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Discontinuation of Development for an Additional Indication of Cervical Spondylosis of Limaprost Alfadex, an Oral Prostaglandin E₁ Derivative Preparation

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 cervical spondylosis. The phase II study was performed to explore efficacy in patients with the disease but failed to demonstrate the anticipated efficacy.

Limaprost, an oral prostaglandin E1 derivative, jointly developed by Ono and DSP, was approved in 1988 with an indication for the "improvement of various ischemic symptoms such as ulcer, pain and feeling of coldness associated with thromboangiitis obliterans." The product was also approved in 2001 with an additional indication for the "improvement of subjective symptoms (pain and numbness of lower legs) and gait ability associated with acquired lumbar spinal canal stenosis." The product has been marketed by the two companies under two independent brands (Ono: OPALMON® Tablet 5 μ g; DSP: PRORENAL® Tablet 5 μ g).

<<Reference>>

Cervical spondylosis is a disorder mainly caused by age-related changes in the cervical spine (deformation of intervertebral disc and protrusion of a bone called spur), which compress spinal marrow and nerve root, eventually resulting in nerve functional impairment. It is said that the poor blood circulation attributed to the compressed nervous system is involved in the onset of cervical spondylosis leading to symptoms such as numbness and pain in extremities.