

ASX RELEASE 2<sup>nd</sup> Aug 2023

## **ACCENT Trial Recruitment Update**

**Melbourne, Australia:** Amplia Therapeutics Limited (ASX: ATX), ("Amplia" or the "Company"), is pleased to provide an update on progress in the ongoing Phase 1b/2a ACCENT clinical trial in first-line patients with advanced pancreatic cancer.

The current Phase 1b stage of the ACCENT trial is designed to test ascending doses of AMP945 in patients, given in combination with gemcitabine and nab-paclitaxel. The dose-escalation stage will cease, and a recommended dose for the Phase 2a stage of the trial identified, when either two or more dose-limiting toxicities (DLTs) are observed and/or when the pharmacokinetic and pharmacodynamic profiles are predicted to be optimised.

We are currently dosing the third cohort of patients in the dose-escalation phase of the trial. At this time 12 patients have been dosed across the 3 cohorts and have completed their first full cycle of treatment (28 days). Notably all patients, in consultation with their physicians, elected to stay on the study drug after completion of the first cycle of treatment. A DLT signal was reported in one patient in the current cohort, and consistent with the trial protocol, we expanded this third cohort with an additional three patients. We are now pleased to report the final patient in this cohort has been recruited and began dosing yesterday. Importantly, all other patients in this cohort have completed their first full 28-day cycle and continue to remain on drug at this dose. In line with the study protocol, we will continue to collect the data for this expanded cohort to determine whether further dose-escalation is warranted. The combined data will be reviewed by the Safety Committee once all patients in this cohort have been dosed for a complete 28-day cycle.

Amplia's CEO and Managing Director Dr Chris Burns commented: "While the cohort expansion has resulted in a delay for the complete data from this cohort to be reviewed by the safety committee, we continue to be encouraged by the data reported from all trial sites. We are grateful for the patients who are participating in the trial, and I look forward to reporting the outcomes from the Safety Committee meeting next month."

## **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 nab-paclitaxel (Abraxane®) in first-line patients with advanced pancreatic cancer.

The second, Phase 2a, stage of the trial is designed to perform an assessment of the optimal dose of AMP945, in combination with gemcitabine and nab-paclitaxel, with the primary endpoint being Objective Response Rate (ORR). Further endpoints will assess efficacy by other means as well as safety and tolerability.

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 <a href="NCT05355298">NCT05355298</a>. The Company will provide further updates on the trial as recruitment proceeds.

This ASX announcement was approved and authorised 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 immunology and Amplia has a particular development focus in fibrotic cancers such as pancreatic cancer. FAK also plays a significant role in a number of chronic diseases, such as idiopathic pulmonary fibrosis (IPF). For more information visit <a href="www.ampliatx.com">www.ampliatx.com</a> and follow Amplia on <a href="www.ampliatx.com">Twitter</a> (@ampliatx) and <a href="www.ampliatx.com">LinkedIn</a>.