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News Release

Submission of a Supplemental New Drug Application for ASP1585 Granule, a Treatment for Hyperphosphatemia, in Japan

Tokyo, September 30, 2015 - Astellas Pharma Inc. (TSE: 4503; President and CEO: Yoshihiko Hatanaka, "Astellas") today announced that it submitted a supplemental new drug application for ASP1585 granule (generic name: Bixalomer), an additional formulation of Kiklin® Capsules 250 mg ("Kiklin®"), for the indication of hyperphosphatemia in patients on dialysis with chronic kidney disease ("CKD") to the Ministry of Health, Labor and Welfare in Japan.

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. Bixalomer is 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.

Bixalomer was discovered by Ilypsa, Inc., now a wholly-owned subsidiary of Amgen Inc. In April 2006, Astellas and Ilypsa, Inc. entered into a license agreement that grants Astellas exclusive rights to develop and commercialize Kiklin® for the treatment of hyperphosphatemia in Japan. Since then, Astellas has conducted development of Kiklin® in Japan. Astellas and Sanwa Kagaku Kenkyusho Co., Ltd. co-promote Kiklin® while Astellas is solely responsible for its distribution.

On June 26, 2012, Astellas launched Kiklin®, approved for the indication of hyperphosphatemia in patients on dialysis with CKD, in Japan. Astellas submitted the supplemental new drug application of Kiklin® for the treatment of CKD patients not on dialysis with hyperphosphatemia on March 17, 2015. The application on granule formulation is based on the results of bioequivalence studies in healthy adults.

Astellas expects to further contribute to hyperphosphatemia treatment by introducing ASP1585 granule which can further improve the compliance with its more convenient dosing option into Japanese market.

In connection with the submission of this supplemental new drug application, there are no impact on Astellas' forecasts for fiscal year ending March 2016.

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About Astellas

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. We focus on Urology, Oncology, Immunology, Nephrology and Neuroscience as prioritized therapeutic areas while advancing new therapeutic areas and discovery research leveraging new technologies/modalities. We are also creating new value by combining internal capabilities and external expertise in the medical/healthcare business. Astellas is on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at www.astellas.com/en.

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