

ASX RELEASE

17 November 2021

INHIBITION OF FOCAL ADHESION KINASE (FAK) BY AMP945 IN PHASE 1 CLINICAL TRIAL

- Supplementary data from the Amplia Phase 1 clinical trial of AMP945 in healthy human volunteers shows that oral dosing of AMP945 achieved the desired outcome of reducing FAK activity.
- FAK activity was measured in skin samples taken before and after doses of AMP945. Drug levels achieved at safe and well-tolerated doses of the drug reduced FAK activity in humans.
- The data will be used to further refine the doses of AMP945 to be used in the upcoming Phase 2 clinical trial in patients with pancreatic cancer. It will also provide guidance for the Phase 2 trial in pulmonary fibrosis planned for the second half of 2022.

Melbourne, Australia: Amplia Therapeutics Limited (ASX: ATX), (“Amplia” or the “Company”), a company developing new drugs for the treatment of cancer and fibrosis, is pleased to report that it has received new data from its recent Phase 1 clinical trial that demonstrates the ability of AMP945 to inhibit the intended target, Focal Adhesion Kinase (FAK), in human volunteers when given as an orally administered capsule. This supplementary data further strengthens the Company’s confidence in the planned Phase 2 clinical program as it shows that safe and well-tolerated oral doses of AMP945 can achieve sufficient drug levels in humans to inhibit FAK.

The primary focus of Amplia’s recent Phase 1 clinical trial was to establish the safety, tolerability and pharmacokinetics of AMP945. 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. The data from these studies 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.

“We are very encouraged by the way all the data is lining up as we prepare to start our first Phase 2 clinical trial of AMP945,” said Dr Mark Devlin, Chief Scientific Officer at Amplia. “Being able to observe inhibition of FAK in human volunteers is an important piece of the jigsaw. We have observed inhibition of FAK by AMP945 in animal models and this has been associated with anti-tumour and anti-fibrotic activity. Getting such clear and compelling FAK inhibition data in our Phase 1 trial is very pleasing and provides additional comfort as we start trialling AMP945 in patients. Furthermore, we now have an assay for monitoring the effects of AMP945 that can be used to guide dosing in our upcoming Phase 2 trials in pancreatic cancers and other fibrotic diseases.”

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

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For Further Information

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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 pancreatic and ovarian cancer. FAK also plays a significant role in a number of chronic diseases, such as idiopathic pulmonary fibrosis (IPF).

About Pancreatic Cancer

Approximately 60,000 people in the US, and nearly 4,000 people in Australia, are diagnosed with pancreatic cancer each year. It is one of the most deadly cancers with a 5-year survival rate of only 5%-10%. The only potential cure available for pancreatic cancer is surgical excision. However, only 20% of patients are eligible for surgery with the remainder of patients having either localised, non-resectable (40%) or metastatic (40%) disease. The standard first-line therapy for these patients is chemotherapy with either gemcitabine/Abraxane® or FOLFIRINOX. Only 40%-50% of first-line patients are able to receive a second line therapy, and there is no standard treatment for second line pancreatic cancer patients.