

Company News

April 23, 2001

Ono Pharmaceutical Co., Ltd.
Dainippon Pharmaceutical Co., Ltd.

Additional Indication Approved for Limaprost, Oral Prostaglandin E₁ Derivative

Limaprost alfadex, an oral prostaglandin E₁ derivative, jointly developed by Ono Pharmaceutical Co., Ltd. (Ono) and Dainippon Pharmaceutical Co., Ltd. (Dainippon), was approved in 1988 with an indication for treatment of various ischemic symptoms such as ulcer, pain and sensation of coldness of the hands and feet associated with thromboangiitis obliterans. This product has since been marketed by the two companies under two independent brands (Ono: OPALMON[®] Tablet; Dainippon: PRORENAL[®] Tablet).

The two companies have jointly sought since 1991 to further expand the indication of limaprost for the treatment of lumbar spinal canal stenosis, based on the report that limaprost improved blood flow not only of limbs but of blood vessels supplying nutrition to the cauda equina, a mass of spinal nerves extending within lumbar spinal canal.

With the efficacy and safety successfully confirmed by the two companies' research efforts, limaprost was approved on April 4, 2001 for "improvement in subjective symptoms (pain and numbness in lower limbs) and walking ability, which accompany acquired lumbar spinal canal stenosis (patients who show bilateral intermittent claudication but with normal Straight Leg Raising (SLR) test)." No other agent has ever obtained approval for this indication, either in Japan or abroad.

Since lumbar spinal canal stenosis is mainly observed among the elderly people, the number of patients suffering from the disease is anticipated to increase as the population ages. Age-related changes in a bone (deformation of intervertebral joints and vertebra) and/or hypertrophy of the ligaments that cover the inner wall of the spinal canal contribute to a narrowing of the lumen of the lumbar spinal canal. Such a narrowed lumen contributes to poor blood circulation of the cauda equina, leading to lack of nutrition in the area and eventually resulting in neurologic functional impairment. As a result, pain and numbness are caused in lower limbs, which consequently lead to difficulty in walking (intermittent claudication) in many cases.

Limaprost improves the supply of nutrients to the cauda equina by stimulating blood circulation. Better neurologic function of the cauda equina will help reduce pain and numbness of the limbs and improve walking ability (intermittent claudication). It is therefore greatly expected that limaprost will be useful in promoting quality of life (QOL) of patients by remitting various symptoms accompanying lumbar spinal canal stenosis.