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Ono Enters Into Joint Development/Co-Marketing Agreement on an Additional Indication for Cervical Spondylosis of Limaprost Alfadex, an Oral Prostaglandin E_1 Derivative Preparation, with Dainippon Sumitomo

Ono Pharmaceutical Co., Ltd. (Ono) announced today that the company had signed a joint development/co-marketing agreement with Dainippon Sumitomo Pharma Co., Ltd. (Dainippon) in order to obtain approval for an additional indication for cervical spondylosis of limaprost alfadex (generic name: hereinafter referred to as limaprost).

Limaprost, an oral prostaglandin E_1 derivative, jointly developed by Ono and Dainippon, 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.” This 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.” This product has been marketed by the two companies under two independent brands (Ono: OPALMON® Tablet 5 μg; Dainippon: PRORENAL® Tablet 5 μg).

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. Symptoms such as numbness and pain in extremities occur.

Limaprost, an improvement drug for peripheral circulatory failure with a vasodilator action and an antithrombotic effect, improves poor blood flow in the nerve tissue in cervical spondylosis and normalizes the nerve function. It is therefore greatly expected that limaprost will be developed as a drug for remitting numbness and pain in the extremities.