ONO PHARMACEUTICAL CO.,LTD.

May 24, 2016

ONO Announces Results from Phase 1/2 and Phase 3 Clinical Studies of "Etelcalcetide Hydrochloride (ONO-5163)" in Hemodialysis Patients with Secondary Hyperparathyroidism in Japan at ERA-EDTA Congress

ONO PHARMACEUTICAL CO., LTD. (Osaka, Japan; President, Representative Director and CEO: Gyo Sagara; "ONO") today announced the results from Japanese Phase 1/2 and Phase 3 clinical studies of etelcalcetide hydrochloride (ONO-5163; "etelcalcetide") in hemodialysis patients with secondary hyperparathyroidism. The results were presented at the 53rd European Renal Association - European Dialysis and Transplant Association (ERA-EDTA) Congress in Vienna on May 23 (Austria time).

Secondary hyperparathyroidism, one of complications of chronic renal failure, is a pathological condition where excessive parathyroid hormone (PTH) is secreted by 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.*

Phase 1/2 clinical study - Safety, Tolerability, Pharmacokinetics and Pharmacodynamics
The results showed that the serum intact parathyroid hormone (iPTH)-lowering effect was maintained following single or 4-week multiple dose administration of etelcalcetide in a dose dependent manner in Japanese hemodialysis patients with secondary hyperparathyroidism.

Phase 3 clinical study - Efficacy and Safety
The results showed that the percentage of patients achieving serum iPTH management level within 60-240 pg/mL (recommended by JSDT guideline*) at 85 days after the first dose of study drug, the primary endpoint, was significantly higher in the etelcalcetide group (59.0%) than in the placebo group (1.3%) following 12-week multiple dose.

Etelcalcetide hydrochloride is currently developed in an intravenous formulation to be administered through dialysis circuit by physician or medical staff upon completion of dialysis, and such administration is expected to reduce the burden of medication in patients.

In Japan, ONO entered into an exclusive license agreement with former KAI Pharmaceuticals, Inc. (now a subsidiary of Amgen) in September 2011 to develop and commercialize etelcalcetide.

In January 2016, ONO submitted a Manufacturing and Marketing Application for etelcalcetide in Japan for the treatment of secondary hyperparathyroidism in hemodialysis patients.
In the U.S. and Europe, Amgen submitted a New Drug Application of etelcalcetide for the treatment of secondary hyperparathyroidism in patients with chronic kidney disease on hemodialysis to the US Food and Drug Administration in August 2015, and submitted a Marketing Authorization Application to the European Medicines Agency via the centralized review procedure in September 2015, respectively.

* 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.

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