

ASX RELEASE

6 April 2022

Amplia Receives Ethics Clearance for Phase 2 Trial in Pancreatic Cancer Patients

- *Human Research Ethics Committee approval received to initiate a Phase 2 clinical trial of AMP945 in first-line pancreatic cancer patients*
- *Trial on track to commence recruitment in the coming weeks with the first patient expected to be dosed in April-May 2022*
- *Initial 12-patient dose-ranging study followed by 26-patient efficacy study with interim analysis anticipated in 2023*

Amplia Therapeutics Limited (ASX: ATX) (“Amplia” or the “Company”) is pleased to announce it has received Human Research Ethics Committee (HREC) approval to initiate the Company’s Phase 2 clinical trial of its Focal Adhesion Kinase (FAK) inhibitor, AMP945, in first-line patients with advanced pancreatic cancer. With this approval in hand, Amplia expects to initiate recruitment for the trial in the coming weeks, with the first patient expected to be dosed during April or May 2022.

The open-label single arm Phase 2 clinical trial has two parts, with the first part designed to identify the optimal dose of AMP945 in approximately 12 patients. In this part, first line patients with advanced pancreatic cancer will be treated with a range of doses of AMP945, in addition to clinically established doses of a current standard-of-care combination therapy consisting of gemcitabine and nab-paclitaxel. Selection of the optimal dose will be based on safety, pharmacokinetic and pharmacodynamic measures and will be overseen by a Data Monitoring Committee.

Following selection of the optimal dose, approximately 26 first-line patients will be treated with the optimised dose of AMP945 in combination with gemcitabine and nab-paclitaxel. Data from the trial will be used to conduct an interim analysis around mid-2023. The primary endpoint of the trial will be patients’ Objective Response (OR) as measured using standardised RECIST criteria.

The HREC approval announced today allows the study to commence at sites in NSW, Australia. A second application for HREC approval which will cover Victorian sites has been submitted and the Company expects a final response in the very near future.

Dr John Lambert, Amplia’s CEO and Managing Director commented that “Today is a very exciting day for Amplia and we welcome the HREC’s clearance to commence the first clinical trial of AMP945 in pancreatic cancer patients. Given the challenges that have historically been faced in the clinic by new treatments for this devastating disease, we believe that the best opportunity to improve treatment outcomes is to enhance the efficacy of current standards of care. The preclinical data that we have generated to date has consistently indicated that AMP945 may be able to significantly improve the effectiveness of standard gemcitabine/nab-paclitaxel combination therapy. It’s a great tribute to our shareholders, the Amplia team, the original researchers and our Garvan collaborators that we are able to initiate this very important clinical trial and we are excited to see the results as they emerge.”

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).