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Amplia Therapeutics Provides Quarterly Update

The Company is pleased to provide the following information about the development activities recently completed and that are planned for the coming quarter.

Manufacturing of AMP945 Drug Substance Complete

Amplia has been working with its contract manufacturer to optimise the manufacturing process for lead drug candidate AMP945, ensuring that the manufacturing methods are sufficiently robust to produce AMP945 at 1kg batch scale and to produce material using the principles of Good Manufacturing Practice (GMP) of suitable quality for use in the Company's forthcoming Phase 1 clinical study.

Research and development costs incurred in the quarter ended June 30 were associated with our contract manufacturer meeting the agreed milestones of (i) completion of manufacture of the clinical batch to be used in the Phase 1 study; (ii) submission to Amplia of a production optimisation report and (iii) initiation of stability testing of the AMP945 clinical material.

During the next quarter, research and development costs relating to supply of clinical trial material will be limited to those required to support ongoing stability testing of AMP945.

Initial Toxicology Studies Completed

In preparation for Amplia's planned Phase 1 clinical trial in the early part of 2020, a standard panel of safety assessments must be carried out. Amplia recently completed the initial studies required as part of the required safety panel. These studies affirmed a positive view of the safety profile of AMP945 and supports progression to the final stages of clinical-enabling studies.

Selectivity of AMP945 Confirmed

AMP945 targets focal adhesion kinase (FAK) and has the potential to enhance the efficacy of both immunooncology drugs and chemotherapies. A differentiating feature of Amplia's lead candidate, AMP945 is the molecule's selectivity for inhibition of focal adhesion kinase (FAK), with minimal inhibition of other non-target kinases.

Selectivity for the target kinase is important because the non-selective inhibition of other kinase targets can result in unwanted side-effects.

To reaffirm the selectivity of AMP945, in particular compared to defactinib, a FAK inhibitor currently in Phase 2 clinical development, Amplia recently tested AMP945 against a more extensive panel of 468 human kinases.

We can report that this independent testing confirmed that:

- AMP945 potently inhibited FAK, being the molecule's specific target kinase;
- Inhibition of other kinases by AMP945 was minimal and notably less than defactinib.

Specifically, whereas defactinib has been reported to bind to approximately 100 kinases*, AMP945 binds to fewer than 30 kinases under similar conditions indicating that AMP945 is a more selective kinase inhibitor than defactinib. A comparison of the binding patterns of AMP945 and defactinib are presented below.

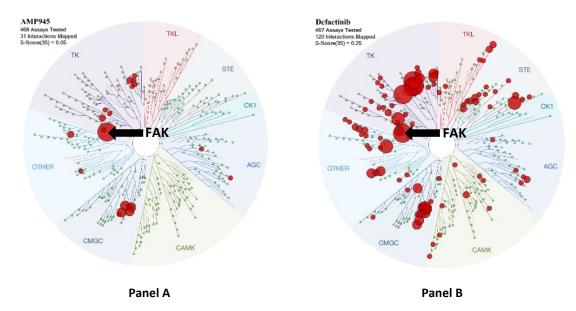


Figure: Dendrogram showing the selectivity profiles of AMP945 and defactinib measured using the DiscoverX KINOMEscan[™] assay and displayed using TREEspot[™]. Panel A: results for AMP945; Panel B: published* results for defactinib. Red spots indicate detected kinase interactions, with spot size indicating extent of binding.

The results support the contention that AMP945 is a superior candidate to other molecules currently in clinical development. The Company is preparing to publish this work in an appropriate peer-reviewed journal.

Further profiling of AMP945 for the purpose of distinguishing it from competitor molecules in development is also planned for the coming quarter.

* Cromm, P.M. et al., J. Am. Chem. Soc. 2018, 140, 17019–17026

Immunomodulatory Properties of AMP945

During the Quarter ended June 30, Amplia's collaborators at the University of Edinburgh completed studies to show the immunomodulatory effects of AMP945 in a squamous cell carcinoma model. As previously reported, these results were highly encouraging and we are now seeking to expand the scope of the collaboration as well as use other preclinical disease models to characterise the activity of AMP945 in combination with immuno-oncology drugs.

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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).