

April 2, 2008

## **The FDA Accepts the Complete Response for Clinical Holds of FG-2216\*/FG-4592 for the Treatment of Anemia**

Japan, April 2, 2008- Astellas Pharma Inc. (“Astellas”; headquarters: Tokyo; President and CEO: Masafumi Nogimori) announced that the Food and Drug Administration accepted the complete response seeking to resume clinical trials of FG-2216\* and FG-4592. These are compounds for oral anemia treatment, which Astellas licensed from FibroGen, Inc. (“FibroGen”; headquarters: South San Francisco, CA; Chairman, founder and CEO: Thomas B. Neff) for exclusive development and marketing in Japan, Europe, etc.

All clinical trials of FG-2216 and FG-4592 have been on clinical hold since May 2007 due to one case of death by fulminant hepatitis during a Phase II clinical trial of FG-2216 for patients with anemia associated with chronic kidney disease (CKD) and not requiring dialysis being conducted in the United States by FibroGen. FibroGen submitted a response to the Agency in February 2008. In a letter dated March 24, the FDA informed FibroGen that the submissions for FG-2216 and FG-4592 were complete responses and that clinical trials may be resumed for both compounds. Study protocols proposed by FibroGen were overall accepted for resumption of the Phase II study programs. We will continue to seek FDA advice at appropriate intervals as we continue development.

FG-2216 and FG-4592 are hypoxia inducible factor prolyl hydroxylase inhibitors (HIF-PHI) discovered and synthesized by FibroGen to meet unmet medical needs as the world’s first oral drugs for the treatment of anemia. At present, the mainstay of treatment for anemia is recombinant human erythropoietin (rHuEPO) administered by subcutaneous injection or intravenous infusion and often requiring intravenous iron supplementation to achieve increases in hemoglobin. FG-2216 and FG-4592 have been shown to increase hemoglobin levels in a dose-dependent manner through induction of “complete erythropoiesis” via the HIF erythropoietic cascade wherein circulating levels of endogenous EPO remain within the normal physiologic range.

\* Development code. Astellas code name: YM 311

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