

ASX RELEASE

19th May 2020

FDA Awards Amplia Orphan Drug Designation for Idiopathic Pulmonary Fibrosis

Amplia Therapeutics Limited (ASX: ATX) (“Amplia” or the “Company”) today announced that the United States Food and Drug Administration (FDA) has awarded a second Orphan Drug Designation for Amplia’s Focal Adhesion Kinase inhibitor (FAKi) AMP945, this time for its use in the treatment of idiopathic pulmonary fibrosis (IPF).

The designation means that Amplia will qualify for waived FDA fees, clinical trial protocol assistance and other incentives. Furthermore, if Amplia secures US regulatory clearance for AMP945 for the treatment of IPF, AMP945 will qualify for seven years’ market exclusivity in FDA-administered markets.

IPF is a devastating disease caused by the progressive build up of fibrotic tissue in patients’ lungs. It is estimated to affect over 3 million people worldwide, including over 130,000 people in the US. The disease has a profound impact on a patient’s quality of life and a median survival of only 3-5 years if left untreated. The two drugs (pirfenidone and nintedanib) that have been approved for treatment of IPF are able to slow progression of the disease by up to 50%, but are not able to treat it. In preclinical studies using the industry standard chemically-induced (bleomycin) lung fibrosis model, AMP945 was able to both reduce and reverse the formation of fibrotic tissue in the lungs.

Amplia intends to start a Phase 1 clinical trial of AMP945 in healthy volunteers later this year to confirm that, like other FAKi’s, it is well tolerated. This trial will provide the safety, pharmacokinetic and exploratory pharmacodynamic data to enable AMP945 to progress into Phase 2 clinical trials in cancer and IPF patients in 2021.

Commenting on the Orphan Drug Designation, Dr John Lambert, Amplia’s CEO and Managing Director noted that “This Orphan Drug Designation further highlights the extensive opportunities provided by Amplia’s pipeline. With the preclinical toxicology program for AMP945 nearing completion, the company is rapidly moving toward commencement of a Phase 1 study in healthy volunteers later this year. Our development plan for AMP945 has been specifically structured to leverage the Company’s opportunities in both cancer and fibrosis. This Orphan Drug Designation for the use of AMP945 to treat patients with IPF provides further validation of the pipeline of opportunities we are putting in place for our proprietary FAK inhibitors”.

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).

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