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

ONO PHARMACEUTICAL CO.,LTD ("ONO"; Osaka, Japan; President, Representative Director and CEO, Gyo Sagara) and Sumitomo Dainippon Pharma Co., Ltd. ("Sumitomo Dainippon"; Osaka, Japan; President, Representative Director and CEO, Masayo Tada) announced today that the companies received approval in Japan on October 3, 2014 for a new stability-improved formulation of limaprost alfadex (generic name), a drug for peripheral circulatory disturbance which has been marketed by the two companies.

The new formulation has been improved in stability to humidity under conditions of being taken out from PTP sheet. Also bottled products have been newly launched. 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.

About Limaprost

Limaprost is an oral prostaglandin E1 analogue and was discovered from collaborative research between ONO and Sumitomo Dainippon. 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 Sumitomo Dainippon in Japan.