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ONO Submits Manufacturing and Marketing Approval Application in Japan for "Etelcalcetide Hydrochloride" (ONO-5163), a Calcimimetic Agent, for Secondary Hyperparathyroidism in Patients on Hemodialysis

ONO PHARMACEUTICAL CO., LTD. (Osaka, Japan; President, Representative Director and CEO: Gyo Sagara, "ONO") today announced the submission of Manufacturing and Marketing Approval Application in Japan for "etelcalcetide hydrochloride" (ONO-5163) , a calcimimetic agent, to seek an indication for the treatment of secondary hyperparathyroidism in patients with chronic kidney disease on hemodialysis.

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.*

Etelcalcetide hydrochloride activates calcium sensing receptor in the parathyroid and suppresses excessive PTH secretion, and also lowers phosphorus and serum calcium level. 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 hydrochloride.
Amgen submitted a New Drug Application for etelcalcetide to the US Food and Drug Administration for the treatment of secondary hyperparathyroidism in patients with chronic kidney disease on hemodialysis in August 2015 and submitted a Marketing Authorization Application to the European Medicines Agency via the centralized review procedure in September 2015.

* 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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