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News Release

Astellas Receives Approval for a Supplemental New Drug Application for Kiklin® Capsules, a Treatment for Hyperphosphatemia, in Japan

Tokyo, February 29, 2016 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Yoshihiko Hatanaka, "Astellas") today announced that it received an approval for a supplemental new drug application for "Kiklin® Capsules 250mg (generic name: Bixalomer, "Kiklin®")" from the Ministry of Health, Labour and Welfare in Japan.

In association with the approval of the additional indication, the indication has been revised as shown below:

After revision (Underlined text to be added)	Before revision (Dotted-underlined text to be deleted)
[Indication] Treatment of hyperphosphatemia in patients with chronic kidney disease	[Indication] Treatment of hyperphosphatemia in patients on dialysis with chronic kidney disease

In June 2012, Astellas launched Kiklin®, approved for the indication of hyperphosphatemia in patients on dialysis with chronic kidney disease ("CKD"), in Japan. With this approval, Kiklin® is indicated for the treatment of hyperphosphatemia, allowing the use of this product for patients suffering from CKD who are not receiving dialysis.

Hyperphosphatemia occurs in patients with reduced renal function, resulting from decreased phosphate excretion into urine via kidney which induces consequent accumulation 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 increase. 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® is an amine-functional polymer which decreases 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 grants Astellas exclusive rights to develop and commercialize Kiklin® for the treatment of hyperphosphatemia in Japan. Since then, Astellas has conducted development activities for Kiklin® in Japan. Astellas and Sanwa Kagaku Kenkyusho Co., Ltd. co-promote Kiklin® while Astellas is solely responsible for its distribution.

Astellas expects that the additional indication for Kiklin® will further contribute to the treatment of hyperphosphatemia in patients with CKD.

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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