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FibroGen, Astellas start trial of anemia therapeutic agent

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FibroGen, Astellas start phase III trial of anemia therapeutic agent

Singapore: FibroGen and Japanese company Astellas Pharma have initiated the first clinical study in the phase III clinical development program of FG-4592/ASP1517, an orally administered small molecule, for treatment of anemia associated with chronic kidney disease in patients not on dialysis and on dialysis, to support approval in the US and Europe. FG-4592/ASP1517 is an inhibitor of hypoxia-inducible factor (HIF) prolyl hydroxylase, belonging to a new class of anemia therapeutic agents.

Astellas has licensed from FibroGen certain rights to FG-4592/ASP1517 (Astellas designation ASP1517) in Japan, Europe, the Commonwealth of Independent States, Middle East and South Africa. As part of these agreements, FibroGen and Astellas equally share development costs for FG-4592/ASP1517 in the US and Europe, and Astellas makes milestone payments for its clinical advancement and approvals in Europe and in Japan, as well as other subsequent events. In Japan, phase I studies have been completed and a phase II program is expected to start in early 2013.

The decision to initiate the phase III program in the US and Europe is based on the completion of phase II clinical studies showing that FG-4592/ASP1517 met its primary objective of demonstrating anemia correction in treatment naÃ¯ve CKD patients not on dialysis as well as maintenance of hemoglobin in CKD patients on dialysis and not on dialysis.

Results relating to phase II clinical development of FG-4592/ASP1517 were most recently presented at the American Society of Nephrology Kidney Week 2012, in San Diego, California.

"Based on the encouraging results from FG-4592/ASP1517 phase II clinical studies, we are pleased to advance to phase III development of FG-4592/ASP1517," said Mr Thomas B Neff, president and chief executive officer of FibroGen. "FG-4592/ASP1517 has the potential to offer CKD patients a more convenient oral therapy for anemia, one that is effective without intravenous (IV) iron supplementation, and that provides the additional benefits of cholesterol reduction and reduction in hypertension, which may have importance relative to the current standard of care in CKD management."

Dr Steven Ryder, president of Astellas Pharma Global Development, said, "The initiation of phase III clinical development of

FG-4592/ASP1517 reaffirms our commitment to the treatment of kidney disease. Through this new mechanism of action, we hope to provide significant therapeutic benefits to patients with anemia associated with chronic kidney disease."