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AMPLIA REPORTS RESULTS FROM SUCCESSFUL PHASE 1 CLINCIAL TRIAL OF AMP945

- Unblinded results from Phase 1 trial confirm AMP945 is safe and well tolerated
- Oral dosing achieved plasma concentrations in excess of those required to inhibit focal adhesion kinase (FAK)
- Results support further development of AMP945 in cancer and fibrosis

Melbourne, Australia: Amplia Therapeutics Limited (ASX: ATX), ("Amplia" or the "Company"), a company developing new approaches for the treatment for cancer and fibrosis, is pleased to announce it has received the unblinded results of its successful Phase 1 clinical trial of AMP945. The results confirm the Company's preliminary analyses and show that, in the trial, AMP945 was safe and well tolerated at all doses tested, supporting its progression into later stages of clinical development in both cancer and fibrosis. Further details about the trial and its results are provided below.

About the Phase 1 Trial

The clinical trial, designated as AMP945-101 and entitled "*A Phase I, randomised, double blind, placebo-controlled study of the safety, tolerability and pharmacokinetics of single and repeat doses of AMP945 administered orally to healthy adult volunteers*", was conducted at Nucleus Network in Melbourne. The study was conducted under a protocol approved by the Alfred Hospital Human Research Ethics Committee (HREC) in September 2020.

The Primary Endpoints for the trial were focused on the safety and tolerability of orally administered AMP945 which were assessed by evaluating the nature, incidence and severity of adverse events, withdrawals, physical examinations, vital signs, ECGs and safety laboratory test results including assessment of biochemical and haematological markers. Secondary endpoints assessed the pharmacokinetics of AMP945.

Overall, the trial recruited 56 healthy volunteers who were dosed with either single or multiple doses of AMP945 or placebo. Single and multiple doses of AMP945 up to 125mg and 100mg respectively, were given. Multiple doses were taken once daily for seven days. To study the effect of food on absorption of AMP945, one cohort of participants was given AMP945 both before and after food. Participants in the trial ranged in age from 18-65.

Safety and Tolerability

AMP945 was well tolerated at all doses given and there were no withdrawals or serious adverse events recorded in the trial. Adverse events were generally mild or moderate and were distributed evenly across participants assigned to AMP945 or placebo. Mild headache was the most frequently observed adverse event and the majority of safety findings were considered as either not related or unlikely to be related to AMP945. Events that were considered 'possibly' related to AMP945 included one incidence of diarrhoea, two incidences of headache, one taste disorder and one hot flush. There were no clinically significant changes in vital signs, clinical or laboratory parameters associated with AMP945. No adverse safety signals or dose-related trends were detected in any of the parameters measured.

Pharmacokinetics

AMP945 was delivered via capsules, taken with a glass of water. Following oral dosing, the plasma half-life of AMP945 was approximately 20 hours indicating that AMP945 was both orally bioavailable and could be administered once daily. Plasma levels of AMP945 exceeded the concentrations required to inhibit the intended target (FAK) with maximum plasma levels (C_{max}) being achieved after approximately 2-4 hours post dose. Exposure parameters, including C_{max} and area under the curve (AUC), all increased in a dose-dependent manner. There was no evidence of any food effect on the absorption of AMP945. Studies are ongoing to measure the inhibitory activity of AMP945 on FAK in skin punch biopsies and to assess the plasma metabolite profiles of AMP945.

Amplia's CEO and Managing Director, Dr John Lambert, commented that "This Phase 1 trial has delivered exactly what we wanted: AMP945 has been shown to have a safety and tolerability profile suitable for progressing it into Phase 2 trials in both pancreatic cancer and pulmonary fibrosis. We are now planning those trials and expect to start the Phase 2 trial in pancreatic cancer around the end of 2021. With the successful completion of this Phase 1 trial Amplia has hit yet another significant milestone and I would like to thank our team, Amplia's investors and the volunteers who stepped forward to participate in this successful trial."

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

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For Further Information
Dr. John Lambert
CEO and Managing Director
john@ampliatx.com
www.ampliatx.com

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 fibrosis and Amplia has a particular development focus in fibrotic cancers such as pancreatic and ovarian cancer. In addition, the company is pursuing the potential of its FAK inhibitors in pulmonary fibrosis.