

Astellas Receives Approval for Kiklin[®] Granules, a Treatment for Hyperphosphatemia, in Japan

Tokyo, September 28, 2016 - Astellas Pharma Inc. (TSE: 4503; President and CEO: Yoshihiko Hatanaka, “Astellas”) announced that it received a marketing approval of Kiklin[®] Granules 86.2% (development code: ASP1585, generic name: bixalomer, “Kiklin[®] Granules”), an additional dosage formulation of Kiklin[®] Capsules 250 mg (“Kiklin[®] Capsules”), for the indication of treatment of hyperphosphatemia in patients with chronic kidney disease (“CKD”) in Japan on September 21, 2016. Astellas expects to further contribute to hyperphosphatemia treatment by introducing Kiklin[®] Granules which can further improve the compliance with its more convenient dosing option into Japanese market.

Hyperphosphatemia occurs in patients whose renal function is decreased, 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 bixalomer in Japan and then, Astellas conducted the development of Kiklin[®] Granules. Astellas and Sanwa Kagaku Kenkyusho Co., Ltd. co-promote Kiklin[®] Capsules while Astellas is solely responsible for its distribution.

On June 26, 2012, Astellas launched Kiklin[®] Capsules, approved for the indication of hyperphosphatemia in patients on dialysis with CKD in Japan. Astellas also received an approval for a supplemental new drug application of Kiklin[®] Capsules for the treatment of CKD patients not on dialysis with hyperphosphatemia on February 29, 2016.

In connection with the approval, there is no impact on Astellas' forecasts for fiscal year ending March 2017.

Cautionary Notes

In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

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.

###

Contacts for inquiries or additional information
Astellas Pharma Inc. Corporate Communications TEL: +81-3-3244-3201 FAX: +81-3-5201-7473 http://www.astellas.com/en