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ASX RELEASE

POSITIVE RESPONSE FROM US FDA TO AMPLIA THERAPEUTICS' TYPE D MEETING

HIGHLIGHTS

- *Amplia has received favourable responses from the US FDA during a Type D meeting regarding its planned Phase 2b/3 trial combining narmafotinib with gemcitabine and Abraxane® for pancreatic cancer*
- *The FDA supports the two-dose comparison envisaged in the Phase 2b study, leading into the pivotal Phase 3 stage of the trial, and the minor changes proposed will have minimal effect on planned timelines*
- *The full trial protocol will be prepared for FDA review in H1 2026, supporting the goal to commence the registration-enabling study in late 2026*

Melbourne, Australia: Amplia Therapeutics Limited (ASX: ATX; OTCQB: INNMF), referred to as "Amplia" or "the Company," announces it has received positive feedback from the US Food and Drug Administration (FDA) in response to questions posed by the Company as part of a recent Type D meeting.

The Company received a positive response to the Type D questions around the dose optimisation strategy for narmafotinib in the proposed registration-enabling Phase 2b/3 trial which will investigate the combination of the Company's lead compound, narmafotinib, in combination with gemcitabine and Abraxane in pancreatic cancer. The FDA's response gives confidence in meeting current projected timelines for the Phase 2b/3 study planned to commence in late 2026. The full protocol will now be prepared for submission for FDA comment in H1 2026.

Dr Chris Burns, CEO and Managing Director of Amplia, commented, "FDA's response supports the dose comparison design of the Phase 2b portion of this trial prior to the pivotal Phase 3 stage. We see this as a positive outcome as the changes proposed will have minimal impact to the trial timeline. This feedback also allows us to better plan the trial, and a full protocol will now be drafted for FDA comment in H1 2026."

A Type D meeting is a formal interaction with the FDA that allows companies to obtain focused feedback on specific regulatory questions outside of a standard review cycle.

ABN 16 165 160 841

+61 (0) 3 9123 1140 | info@ampliatx.com

Level 5, 90 William Street, Melbourne VIC 3000 Australia

www.ampliatx.com

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

Investor Contact:	Investor Contact (US):	Media Contact:
Dr Chris Burns *Chief Executive Officer* *chris@ampliatx.com*	Robert Giordano *GGroup Life Sciences* *rjgiordano@ggrouplifesciences.com*	Haley Chartres *haley@hck.digital* *+61 423 139 163*

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 X (@ampliatx) and LinkedIn.

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 confirmed response rate of 33%, superior to 23% reported in the benchmark MPACT study for gemcitabine and Abraxane alone, An interim median PFS of 7.6 months has also been reported. A second trial – AMPLICITY – has recently opened and is being run under an IND at sites in Australia and the US, investigating the combination of narmafotinib with the chemotherapy FOLFIRINOX in advanced pancreatic cancer patients.

About the ACCENT Trial

The ACCENT trial is entitled '*A Phase 1b/2a, Multicentre, Open Label Study of the Pharmacokinetics, Safety and Efficacy of AMP945 in Combination with Nab-paclitaxel and Gemcitabine in Pancreatic Cancer Patients*'.

The trial is a single-arm open label study conducted in two stages. The first stage (Phase 1b), completed in November 2023, determined an optimal dose of narmafotinib (AMP945) by assessing the safety, tolerability, pharmacokinetics and preliminary efficacy when dosed in combination with gemcitabine and Abraxane in first-line patients with advanced pancreatic cancer.

The second stage (Phase 2a) of the trial is designed to assess efficacy in combination with gemcitabine and Abraxane. The primary endpoints are Objective Response Rate (ORR) and safety and tolerability, with secondary endpoints including Progression Free Survival (PFS), Overall Survival (OS) and Duration on Trial (DOT).

The trial is being conducted at seven sites in Australia and five sites in South Korea.

More information about the ACCENT trial can be found via the ACCENT trial **site**, the Amplia Therapeutics **website** and at ClinicalTrials.gov under the identifier **NCT05355298**.