
ASX Announcement

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Cytopia lodges IND for JAK2 inhibitor CYT387

Cytopia Ltd (ASX: CYT) announced today that it has filed an Investigational New Drug Application (IND) with the US Food and Drug Administration (FDA) for its novel, potent orally active JAK2 inhibitor CYT387.

Following FDA review, the company intends to commence a Phase I/II trial for CYT387 in patients with myelofibrosis, a serious progressive and chronic condition where scar tissue develops in the bone marrow. CYT387 is expected to be the second Cytopia-developed drug candidate in clinical studies and the first trialled in the United States, with the anti-cancer vascular disrupting agent CYT997 now in Phase II clinical studies in Australia.

Over-activity of the JAK2 enzyme is implicated in a variety of haematological conditions known as the myeloproliferative disorders (MPDs). This suite of conditions includes myelofibrosis, polycythemia vera and essential thrombocythemia. Cytopia has demonstrated that CYT387 inhibits the over-active JAK2 enzyme in an in vivo preclinical model and in cells from patients with MPDs. This data suggests that the compound may exert a profound effect on the human disease.

Myelofibrosis results in a compromised ability of patients to produce sufficient blood cells and a reliance on organs other than the bone marrow, including the liver and spleen, to produce cells. Typical symptoms include an enlarged spleen and progressive anemia and poor overall survival.

“The filing of an IND for CYT387 is the culmination of a comprehensive preclinical development effort by the Cytopia Drug Development team” said Mr Andrew Macdonald, CEO of Cytopia. “Our deep knowledge of the JAK2 target has been integral to the design of this drug and the program is significantly bolstered by the intellectual property we hold over the JAK2 target”.

The clinical utility of CYT387 is also expected to have broader applicability in diseases driven by dysregulated JAK2 signalling, including some cancers and various inflammatory conditions. Cytopia is exploring the utility of CYT387 in these conditions.

About Cytopia

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

The lead program for the company is CYT997, a vascular disrupting agent (VDA) for the treatment of various cancers, currently being trialed in Phase II clinical studies. This compound is delivered orally as well as intravenously. Cytopia also has built on its range of JAK and other kinase inhibitors with CYT387, a novel oral JAK2 inhibitor focused on the treatment of myeloproliferative disorders and cancer, expected to enter Phase I clinical studies in 2009.

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