ONO PHARMACEUTICAL CO.,LTD.

Nov 18, 2016

ONO Announces Results from Phase 1/2 and Long-term Clinical Studies of "Etelcalcetide Hydrochloride (ONO-5163)" in Hemodialysis Patients with Secondary Hyperparathyroidism in Japan at ASN Kidney Week 2016

ONO PHARMACEUTICAL CO., LTD. (Osaka, Japan; President, Representative Director and CEO: Gyo Sagara; "ONO") today announced the results from Japanese Phase 1/2 and Long-term clinical studies of etelcalcetide hydrochloride (ONO-5163; "etelcalcetide") in hemodialysis patients with secondary hyperparathyroidism. These results were presented at the American Society of Nephrology (ASN) Kidney Week 2016 in Chicago, Illinois, US on November 17 (local 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 after 4-week multiple dosing, etelcalcetide dose-dependently decreased serum levels of tartrate-resistant acid phosphatase isoform 5b (TRACP-5b), a bone resorption marker, as well as previously reported serum intact PTH (iPTH) level.

Long-term clinical study - Safety and Efficacy
190 patients were received etelcalcetide, the results of this study showed that etelcalcetide was well-tolerated after its 52-week multiple dosing administration. 87.5% (140/160) of patients achieved the target iPTH range of 60-240 pg/mL (recommended by JSDT guideline*).

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 oral 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. On October 31 of the same year, Japan's Pharmaceutical Affairs and Food Sanitation Council's (PAFSC) First Committee on Drugs recommended approval for etelcalcetide. PAFSC is a key advisory committee that makes recommendations to the Ministry of Health, Labor and Welfare (MHLW).

In the U.S., Amgen submitted a New Drug Application (NDA) of etelcalcetide for the treatment of secondary hyperparathyroidism in adult patients with chronic kidney disease on hemodialysis to the Food and Drug Administration (FDA) in August 2015.
In September 2015, Amgen also submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) via the centralized review procedure for marketing approval in Europe. On Nov. 11 of 2016 (local time), the European Commission (EC) granted the marketing authorization for etelcalcetide (trade name in Europe: Parsabiv™) for the treatment of secondary hyperparathyroidism in adult patients with chronic kidney disease on hemodialysis.

* 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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