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ASX RELEASE

AMPLIA THERAPEUTICS HALTS RECRUITMENT IN AMPLICITY TRIAL

HIGHLIGHTS

- *Recruitment to the AMPLICITY trial has been halted after three Dose Limiting Toxicities (DLTs) related to the chemotherapy regimen mFOLFIRINOX*
- *No toxicity concerns have been identified regarding narmafotinib*
- *Patients already on trial will remain on study and continue treatment*

Melbourne, Australia: Amplia Therapeutics Limited (ASX:ATX; OTCQB:INNMF), (“Amplia” or the “Company”), announces that it is halting further recruitment in the AMPLICITY clinical trial in advanced pancreatic cancer investigating the Company’s lead drug narmafotinib in combination with the chemotherapy regimen modified FOLFIRINOX (mFOLFIRINOX).

Eight (8) patients have been dosed with daily narmafotinib in combination with the mFOLFIRINOX regimen administered on its routine cycle and doses. Three (3) events of protocol-defined dose-limiting toxicity (DLT) have been observed at this time, though importantly none have been attributed to narmafotinib and instead relate to the chemotherapy regimen. Five of the 8 patients remain on study and will continue to receive the narmafotinib – mFOLFIRINOX combination with continuing safety monitoring as before.

FOLFIRINOX has been one of the main chemotherapy regimens used in the treatment of pancreatic cancer patients who are generally fitter and have a higher performance status. It is recognized as being more aggressive and less well tolerated by patients compared to gemcitabine and Abraxane®, the chemotherapies being investigated in combination with narmafotinib in the ongoing ACCENT study. However, Amplia anticipates an increasing preference for less toxic chemotherapeutic regimens in clinical practice and will therefore halt recruitment in AMPLICITY and focus its resources on exploring combinations other than with FOLFIRINOX.

Dr Chris Burns, CEO and Managing Director of Amplia, commented on the latest results: “The DLTs observed are very disappointing for the patients and their families; however, toxicity with FOLFIRINOX chemotherapy is well documented. Given these effects, and the evolving landscape for pancreatic cancer treatment, we will continue to build on our promising ACCENT trial data, as well as plan for additional studies with new, targeted agents being developed for pancreatic cancer.”

While efficacy data from AMPLICITY is early, four of the eight patients in the trial have recorded stable disease at their first (2-month) scan, with one of these patients subsequently recording a partial response at their 4 -month scan. No other efficacy data is available at this time though updates will be reported in due course.

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

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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 [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 tumors. 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 36%, superior to chemotherapy alone and an interim PFS of 7.7 months has been reported. A second trial – AMPLICITY – is being run under an IND investigating the combination of narmafotinib with the chemotherapy FOLFIRINOX in advanced pancreatic cancer patients.