

## **Astellas Pharma Launches Kiklin<sup>®</sup> Capsules, a Treatment for Hyperphosphatemia, in Japan**

### **-Provides a New Option for Patients with Hyperphosphatemia-**

Tokyo, June 25, 2012 - [Astellas Pharma Inc.](#) (“Astellas Pharma”; Tokyo:4503; President and CEO: Yoshihiko Hatanaka) today announced that Kiklin<sup>®</sup> Capsules 250mg (generic name: Bixalomar) will become available in the Japanese market on June 26, 2012, 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.

Astellas Pharma expects to provide an additional therapeutic option in treating hyperphosphatemia by introducing Kiklin Capsules into the Japanese market. Under a strategic alliance established in February 2012 between Astellas Pharma and [Sanwa Kagaku Kenkyusho Co., Ltd.](#) for Japan’s pharmaceutical market in kidney disease, both companies will co-promote Kiklin Capsules while Astellas Pharma will oversee distribution. Astellas anticipates that peak sales of Kiklin may reach 7 billion yen (based on the NHI drug price) in FY2016.

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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.
Package:	Kiklin <sup>®</sup> Capsules 250mg: 100 Capsules, 500 Capsules
Drug Price:	Kiklin <sup>®</sup> Capsules 250mg: 29.70Yen
Drug price listing date:	29 May, 2012
Sales commencement date:	26 June, 2012 (Plan)

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>