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Press Release

[Mitsubishi Tanabe Pharma Corporation](#)

BindRen[®] Granted Marketing Authorization in Europe for
Treatment of Hyperphosphatemia

Osaka, Japan, January 29, 2013—Mitsubishi Tanabe Pharma Corporation (President and CEO: Michihiro Tsuchiya) announced today that its overseas subsidiary Mitsubishi Pharma Europe Ltd. received marketing authorization from the European Commission for non-absorbed phosphate binder BindRen[®] [generic name: colestimide (JAN*), colestilan (INN**)] for the treatment of hyperphosphataemia in adult patients with Chronic Kidney Disease (CKD) Stage 5 receiving haemodialysis or peritoneal dialysis. The marketing authorization follows a positive opinion issued in September, 2012, by the Committee for Medical Products for Human Use (CHMP) of the European Medicines Agency (EMA).

In patients with reduced renal function, phosphorus is not sufficiently excreted into the urine via the kidneys and accumulates in the body, which can lead to hyperphosphatemia. Persistent hyperphosphatemia causes secondary hyperparathyroidism and even nephrogenic osteopathy characterized by bone pain and a tendency for bone fracture. Additionally, phosphorus binds to calcium to form calcium phosphate, which in turn causes calcinosis on vascular walls, heart, lungs and other internal organs, as well as periarticular areas. Because this represents an increased risk for cardiovascular disease, it is of paramount importance to properly manage the serum phosphate level.

This product is a non-absorbed anion exchange resin for oral administration, reducing the serum phosphorus level by adsorbing phosphoric acid in the gastrointestinal tract and excrete it into the feces. In phase 2 and 3 clinical studies in dialysis patients with chronic kidney disease in Europe and the US, the product significantly lowered the serum phosphorus level and calcium-phosphate product. Also observed were LDL cholesterol and HbA1c level reductions thanks to bile acid adsorption in the gastrointestinal tract, as well as serum uric acid level reduction. Reported common adverse reactions include nausea, vomiting, and indigestion.

In Japan, the product has been marketed since 1999 for the treatment of hypercholesterolemia under the brand name of CHOLEBINE[®].

Mitsubishi Tanabe Pharma is planning to prepare for marketing in coming April BindRen[®] in Germany.

We expect to contribute to improving quality of life for patients with chronic kidney disease in Europe through this introduction of BindRen[®] for the treatment of hyperphosphatemia in the nephrology area.

- * JAN: Japanese accepted name
- ** INN: international nonproprietary name

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