinkedIn](#).

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