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Application Submission for Approval for the Stability-Improved Formulation of Limaprost, an Oral Prostaglandin E_1 Analogue in Japan

Osaka, Japan, August 6, 2013 – Ono Pharmaceutical Co., Ltd. (Headquarters: Osaka, Japan; President: Gyo Sagara; "Ono") and Dainippon Sumitomo Pharma Co., Ltd. (Headquarters: Osaka , Japan; President: Masayo Tada; "DSP") announced today that the companies have submitted an application for approval for a new stability-improved formulation of limaprost (generic name), a drug for peripheral circulatory disturbance which have been marketed by the two companies.

Limaprost is an oral prostaglandin E_1 analogue and was discovered from collaborative research between Ono and DSP. It was approved for the improvement of various ischemic symptoms such as ulcer, pain and feeling of coldness associated with thromboangiitis obliterans in 1988, and for the improvement of subjective symptoms (pain and numbness of lower legs) and gait ability associated with acquired lumbar spinal canal stenosis (in patients with bilateral intermittent claudication showing normal SLR test result) 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 in Japan.

The new formulation has been improved in stability to humidity under conditions of being taken out from PTP sheet. Both companies expect the new formulation will improve the handling of prescription, e.g., being packaged together with other drugs may be possible at medical institutions or pharmacies, which will contribute to further improvement of treatment compliance for patients.