

Astellas Pharma Inc.: Submits Application for Marketing Approval of Bixalomer (ASP1585) for Treatment of Hyperphosphatemia, in Japan

Tokyo, March 14, 2011 - Astellas Pharma Inc. (“Astellas”; headquarters: Tokyo; President and CEO: Masafumi Nogimori) announced today that it submitted a market authorization application for an amine-functional phosphate-binding polymer bixalomer (generic name; development code: ASP1585) to the Ministry of Health, Labour and Welfare in Japan. Astellas is seeking an approval for the indication of hyperphosphatemia in patients on dialysis with chronic kidney disease.

Hyperphosphatemia occurs in many patients receiving dialysis whose renal function is reduced, because phosphorus is not sufficiently excreted into urine via the kidneys and consequently accumulates in the body. With the continuous high blood phosphorus concentration, the risk of renal osteodystrophy characterized by a high tendency of bone pain and bone fracture is known to be increased. Additionally, the high blood phosphorus is associated with increased coronary artery calcification and subsequent cardiovascular events. Therefore, it is considered extremely important to maintain an appropriate level of the serum phosphorus concentration in dialysis patients.

Bixalomer is an amine-functional polymer which is decreasing the serum phosphorus concentration through the binding to phosphate in the gastrointestinal tract by inhibiting the absorption of phosphate into the human body. The Phase III studies in patients on dialysis with chronic kidney disease in Japan demonstrated bixalomer’s clinical efficacy in the decrease of the serum phosphorus concentration, as well as a preferable long-term safety profile.

In April 2006, Astellas and Ilypsa, Inc., a wholly-owned subsidiary of Amgen Inc., entered into a license agreement that gives Astellas exclusive rights to develop and market bixalomer for the treatment of hyperphosphatemia in Japan. Since then, Astellas has conducted the development of bixalomer in Japan. Upon submission of this application for marketing approval in Japan, Astellas will pay Ilypsa \$10 million in milestone payments. Although the milestone payment has not been reflected in Astellas’ current fiscal year (from April 1, 2010 to March 31, 2011) financial forecast, the impact will be immaterial.

Astellas expects to provide an additional therapeutic option to the treatment of hyperphosphatemia by introducing bixalomer into the Japanese market.

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