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SUMMARY RESULTS FROM SUCCESSFUL PHASE 1 CLINCIAL TRIAL OF AMP945

- Unblinded results from Phase 1 trial confirm AMP945 is safe and well tolerated at all doses tested
- Oral dosing of AMP945 achieved the desired outcome of reducing FAK activity as measured in skin biopsies
- 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 completed its review of all primary, secondary and exploratory endpoints in its successful Phase 1 clinical trial of AMP945. The results confirm that, in the trial, AMP945 was safe and well tolerated at all doses tested, exhibited excellent pharmacokinetic properties and was able to engage with its intended target, Focal Adhesion Kinase (FAK). 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. An exploratory endpoint assessed the ability of AMP945 to target FAK in skin punch biopsies.

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.

Pharmacodynamics

As part of the trial, skin biopsies were collected from participating healthy volunteers to evaluate the ability of AMP945 to inhibit FAK in human tissues. Analysis of these samples required Amplia to develop a sensitive assay that allowed the measurement of the active form of FAK (phospho-FAK or pFAK) in skin samples before and after AMP945 was administered. Samples collected from 24 volunteers have now been analysed and demonstrate that oral administration of AMP945 results in a decrease in active pFAK and the extent of the inhibition of FAK activity correlates with drug levels of AMP945.

In addition to demonstrating the dose-dependent reduction in pFAK in healthy volunteers, these results verify the utility of the assay used to measure pFAK in human tissue samples, confirming the availability of a test method which can be used to guide dose selection in the Company's planned Phase 2 clinical trials of AMP945.

Amplia's CEO and Managing Director, Dr John Lambert, commented that "Putting all the elements of this trial together, we are now able to declare it as a resounding success. Not only have we found that AMP945 has excellent pharmaceutical properties and appears to be suitable for once-daily oral dosing, we also know that it has a suitable safety profile for further development and, moreover, hits the intended target. Taking all this information together reinforces our confidence that we are on a solid foundation for Phase 2 trials of AMP945 in patients with pancreatic cancer and pulmonary fibrosis"

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.