ONO PHARMACEUTICAL CO.,LTD.

December 19, 2016

ONO Receives Manufacturing and Marketing Approval in Japan for PARSABIV® (INN: Etelcalcetide Hydrochloride; Development Code: ONO-5163), a Calcimimetic Agent, for the Treatment of Secondary Hyperparathyroidism in Patients on Hemodialysis

ONO PHARMACEUTICAL CO., LTD. (Osaka, Japan; President, Representative Director and CEO: Gyo Sagara; "ONO") today announced that ONO received a manufacturing and marketing approval in Japan for PARSABIV® Intravenous Injection for Dialysis 2.5 mg, 5 mg, and 10 mg (Parsabiv), which is a calcimimetic agent, for the treatment of secondary hyperparathyroidism in patients on hemodialysis on December 19, 2016.

Secondary hyperparathyroidism, one of complications of chronic renal failure, is a pathological condition where excessive parathyroid hormone (PTH) is secreted by the parathyroid gland. Excessive PTH secretion promotes phosphorus and calcium efflux from bone which may cause symptoms including bone and joint pain. Further, it is reported that vascular calcification due to accumulation of phosphorus and calcium from bone in vessels aggravates risk of cardiovascular events which adversely affects life prognosis.*

Parsabiv activates the calcium sensing receptor in the parathyroid and suppresses excessive PTH secretion, and also lowers phosphorus and serum calcium level. Parsabiv is an Intravenous injection for dialysis patients to be administered through the dialysis circuit by the physician or medical staff upon completion of dialysis and such administration is expected to reduce the burden of oral medications in patients.

In Japan, ONO has exclusive rights to develop and commercialize Parsabiv, in accordance with the license agreement concluded with KAI Pharmaceuticals, Inc., now a wholly-owned subsidiary of Amgen, in September 2011. In the U.S., Amgen submitted a New Drug Application (NDA) of etelcalcetide for the treatment of secondary hyperparathyroidism in adult patients with chronic kidney disease on hemodialysis to the Food and Drug Administration (FDA) in August 2015. In September 2015, Amgen also submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) via the centralized review procedure. On November 11, 2016, the European Commission (EC) granted the marketing authorization for etelcalcetide (trade name in Europe: Parsabiv™) for the treatment of secondary hyperparathyroidism in adult patients with chronic kidney disease on hemodialysis.

* Japanese Clinical Practice Guideline for the management of chronic kidney disease-mineral and bone disorders (CKD-MBD) issued by the Japanese Society for Dialysis Therapy in 2012.

Overview of Parsabiv®

Product name	Parsabiv® Intravenous Injection for Dialysis 2.5mg Parsabiv® Intravenous Injection for Dialysis 5mg Parsabiv® Intravenous Injection for Dialysis 10mg
Generic name (INN)	Etelcalcetide Hydrochloride
Indication	Secondary hyperparathyroidism in patients on hemodialysis
Dosage and administration	In adults, Parsabiv is usually administered into venous line of the dialysis circuit at the end of dialysis session during rinse back at a dose of 5 mg as etelcalcetide 3 times a week as a starting dose. Thereafter, the dose may be adjusted in a range from 2.5 mg to 15 mg as necessary and administered 3 times a week at the end of dialysis session during rinse back while parathyroid hormone (PTH) and serum calcium level should be carefully monitored in patients.
Manufacturer/distributor	ONO PHARMACEUTICAL CO., LTD.
Conditions for approval	ONO should establish Risk Management Plan to be implemented appropriately.

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