

December 21, 2020

Launch of Parsabiv® Intravenous Injection Syringe for Dialysis, a Calcimimetic Agent in Japan

Ono Pharmaceutical Co., Ltd. (Headquarters: Osaka; President, Representative Director, Gyo Sagara; "ONO") today announced that ONO has launched for Parsabiv® (generic name: etelcalcetide hydrochloride) Intravenous Injection Syringe for Dialysis 2.5 mg, 5 mg and 10 mg ("Parsabiv Syringe"), a calcimimetic agent in Japan.

In addition to the intravenous injection for dialysis (vial formulation) already approved for the treatment of secondary hyperparathyroidism in patients on hemodialysis, Parsabiv is now available as an intravenous injection syringe for dialysis in the same indication in Japan.

Parsabiv Syringe, which is pre-filled with the drug in its syringe, can allow the drug to be administered smoothly. We believe, therefore, that it serves not only to reduce the burden of health professionals involved in the treatment of secondary hyperparathyroidism under hemodialysis, but also to reduce the infection risks. In addition, since the product name of Parsabiv is described on the syringe, it also serves to prevent product mix-up.

About secondary hyperparathyroidism

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*.

* 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.

About Parsabiv

Parsabiv activates the calcium sensing receptor in the parathyroid and suppresses excessive PTH secretion, and also lowers phosphorus and serum calcium level.

Parsabiv is the first intravenous calcium receptor agonist in the world which ONO in-licensed from the former U.S company, KAI Pharmaceuticals, Inc. (later acquired by Amgen) in September 2011. In Japan, ONO received a manufacturing and marketing approval of Parsabiv for the treatment of secondary hyperparathyroidism in patients on hemodialysis in December 2016, and launched it under the product name of "Parsabiv® Intravenous Injection for Dialysis 2.5 mg, 5 mg and 10 mg" in February 2017.

Abroad, Amgen received an approval of Parsabiv in Europe in November 2016 and in the U.S in February 2017 for the treatment of secondary hyperparathyroidism in adult patients with chronic kidney disease on hemodialysis.

Overview of Parsabiv® Intravenous Injection Syringe for Dialysis

Product name	Parsabiv® Intravenous Injection Syringe for Dialysis 2.5mg, 5mg, 10mg
Generic name	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.
Approval date	June 29, 2020
NHI price listing date	November 25, 2020
NHI drug price	Parsabiv® Intravenous Injection Syringe for Dialysis 2.5mg: ¥ 895 Parsabiv® Intravenous Injection Syringe for Dialysis 5mg: ¥1,287 Parsabiv® Intravenous Injection Syringe for Dialysis 10mg: ¥1,864
Distributor	Ono Pharmaceutical Co., Ltd.

Product photograph



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