

ASX RELEASE

25th March 2020

FDA Awards Amplia Orphan Drug Designation for Pancreatic Cancer

Amplia Therapeutics Limited (ASX: ATX) (“Amplia” or the “Company”) today announced that the United States Food and Drug Administration (FDA) has awarded Amplia’s Focal Adhesion Kinase inhibitor (FAKi) AMP945 Orphan-Drug Designation for the treatment of pancreatic cancer.

The designation means that Amplia will qualify for waived FDA fees, clinical trial protocol assistance and other incentives. Furthermore, if FDA ultimately approve AMP945 for the treatment of pancreatic cancer, Amplia would qualify for seven years’ market exclusivity in FDA-administered markets.

Amplia is aiming to start a Phase 1 clinical trial of AMP945 in healthy volunteers later this year to confirm that, like other FAKi, it is well tolerated. If this trial is successful, Amplia plans to initiate its first Phase 2 clinical study of AMP945 in cancer patients in 2021. AMP945 has multiple modes of action that make it an appealing candidate for incorporation into treatment regimes for hard-to-treat solid cancers such as pancreatic, ovarian, breast and lung.

Commenting on the Orphan Drug Designation, Professor Paul Timpson, a member of Amplia’s Scientific Advisory Board noted that “Pancreatic cancer is a seriously unmet medical need and FDA’s designation of AMP945 as an orphan-drug underlines global regulatory agencies’ interest in supporting novel treatments for this deadly disease”.

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).