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Discontinuation of Development for the Additional Indication of Carpal-Tunnel Syndrome, for Limaprost, an Oral Prostaglandin E1 Analogue

Osaka, Japan, January 25, 2013 – Ono Pharmaceutical Co., Ltd. (Ono) and Dainippon Sumitomo Pharma Co., Ltd. (DSP) announced today that the companies had decided to discontinue development of limaprost alfadex (generic name: hereinafter referred to as limaprost) that had been performed jointly by the two companies for an additional indication of carpal-tunnel syndrome.

Limaprost is an oral prostaglandin E1 analogue and was discovered from collaborative research between Ono and DSP. It was approved for the treatment of ischemic symptoms such as skin ulcer, pain and coldness accompanying thromboangiitis obliterans in 1988, and for the treatment of subjective symptoms such as pain and numbness in the lower leg and walking disability associated with acquired lumbar spinal canal stenosis as an additional indication in 2001. The drug has been sold under the trade name of Opalmon[®] Tablets by Ono and Prorenal[®] Tablets by DSP.

Both companies have been jointly developing limaprost for an additional indication of carpal-tunnel syndrome and conducted a phase 2 study to investigate the efficacy of the drug. However, the study failed to demonstrate the anticipated efficacy. Both companies therefore decided to discontinue the development of limaprost for the additional indication of carpal-tunnel syndrome.

[Reference]

Carpal-tunnel syndrome is a neurological disorder mainly associated with numbness and pain in the hands and fingers. It has been reported that it results from compression, from any cause on the median nerve of the base of the hands, and is involved with the reduction in blood flow of the compressed nerve tissue.