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ASIA EDITION

Astellas, FibroGen start CKD anemia trial in Japan

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Singapore: Japan-based Astellas Pharma and US-based FibroGen initiated a phase II clinical study in Japan of ASP1517/FG-4592 for the treatment of anemia associated with chronic kidney disease (CKD) in patients on dialysis.

ASP1517/FG-4592, an orally administered small molecule inhibitor of hypoxia-inducible factor prolyl hydroxylase (HIF-PHI), is a clinically advanced candidate in this new class of potential anemia therapeutic agents.

Astellas plans to conduct an additional phase II clinical study in Japan of ASP1517/FG-4592 in non-dialysis patients in late 2013. FibroGen received a $12.5 million milestone payment from Astellas for the initiation of the phase II Japan study. Astellas is responsible for the development cost of ASP1517/FG-4592 in Japan as part of the terms and conditions of the exclusive license agreement with FibroGen for Japan.

In December 2012, Astellas and FibroGen announced the initiation of the first clinical study in the phase III development of ASP1517/FG-4592 to support approval in the US and Europe.

Astellas has licensed from FibroGen certain rights to ASP1517/FG-4592 in Japan, Europe, the Commonwealth of Independent States, the Middle East, and South Africa. As part of these agreements, FibroGen and Astellas equally share development costs for ASP1517/FG-4592 in the US and in Europe. FibroGen has also completed phase II studies for ASP1517/FG-4592 for the treatment of CKD anemia in China.