

ASX ANNOUNCEMENT

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Cytopia's CYT387 receives FDA clearance to start US clinical trials

Cytopia Limited's (ASX:CYT) Investigational New Drug Application (IND) for CYT387 has passed US Food and Drug Administration (FDA) review. CYT387 is a small-molecule oral JAK1/JAK2 kinase inhibitor designed to treat various haematological disorders. The company's IND application is now active and Cytopia is able to proceed with clinical trials for CYT387 in the United States.

CYT387 will be the second of Cytopia's compounds to enter clinical trials. The company's anti-cancer vascular-disrupting agent CYT997 is already in Phase II studies in Australia.

Hyperactivity of the JAK2 enzyme is known to cause a number of haematological conditions known as myeloproliferative disorders (MPDs). This group of diseases includes myelofibrosis, polycythemia vera and essential thrombocythemia. In addition, Cytopia has identified potential activity of CYT387 in a range of cancers which may substantially enlarge the value of this compound.

Dual JAK1/JAK2 inhibition is likely to increase the clinical benefit in these disease indications and broaden the therapeutic opportunities for CYT387. JAK kinase inhibitors with similar profiles are also being trialled in inflammatory diseases such as rheumatoid arthritis. CYT387 possesses optimised JAK1/JAK2 inhibition while minimising unwanted activity seen with other JAK2 inhibitors in clinical development.

Preparations for the company's initial Phase I/II trial of CYT387 in patients with myelofibrosis are currently being finalised. Myelofibrosis is a life-threatening scarring of the bone marrow. This study will be undertaken at the Mayo Clinic in Rochester Minnesota under the chairmanship of Dr Ayalew Tefferi, a key opinion leader in MPD treatment. The company anticipates opening the study to enrolment in the fourth quarter of 2009. Further details of the study will be disclosed following site ethics committee approval.

"Approval of the company's second IND marks another milestone in the development of Cytopia's suite of small molecule drugs," said Mr Andrew Macdonald, CEO. "With a strong package of preclinical data, the prospects for CYT387 are excellent and we look forward to commencing the clinical trial with Dr Tefferi at the Mayo Clinic later this year."

There has been considerable commercial interest in the JAK2 target with no selective JAK inhibitors having yet successfully completed late stage clinical trials and few compounds in development that meet a desirable product profile. Cytopia will seek to develop CYT387 through a commercial partnership and has been in discussions with potential partners for some time. A similar JAK2 inhibitor in clinical development was recently licensed by Onyx Pharmaceuticals for \$550 million including a \$25 million up-front payment and double-digit royalties.

About Cytopia

Cytopia Ltd is an Australian biotechnology company focused on the discovery and development of new drugs to treat cancer and other diseases. Cytopia conducts its research and drug development through subsidiaries based in Melbourne, Australia and California, USA and specialises in developing new small molecule compounds with an improved therapeutic profile for the treatment of cancer.

The company's lead drug candidate is CYT997, a vascular disrupting agent (VDA) for the treatment of various cancers, which is currently being trialled in Phase II clinical studies. Cytopia is continuing to build on its range of JAK inhibitors and kinase expertise, with CYT387, a novel oral JAK1/JAK2 inhibitor focused on the treatment of myeloproliferative disorders, to enter Phase I clinical studies in 2009.

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