ONO PHARMACEUTICAL CO.,LTD.

February 15, 2017

Launch of PARSABIV® Intravenous Injection for Dialysis (Generic Name: Etelcalcetide Hydrochloride), a Calcimimetic Agent, for Treatment of Secondary Hyperparathyroidism in Patients on Hemodialysis

Ono Pharmaceutical Co., Ltd. (Osaka, Japan; President, Representative Director and CEO, Gyo Sagara; "ONO") announced today that it launched PARSABIV® Intravenous Injection for Dialysis 2.5 mg, 5 mg and 10 mg (generic name: etelcalcetide hydrochloride, "Parsabiv") for the treatment of secondary hyperparathyroidism in patients on hemodialysis on February 15, 2017.

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 in September 2011 with KAI Pharmaceuticals, Inc., now a wholly-owned subsidiary of Amgen. In Europe, Amgen received an approval for a Marketing Authorization Application (MAA) of Parsabiv from the European Commission (EC) for the treatment of secondary hyperparathyroidism in adult patients with chronic kidney disease on hemodialysis on November 11, 2016. In the US, Amgen received an approval for a New Drug Application (NDA) of Parsabiv for the treatment of secondary hyperparathyroidism in adult patients with chronic kidney disease on hemodialysis from the Food and Drug Administration (FDA) on February 7, 2017.

* 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® Intravenous Injection for Dialysis

Product name	Parsabiv® Intravenous Injection for Dialysis 2.5 mg Parsabiv® Intravenous Injection for Dialysis 5 mg Parsabiv® Intravenous Injection for Dialysis 10 mg
Generic name	Etelcalcetide Hydrochloride
Indications	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.
Packaging	Parsabiv Intravenous Injection for Dialysis 2.5mg : 10 vial Parsabiv Intravenous Injection for Dialysis 5mg : 10 vial Parsabiv Intravenous Injection for Dialysis 10mg : 10 vial
Manufacturing and marketing approval date	December 19, 2016
Drug price listing date	February 15, 2017
Drug price	Parsabiv Intravenous Injection for Dialysis 2.5mg vial: ¥873 Parsabiv Intravenous Injection for Dialysis 5mg vial: ¥1,283 Parsabiv Intravenous Injection for Dialysis 10mg vial: ¥1,885
Launched date	February 15, 2017
Distributor	Ono Pharmaceutical Co., Ltd.
Conditions for approval	ONO should establish Risk Management Plan to be implemented appropriately.

Product photograph

ONO PHARMACEUTICAL CO., LTD.
Corporate Communications
public_relations@ono.co.jp