Astellas and FibroGen Announce the Initiation of a Phase 2 Clinical Study in Japan of ASP1517/FG-4592 for Treatment of Anemia of Chronic Kidney Disease

Tokyo and San Francisco -- July 30, 2013 -- Astellas Pharma Inc. (Tokyo:4503) (Astellas) and FibroGen, Inc. (FibroGen) announced today the initiation of a Phase 2 clinical study in Japan of ASP1517/FG-4592 for 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 the most clinically advanced candidate in this new class of potential anemia therapeutic agents.

Astellas plans to conduct an additional Phase 2 clinical study in Japan of ASP1517/FG-4592 in non-dialysis patients in late 2013.

FibroGen has received a $12.5 million milestone payment from Astellas for the initiation of the Phase 2 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 3 development of ASP1517/FG-4592 to support approval in the U.S. 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 U.S. and in Europe. Astellas makes milestone payments to FibroGen upon clinical advancement and approvals in Europe and in Japan, as well as for other subsequent events. FibroGen retains the rights to its anemia therapies in North America and South America, remaining parts of Africa, and all of Asia Pacific outside of Japan. FibroGen has also completed Phase 2 studies for ASP1517/FG-4592 for the treatment of CKD anemia in the People’s Republic of China.

About FG-4592/ASP1517
Astellas and FibroGen are developing ASP1517/FG-4592, a novel oral small molecule inhibitor of hypoxia-inducible factor (HIF) prolyl hydroxylase activity, for the treatment of anemia in patients with chronic kidney disease (CKD). ASP1517/FG-4592 has been shown to correct and maintain hemoglobin levels without the need for supplementation with intravenous iron in CKD patients not yet receiving dialysis and in end-stage renal disease patients receiving dialysis. An Independent Data Monitoring Committee has found no signals or trends to date to suggest that treatment with ASP1517/FG-4592 is associated with increased risk of cardiovascular events, thrombosis, or increases in blood pressure requiring initiation or intensification of antihypertensive medications.

About Chronic Kidney Disease (CKD)
CKD is a global healthcare problem that affects more than 10 percent of the world’s population, significantly increasing morbidity and mortality rates and driving significant healthcare costs. Per the National Health and Nutrition Evaluation Survey (NHANES), prevalence of CKD in the U.S. has increased dramatically in past decades, from 10 percent of the U.S. adult population (or approximately 20 million U.S. adults) 1988-1994, to 15 percent (or approximately 30 million adults) in NHANES 2003-2006. In 2010, overall Medicare costs for CKD patients were $41 billion. Patients with both anemia and CKD have a greater risk of hospitalization and reduced quality of life, yet the condition tends to be
undertreated. Whereas nearly all patients in the U.S. on hemodialysis have easy access to ESA therapy, only 2 percent of CKD patients in the U.S. receive treatment with ESAs prior to referral to a nephrologist.3

About Astellas
Astellas Pharma Inc. is a pharmaceutical company dedicated to improving the health of people around the world through provision of innovative and reliable pharmaceuticals. Astellas has approximately 17,000 employees worldwide. The organization is committed to becoming a global category leader in Urology, Immunology (including Transplantation) and Infectious Diseases, Oncology, Neuroscience, and DM Complications and Kidney Diseases. For more information on Astellas Pharma Inc., please visit our website at www.astellas.com.

About FibroGen
FibroGen, Inc., is a privately-held biotechnology company focused on the discovery, development, and commercialization of therapeutic agents for treatment of fibrosis, anemia, cancer, and other serious unmet medical needs. FibroGen’s FG-3019 monoclonal antibody is in early-stage clinical development for treatment of idiopathic pulmonary fibrosis and other proliferative diseases, including pancreatic cancer and liver fibrosis, and FG-4592 is a small molecule inhibitor of hypoxia-inducible factor (HIF) prolyl hydroxylase currently in clinical development for the treatment of anemia. FibroGen is also currently pursuing the use of proprietary recombinant human type III collagens in synthetic corneas for treatment of corneal blindness. For more information please visit: www.fibrogen.com

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References