ONO PHARMACEUTICAL CO.,LTD.

June 29, 2020

ONO Receives Manufacturing and Marketing Approval in Japan for Parsabiv® Intravenous Injection Syringe for Dialysis, a Calcimimetic Agent

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

With this approval, Parsabiv is available as a new intravenous injection syringe for dialysis, in addition to the intravenous injection for dialysis already approved for the treatment of secondary hyperparathyroidism in patients on hemodialysis.

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. Since the product name of Parsabiv is put on the syringe, it is also served 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 for Parsabiv 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, Parsabiv was approved 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 2.5 mg, 5 mg and 10 mg

Product name	Parsabiv® Intravenous Injection Syringe for Dialysis 2.5mg Parsabiv® Intravenous Injection Syringe for Dialysis 5mg Parsabiv® Intravenous Injection Syringe for Dialysis 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.
Packaging	Parsabiv® Intravenous Injection Syringe for Dialysis 2.5mg: 10 syringe Parsabiv® Intravenous Injection Syringe for Dialysis 5mg: 10 syringe Parsabiv® Intravenous Injection Syringe for Dialysis 10mg: 10 syringe
Approval date	June 29, 2020
Distributor	Ono Pharmaceutical Co., Ltd.

Contact
Ono Pharmaceutical Co., Ltd.
Corporate Communications
public_relations@ono.co.jp