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AMP945 Shows Efficacy in Model of Lung Fibrosis

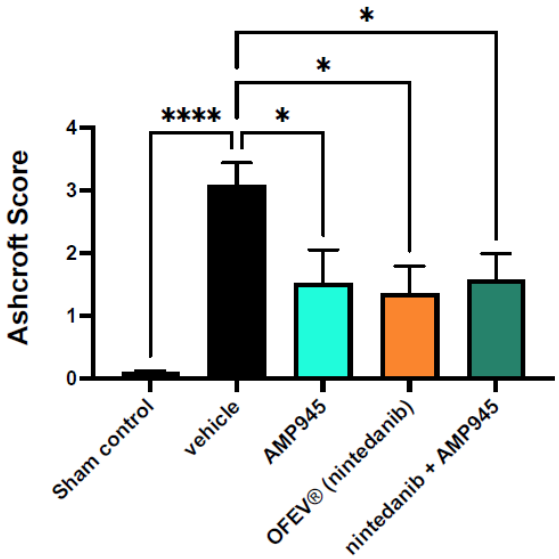
- Highly selective FAK inhibitor AMP945 shows similar efficacy to a current standard of care in a recognised model of IPF

Amplia Therapeutics Limited (ASX: ATX) ("Amplia" or the "Company") is pleased to announce new data showing the efficacy of its investigational focal adhesion kinase (FAK) inhibitor, AMP945, in a preclinical model of idiopathic pulmonary fibrosis (IPF).

Current pharmaceutical standards of care for idiopathic pulmonary fibrosis (IPF) are either OFEV® (nintedanib) or Esbriet® (pirfenidone). Both of these drugs have significant side effect profiles which limit their utility and there is considerable effort underway to find more tolerable and effective treatments for this debilitating and deadly disease. In 2020, net sales of OFEV® and Esbriet® were respectively 2.5 billion Euro (AUD 3.7 billion) and 1.1 billion CHF (AUD 1.6 billion).

New data from preclinical studies show that in the industry-standard bleomycin challenge mouse model of IPF, AMP945 had comparable activity to OFEV®, the current market leader. The studies were performed by an independent Contract Research Organisation (CRO) specialising in fibrosis disease models. Of note, in a study arm combining treatment with AMP945 and OFEV® there was no detectable increase in efficacy suggesting that, in this model, the maximum effect had been reached for both AMP945 and OFEV®.

The study was designed as a more demanding and meaningful treatment model as opposed to often used prevention models. Accordingly, mice were challenged with saline only (sham) or bleomycin and lung fibrosis was allowed to develop for 7 days. Mice which had been challenged with bleomycin were then randomised into four groups and treated orally with inactive drug delivery vehicle, AMP945, OFEV® or AMP945 + OFEV® for 14 days. Following treatment, lung fibrosis was measured using the Ashcroft score which is a standardised numerical scale used to quantify the extent of lung fibrosis in histological samples. The figure below shows that AMP945 and OFEV® reduce lung fibrosis to a statistically significant extent, compared to treatment with vehicle.



**** p < 0.0001; * p < 0.05. Error bars are ± standard error of mean (SEM), N =12 per group

Dr John Lambert, Amplia's CEO and Managing Director commented that "We have established that AMP945 is a highly selective FAK inhibitor and our clinical studies to date have shown that AMP945 has an excellent safety and tolerability profile at doses that result in measurable inhibition of its intended target. These new results reconfirm the efficacy of AMP945 in the industry-standard preclinical IPF model and show that, in a head-to-head comparison, the activity of AMP945 is comparable to the current market leader, OFEV®. This information should provide significant encouragement to clinical investigators and patients in our planned clinical trials of AMP945 in this devastating disease. It will also strengthen our ongoing discussions with potential commercial and strategic partners."

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

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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).