

## **ASX RELEASE**

## 2 September 2019

## **Amplia Therapeutics Provides Manufacturing Update**

Amplia Therapeutics ("Amplia", the "Company") is pleased to provide an update on the status of its cGMP manufacturing program for AMP945 (anti-FAK kinase inhibitor). The purpose of this program is to produce clinical grade (human use) material for the Company's planned clinical studies.

This week, the Company's contract manufacturing organisation (CMO) released the final quality certificate for a 1 kg batch of clinical grade AMP945 marking the successful completion of all stages of the scale-up manufacturing of AMP945.

The company has previously disclosed that the manufacturing development work was completed in May 2019, culminating in kilogram-scale production of AMP945. This work demonstrated that the production process is robust and scalable, and has the necessary purity profile to be suitable for human use.

Amplia's CEO, Dr John Lambert commented that "As for many small molecule drugs, the manufacturing process for AMP945 is a multi-step process and each step must be carefully performed before the materials can be released for use in clinical trials. Securing this cGMP certificate allows the release of enough clinical-grade AMP945 to meet our needs for the coming year, including completion of our first clinical study. This achievement takes a lot of risk off the table for Amplia and represents a significant milestone for the company."

Preclinical safety studies are scheduled to finish in Q1 2020 with the Phase 1 clinical trial planned to commence in Q2 2020.

\* cGMP = Current Good Manufacturing Practice

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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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