FibroGen and Astellas Announce Initiation of Phase 3 Trial of FG-4592/ASP1517 for Treatment of Anemia of Chronic Kidney Disease

San Francisco and Tokyo, December 12, 2012 - FibroGen, Inc. ("FibroGen"), and Astellas Pharma Inc. (Tokyo:4503, "Astellas"), announced today the initiation of the first clinical study in the Phase 3 clinical development program of FG-4592/ASP1517, an orally administered small molecule, for treatment of anemia associated with chronic kidney disease ("CKD") in patients not on dialysis and on dialysis, to support approval in the U.S. and Europe. FG-4592/ASP1517 is an inhibitor of hypoxia-inducible factor (HIF) prolyl hydroxylase (a "HIF-PHI"), belonging to a new class of anemia therapeutic agents.

The decision to initiate the Phase 3 program in the U.S. and Europe is based on the completion of Phase 2 clinical studies showing that FG-4592/ASP1517 met its primary objective of demonstrating anemia correction in treatment-naïve CKD patients not on dialysis as well as maintenance of hemoglobin in CKD patients on dialysis and not on dialysis. Results relating to Phase 2 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 2 clinical studies, we are pleased to advance to Phase 3 development of FG-4592/ASP1517," said 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."

Steven Ryder MD, FACP, President of Astellas Pharma Global Development Inc., stated, "The initiation of Phase 3 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."

Astellas has licensed from FibroGen certain rights to FG-4592/ASP1517 (Astellas designation ASP1517) 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 FG-4592/ASP1517 in the U.S. 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 1 studies have been completed and a Phase 2 program is expected to start in early 2013. FibroGen retains the rights to its anemia therapies in North America and South America, remaining parts of Africa, and all of Asia Pacific ex-Japan. FibroGen is also developing FG-4592 for the treatment of CKD anemia in the People's Republic of China, where Phase 2 studies have been completed.

FibroGen has received a $50 million milestone from Astellas for the initiation of the Phase 3 program.

About FG-4592/ASP1517

FibroGen and Astellas are developing FG-4592/ASP1517, a novel oral HIF-PHI, for the treatment of anemia in patients with CKD. FG-4592/ASP1517 has been shown to correct and maintain hemoglobin levels in patients with CKD not receiving dialysis[2] and in patients with end-stage renal disease receiving dialysis[3] without the need for supplementation with intravenous iron. An Independent Data Monitoring Committee has found no signals or trends to date to suggest that treatment with FG-4592/ASP1517 is associated with increased risk of cardiovascular events, thrombosis, or increases in blood pressure requiring initiation or intensification of antihypertensive medications.

About CKD

CKD is a worldwide critical healthcare problem that affects millions of people and drives significant healthcare cost. In the U.S., prevalence of CKD has increased dramatically in the past 20 years, from 10% of the U.S. adult population (or approximately 20 million U.S. adults) per the National Health and Nutrition Evaluation Survey (NHANES) 1988-1994, to 15% (or approximately 30 million adults) in NHANES 2003-2006. In 2009, total

Medicare costs for CKD patients were $34 billion.

Anemia is the condition of having fewer red blood cells and/or lower hemoglobin levels than is normal. The prevalence of anemia increases with the progression of CKD and is a demonstrated risk multiplier in patients with preexisting cardiovascular disease. Anemia has been associated with adverse outcomes in CKD patients, increased hospitalization rates, increased mortality, and reduced quality of life, but the condition tends to be undertreated due in part to the cost and complexity of treatment with injectable erythropoiesis-stimulating agents (ESAs) and intravenous iron supplements. Whereas nearly all patients on hemodialysis have easy access to ESA therapy, only 2% of CKD patients receive treatment with ESAs prior to referral to a nephrologist in the U.S.[1] Under-treatment of anemia in the primary care setting can be attributed in part to lack of convenience and reimbursement rules, requiring physicians to buy ESA inventory and bill after procedures. This deters physicians in the primary care setting where anemic patients are a minority of total patients. FibroGen estimates there are 1 million late-stage CKD patients (CKD Stages 3-5) with anemia in the U.S., and less than 20% are treated with ESAs prior to initiation of dialysis.[1]

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/en.

About FibroGen
FibroGen, Inc., is a biotechnology company focused on the discovery, development, and commercialization of therapeutics for fibrosis, anemia, cancer, and other serious unmet medical needs. FibroGen's research into the role of CTGF in various proliferative diseases has led to the development of therapies for the treatment of idiopathic pulmonary fibrosis and cancers, including pancreatic cancer, and other life-threatening disorders. FibroGen's expertise in the area of prolyl hydroxylase inhibition has led the development of an extensive library of small molecule inhibitors of hypoxia-inducible factor (HIF) prolyl hydroxylase inhibitors, including FG-4592 and FG-6874, currently in clinical development for the treatment of anemia. FibroGen also develops and produces recombinant biomaterials, such as human collagens and gelatins, for various purposes, and is currently pursuing the use of recombinant human type III collagen in synthetic corneas for treatment of corneal blindness. FibroGen was founded in 1993 and is based in San Francisco, California. For more information on FibroGen, Inc., please visit our website at www.fibrogen.com.

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1. U.S. Renal Data System, USRDS 2012 Annual Data Report: Atlas of Chronic Kidney and End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2012
2. Besarab A, et al (2011) J Am Soc Nephrol 22:196A
3. Provenzano R, et al. (2011) Am. J. Kidney Dis Vol. 57 4:B80