

ASX RELEASE

4th Dec 2023

APPROVAL FROM KOREAN REGULATOR TO INITIATE PHASE 2 ACCENT PANCREATIC CANCER TRIAL IN KOREA

HIGHLIGHTS

- *The Korean Ministry of Food and Drug Safety have approved the Phase 2a ACCENT clinical trial*
- *Amplia is working with the chosen clinical trial sites so that screening and recruitment of patients for inclusion in the trial begins as quickly as possible*

Melbourne, Australia: Amplia Therapeutics Limited (ASX: ATX), (“Amplia” or the “Company”), is pleased to announce that the Korean Ministry of Food and Drug Safety (MFDS) have approved the clinical trial to test narmafotinib (AMP945) in combination with gemcitabine and Abraxane®, in advanced pancreatic cancer patients in Korea.

This approval means that the five preselected clinical trial sites in Korea can be opened shortly to commence enrolment of patients. Six sites in Australia were opened in November and experience at these sites with the initial 1B Phase of the ACCENT trial will help optimise the recruitment and management of patients in this important Phase 2 stage of the trial both in Australia and Korea.

Amplia’s CEO and Managing Director Dr Chris Burns commented: “The approval from the Korean MFDS comes after many months of hard work from the Amplia team, who have worked closely with the Korean regulators, to achieve this important approval. The Korean health system and their clinical trial capability is world class, and recruitment into pancreatic cancer trials has been historically strong. We look forward to opening our planned sites in Korea and working with the excellent clinical groups, to further test the impact of our drug narmafotinib in the treatment of advanced pancreatic cancer.”

About the ACCENT Trial

The protocol for 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 Phase 1b stage of the trial, now complete, determined an optimal dose of AMP945 when dosed in combination with gemcitabine and Abraxane, in first-line patients with advanced pancreatic cancer.

The Phase 2a, second stage of the trial, is designed to assess efficacy of the triple drug combination of narmafotinib, gemcitabine and Abraxane. The primary endpoint is Objective Response Rate (ORR) with secondary endpoints including Progression Free Survival (PFS) and Overall Survival (OS). Safety and tolerability will continue to be assessed.

More information about the ACCENT trial, including a list of participating sites, can be found via our website and at ClinicalTrials.gov under the identifier [NCT05355298](https://clinicaltrials.gov/ct2/show/study/NCT05355298).

The Company will provide further updates as recruitment proceeds.

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

Media Contact:

HACK Director, 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 [Twitter](https://twitter.com/ampliatx) (@ampliatx), [Threads](https://www.threads.net/@ampliatx) (@ampliatx) and [LinkedIn](https://www.linkedin.com/company/amplia-therapeutics).

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