

ASX RELEASE

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## FDA CLEARANCE OF AMPLIA'S IND FOR PANCREATIC CANCER TRIAL IN US

### HIGHLIGHTS

- *The US FDA has cleared Amplia's Investigational New Drug (IND) Application for a clinical trial of narmafotinib in the USA*
- *The proposed trial would explore the combination of narmafotinib and FOLFIRINOX in advanced pancreatic cancer patients in the USA*

**Melbourne, Australia:** Amplia Therapeutics Limited (ASX: ATX), ("Amplia" or the "Company"), is pleased to announce that the US FDA have cleared Amplia's IND application for a trial of Amplia's best-in-class focal adhesion kinase (FAK) inhibitor narmafotinib in pancreatic cancer. The proposed trial will explore the safety, tolerability and efficacy of a combination of narmafotinib with the chemotherapy regime FOLFIRINOX.

The company is currently undertaking a Phase 2a clinical trial of narmafotinib, in combination with two chemotherapy drugs, gemcitabine and Abraxane®, in advanced pancreatic patients in Australia and South Korea. In contrast, the IND application reviewed by the US Food and Drug Administration (FDA) supports the use of narmafotinib in combination with a different chemotherapy called FOLFIRINOX (a four drug regimen), which is widely employed in the US for the treatment of pancreatic cancer.

The IND document is an extensive dossier that details all preclinical and clinical data amassed to date for narmafotinib, along with complete CMC (chemistry, manufacturing and controls) information. The final document comprised more than 10,000 pages and represented a major undertaking by the company over the previous months.

Amplia CEO and MD Dr Chris Burns commented: "Clearance of the IND by the US FDA is a significant step forward for the Company. We will now start planning the combination trial of narmafotinib with FOLFIRINOX in the US, which expands the clinical opportunities for our best-in-class FAK inhibitor. FOLFIRINOX is the preferred treatment for pancreatic patients in the USA and most of Europe, and therefore this combination trial is highly relevant as we position narmafotinib as the preferred drug to enhance the effectiveness of existing chemotherapy combinations in pancreatic cancer."

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

**Investor Contact:**

Dr Chris Burns  
Chief Executive Officer  
[chris@ampliatx.com](mailto:chris@ampliatx.com)

**Media Contact:**

HACK Director, Haley Chartres  
[haley@hck.digital](mailto: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](http://www.ampliatx.com) and follow Amplia on [Twitter](https://twitter.com/ampliatx) (@ampliatx), [Threads](https://www.threads.net/@ampliatx) (@ampliatx) and [LinkedIn](https://www.linkedin.com/company/amplia-therapeutics).