

Astellas Submits Supplemental New Drug Application for Kiklin[®] Capsules, a Treatment for Hyperphosphatemia, in Japan

Tokyo, March 17, 2015 - [Astellas Pharma Inc.](#) (“Astellas”; Tokyo:4503; President and CEO: Yoshihiko Hatanaka) today announced that it submitted a supplemental new drug application for “Kiklin[®] Capsules 250mg (generic name: Bixalomer)” to the Ministry of Health, Labour and Welfare in Japan.

In June 26, 2012, Astellas launched Kiklin[®] Capsules 250mg with the indication of hyperphosphatemia in patients on dialysis with chronic kidney disease (“CKD”) in Japan. Astellas expects to contribute the treatment of CKD patients on non-dialysis with hyperphosphatemia by submission of this supplemental new drug application.

The application is based on the results of Phase III studies (the double blind, placebo-controlled study and long term study) in CKD patients on non-dialysis in Japan demonstrated Kiklin[®] Capsules’ clinical efficacy and a preferable safety profile.

Hyperphosphatemia occurs in patients whose renal function is reduced, since phosphorus is not sufficiently excreted into urine via the kidneys and consequently accumulates in the body. With 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, high blood phosphorus concentration is associated with increased coronary artery calcification and subsequent cardiovascular events. Therefore, it is considered extremely important to maintain the serum phosphorus concentration at an appropriate level in CKD patients.

Kiklin[®] Capsules are amine-functional polymers which decrease the serum phosphorus concentration by binding to phosphate in the gastrointestinal tract, thus inhibiting absorption of phosphate into the human body.

In April 2006, Astellas and Ilypsa, Inc., now a wholly-owned subsidiary of Amgen Inc., entered into a license agreement that gives Astellas exclusive rights to develop and market Kiklin[®] Capsules for the treatment of hyperphosphatemia in Japan. Since then, Astellas has conducted development of Kiklin[®] Capsules in Japan. Astellas and Sanwa Kagaku Kenkyusho Co., Ltd. co-promote Kiklin[®] Capsules while Astellas oversees its distribution.

In connection with the submission of this supplemental new drug application, there are no impacts to Astellas’ forecasts for fiscal year ending March 2015.

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