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AMP945 Pre-IND Meeting Outcome

Amplia Therapeutics Limited (ASX: ATX) ("Amplia" or the "Company") is pleased to announce that a pre-Investigational New Drug (pre-IND) interaction with the United States Food and Drug Administration ("FDA") Division of Oncologic Diseases has been conducted.

Amplia requested a pre-IND (Type B) meeting to discuss the Company's proposed development plans for its investigational focal adhesion kinase inhibitor, AMP945, in people with pancreatic cancer. In particular, the Company sought FDA's feedback on the design of its planned clinical study of AMP945 in first-line patients with advanced pancreatic cancer which is scheduled to commence recruitment in the current calendar quarter.

The FDA advised Amplia that the design of the trial, including selection of the first-line patient population and the proposed dose-escalation followed by a Simon 2-stage design, is generally acceptable. FDA recommended some further pharmacokinetic sampling to more thoroughly interrogate patient exposures to AMP945, gemcitabine and nab-paclitaxel. These recommendations can be readily applied without delaying the trial and Amplia intends to implement the additional assessments in full. FDA also confirmed Amplia's understanding that dose selection for the Simon 2-stage expansion phase of the trial should be based on a combined view of safety, efficacy, pharmacokinetics and pharmacodynamics across a wide range of doses.

Overall, the FDA commented that the available and planned pre-clinical data appear to support both the trial and a future marketing application in the proposed indication. Furthermore, FDA reviewed the Company's proposed drug substance and drug product specifications and advised that these appear reasonable.

Amplia has already secured an Orphan Drug Designation (ODD) from the FDA covering the use of AMP945 in the treatment of patients with pancreatic cancer which grants seven years exclusivity and a waiver of FDA fees.

Amplia's CEO and Managing Director, Dr John Lambert commented that "We are very pleased to receive FDA's timely and helpful feedback. This pre-IND advice provides early insight into FDA's priorities and equips us to address these proactively. It also allows us to enter our planned clinical study reassured that our intent to bring first-line patients into the trial is reasonable and acceptable."

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