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Amplia Receives Human Research Ethics Committee Clearance to Conduct Phase 1 Clinical Trial

Amplia Therapeutics Limited (ASX: ATX) ("Amplia" or the "Company") is pleased to announce it has received clearance from the Alfred Hospital Human Research Ethics Committee (HREC) to conduct a Phase 1 clinical trial of its Focal Adhesion Kinase (FAK) inhibitor, AMP945, in healthy volunteers. With this clearance in hand, Amplia expects to initiate its Phase 1 trial in the coming weeks with the first subject likely to be dosed by early October.

The double blind, placebo-controlled Phase 1 trial is designed to establish the safety profile of oral doses of AMP945 in up to 64 healthy adult volunteers as well as provide data on the pharmacodynamics and pharmacokinetics of the drug in human subjects. The trial protocol that has been approved by the HREC includes an initial single ascending dose (SAD) study, followed by a multiple ascending dose (MAD) study. With the HREC clearance now in hand, Amplia is on track to complete dosing of subjects for the SAD component of the Phase 1 trial by the end of the year and have data from the completed trial in the first half of 2021. Recruitment for the trial is not expected to be impacted by the current COVID-19 pandemic.

Data from this trial will be used to support Phase 2 clinical trials of AMP945 for the treatment of patients with specific, hard-to-treat cancers or with certain fibrotic diseases. Earlier this year, Amplia secured Orphan Drug Designations (ODDs) from the US Food and Drug Administration (FDA) covering the use of AMP945 in the treatment of both pancreatic cancer and idiopathic pulmonary fibrosis (IPF). As the Phase 1 trial is being conducted in healthy volunteers rather than in patients, data from the trial is expected to support the progression of AMP945 into Phase 2 trials for a range of different diseases (indications). Amplia is also continuing with the conduct of a program of non-clinical studies to further define and enhance the next stage of the clinical development program for AMP945.

"We are very excited to receive ethics approval for Amplia's first clinical trial and to deliver on our commitment to advance AMP945 into human clinical trials during 2020" said Chief Executive Officer, Dr John Lambert. "Despite the challenges thrown up by the current COVID-19 pandemic, in the past few months we have managed to secure two Orphan Drug Designations, complete the preclinical studies required to support the Phase 1 trial, secure funding to conduct the trial, and now receive the approval required to initiate the trial. We are extremely grateful for the support we have received from our partners, providers and shareholders that has allowed us get to this stage and initiate the first-in-human study for AMP945."

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).