

ASX RELEASE

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AMPLIA TO CONDUCT PHASE 2 TRIAL IN FIRST-LINE PANCREATIC CANCER PATIENTS

- First-line cancer patients to be assessed in Phase 2 clinical trial of AMP945
- Provides access to largest relevant patient population for the clinical trial
- Patient recruitment planned to start in Q1 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 announce it has completed the design for a Phase 2 clinical trial of its Focal Adhesion Kinase (FAK) inhibitor, AMP945. This trial will be conducted in newly diagnosed patients receiving first-line therapy for pancreatic cancer.

Amplia’s planned Phase 2 clinical trial will add AMP945 to chemotherapy with gemcitabine and nab-paclitaxel, which is a standard of care currently used to treat the majority of newly diagnosed advanced pancreatic cancer patients. In the trial, designated AMP945-202, AMP945 will be administered orally to patients prior to each dose of their standard gemcitabine/nab-paclitaxel chemotherapy. The design of this trial is based on studies conducted in collaboration with Professor Paul Timpson’s group at the Garvan Institute of Medical Research, Sydney, where it has been shown that intermittent dosing of AMP945 makes tumours more responsive to standard chemotherapy treatments in animal models of pancreatic cancer.

Conducting the Phase 2 clinical trial in first-line patients is expected to expedite recruitment for the trial and provides the best opportunity to detect any efficacy signal from the addition of AMP945 to chemotherapy. The ability to test AMP945 in a first-line setting is also made possible by the excellent safety and tolerability profile demonstrated in Amplia’s recent Phase 1 clinical trial.

Dr Adnan Nagrial, of Sydney’s Westmead Hospital and lead investigator on the trial, commented that “Patients with advanced pancreatic cancer have very limited treatment options and we desperately need new therapies with novel mechanisms of action. Based on the evidence we have seen so-far, FAK inhibitors deserve to be tested in the clinic and I am excited to be part of this trial”.

The Phase 2 trial of AMP945 will be an open-label single arm trial conducted in two stages. In the first stage, an optimal dose of AMP945 will be selected and a preliminary assessment of efficacy will be performed in approximately 40 pancreatic cancer patients. In the second stage, up to an additional 24 pancreatic cancer patients will be recruited in order to increase confidence in the preliminary results. All patients are expected to receive multiple rounds of treatment.

The Company plans to initiate patient recruitment at Australian sites in the first quarter of 2022. Currently, the Company expects that recruitment will take 18-24 months but is working with vendors to accelerate key aspects of the trial. The primary endpoint for the trial will be based on the objective response rate from treatment compared to historical controls. In addition, multiple other signals of efficacy will be assessed in the trial’s secondary and exploratory endpoints including duration of response, disease progression rates, survival and effects on biomarkers of disease.

“Clinical evaluation of AMP945 as part of a first-line treatment for pancreatic cancer significantly de-risks the program and makes the drug relevant for a much larger patient base.” said Dr John Lambert, CEO of Amplia Therapeutics. “If we are able to see positive signs that AMP945 improves the leading current treatment option we will commence discussions with regulators and potential partners concerning future trials required to support product approval.”

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/nab-paclitaxel 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.