

## **Astellas Pharma Obtains Approval in Japan for Treating Hyperphosphatemia with Kiklin<sup>®</sup> Capsules**

Tokyo, March 30, 2012 - [Astellas Pharma Inc.](#) (“Astellas Pharma”; Tokyo:4503; President and CEO: Yoshihiko Hatanaka) announced that Kiklin<sup>®</sup> Capsules (development code: ASP1585, generic name: Bixalomar) were granted Japanese marketing approval today 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 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 dialysis 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. Phase III studies in patients on dialysis with chronic kidney disease in Japan demonstrated Kiklin Capsules’ clinical efficacy in decreasing serum phosphorus concentration, as well as a preferable long-term safety profile.

In April 2006, Astellas Pharma 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 Pharma has conducted development of Kiklin Capsules in Japan. Upon this approval in Japan, Astellas will pay Ilypsa \$22 million in milestone payments. The milestone payment has been reflected in Astellas’ current fiscal year (from April 1, 2011 to March 31, 2012) financial forecast.

Under a strategic alliance established in February between Astellas Pharma and [Sanwa Kagaku Kenkyusho Co., Ltd.](#) (“SKK”; Headquarters: Nagoya; President: Kazuo Yamamoto) for Japan’s pharmaceutical market in kidney disease, both companies will co-promote Kiklin Capsules while Astellas Pharma will oversee distribution.

Astellas Pharma expects to provide an additional therapeutic option in treating hyperphosphatemia by introducing Kiklin Capsules into the Japanese market.

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PRODUCT SUMMARY

Product name: Kiklin<sup>®</sup> Capsules 250mg

Generic name: Bixalomer

Indication: Treatment of hyperphosphatemia in the following patients:  
Patients on dialysis with chronic kidney disease

Dosage regimen The usual starting dose of Bixalomer for adults is 500mg three times daily just before meals. The dose can be adjusted based on symptoms and serum phosphorus concentration. The maximum daily dose should not exceed 7,500mg.

For inquiries or additional information
Astellas Pharma Inc. Corporate Communications TEL: +81-3-3244-3201, FAX:+81-3-5201-7473 <a href="http://www.astellas.com/en">http://www.astellas.com/en</a>