ABN 16 165 160 841

ASX RELEASE **30th October 2023**

AMPLIA REPORTS PROMISING CLINICAL DATA
FROM PHASE 1B PORTION OF THE ACCENT TRIAL IN PANCREATIC CANCER

HIGHLIGHTS

- *The Phase 1b portion of the ACCENT trial of narmafotinib (AMP945) in combination with gemcitabine and nab-paclitaxel (Abraxane®) has now been completed.*
- *A dose of narmafotinib shown to be safe and well tolerated has been identified for the Phase 2a portion of the trial which will commence shortly.*
- *The trial was not powered for efficacy readouts, however initial activity signals, whilst preliminary, are very encouraging.*

Melbourne, Australia: Amplia Therapeutics Limited (ASX: ATX), ("Amplia" or the "Company"), is pleased to announce the completion of the Phase 1b stage of the ongoing ACCENT clinical trial in first-line patients with advanced pancreatic cancer. A safe and well tolerated dose of narmafotinib, the company's lead asset and best-in-class FAK inhibitor, will now be taken into the Phase 2a portion of the trial that will start imminently.

The Phase 1b stage of the ACCENT trial was designed to test ascending doses of orally-dosed narmafotinib in patients, in combination with the standard-of-care chemotherapy regime of gemcitabine combined with Abraxane. This dose-escalation stage has identified a dose of narmafotinib that provides sufficient circulating drug levels to significantly block the activity of the FAK enzyme. Importantly, this dose has been shown to be safe and well-tolerated across the three cohorts of patients (14 in total) in the trial.

The Phase 1b study was not powered for an efficacy readout, however, all patients were assessed for the impact drug treatment had on their cancer using the international standard Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 criteria[1]. The initial data obtained for the first 14 patients who completed the trial as per protocol, whilst preliminary and in some cases requiring a confirmatory scan, are positive, with 36% of patients demonstrating a partial response as their best overall response, and with a disease control rate (combined partial response and stable disease) of 93% (Table). These numbers compare very favourably with the published data of the clinical benefit of the gemcitabine and Abraxane combination in pancreatic cancer[2]. Across all doses, narmafotinib was shown to be generally safe and well-tolerated. All patients who completed their first 28-day cycle of treatment elected to stay on narmafotinib, with 7 patients (as of 27th October) having received narmafotinib as part of the combination for 5 months or more. As previously reported, one dose-limiting toxicity event was observed and notably, no treatment-related adverse events greater than Grade 3 were considered related to narmafotinib.

	ACCENT (to 27th Oct 2023)	**Gemcitabine + Abraxane[2]**
Classification	Best Overall Response* n=14	Best Overall Response** n=431
Complete Response (CR)	**0 (0%)**	**<1%**
Partial response (PR)	**5 (36%)**	**23%**
Stable Disease (SD)	**8 (57%)**	**27%**
Disease Control Rate (DCR) (=CR+PR+SD)	**13 (93%)**	**50%**
Progressive Disease (PD)	**0 (0%)**	**20%**
Not Evaluable	**1 (7%)**	**30%**

* Investigator reviewed, not 100% Source Document Verified

** Independent review as part of MPACT trial[2]

The clinical trial data has been reviewed by the ACCENT Safety Review Committee who support the dose selection and moving to the Phase 2a (Part B) stage of the trial. The Phase 2a trial will be run at the seven trial sites open in Melbourne, Sydney and Brisbane, with five additional sites in Korea expected to open by the end of this year.

Amplia's CEO and Managing Director Dr Chris Burns commented: "Completion of the Phase 1b stage of the trial is an important milestone for the ACCENT trial. We have now identified a safe and well-tolerated dose of narmafotinib to take into the Phase 2a stage of the trial and the preliminary efficacy signals we have seen to date, across three dose cohorts, are very encouraging. The team at Amplia are now focused on executing the next phase of the trial as quickly and efficiently as possible. As always, we thank the patients for participating in the trial, and the clinical trial staff and investigators for their continued involvement in the trial."

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 first, Phase 1b stage of the trial, will determine an optimal dose of AMP945 by assessing the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary efficacy of AMP945 when dosed in combination with gemcitabine and Abraxane in first-line patients with advanced pancreatic cancer.

The Part B Phase 2a, stage of the trial is designed to assess efficacy in combination with gemcitabine and Abraxane. The primary endpoint being Objective Response Rate (ORR). Further endpoints will assess efficacy. 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.

The Company will provide further updates on the next stage of the trial as recruitment proceeds.

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

References

1. European Journal of Cancer (2009) 45; 228 – 247.

2. New England Journal of Medicine (2013) 369; 1691 – 703.

Investor Contact:
Dr Chris Burns
Chief Executive Officer
chris@ampliatx.com

Media Contact:
H^CK 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 (@ampliatx), Threads (@ampliatx) and LinkedIn.