



Press Release

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Daiichi Sankyo Submits Marketing Application for Mirogabalin in Japan

TOKYO, Japan (February 15, 2018) – Daiichi Sankyo Company, Limited (hereinafter, Daiichi Sankyo) announces that today it filed a marketing application of the $\alpha 2\delta$ ligand^{*1}, mirogabalin, for peripheral neuropathic pain (PNP)^{*2} in Japan.

This application is based on a phase 3 clinical trial in patients with diabetic peripheral neuropathic pain (DPNP)^{*3} and a phase 3 clinical trial in patients with postherpetic neuralgia (PHN)^{*4} carried out in Asia, including Japan (primary endpoints were achieved in both trials).

Daiichi Sankyo expects mirogabalin to benefit patients and healthcare professionals in Japan by providing a new therapeutic option for the treatment of peripheral neuropathic pain.

***1. $\alpha 2\delta$ (Alpha 2 delta) ligand**

$\alpha 2\delta$ ligand binds to the $\alpha 2\delta$ subunits of voltage-dependent calcium channels.

***2. Peripheral neuropathic pain (PNP)**

PNP is caused by damage or functional abnormality of peripheral nerves due to various causes. Typical PNP is diabetic PNP (DPNP)^{*3} and postherpetic neuralgia (PHN)^{*4}.

***3. Diabetic peripheral neuropathic pain (DPNP)**

DPNP is a typical example of PNP caused by nerve damage. Diabetic peripheral neuropathy is a disorder that causes neuropathy and numbness to the extremities and is one of the most common long-term 3 major complications of diabetes. Its symptoms include severe pain, hyperalgesia, numbness, impairment of

equilibrium and muscle movements, burning pain and pricking pain. Pain is often exacerbated during the night and may cause sleep disorders. Of the diabetic population estimated to exceed 10 million in Japan, 9-22% of the patients are reported to suffer DPNP.

*4. Postherpetic neuralgia (PHN)

PHN is a typical example of PNP caused by nerve damage. Onset of herpes zoster is caused by a decline of immunity against varicella-zoster virus which established latent infection in ganglia. In PHN, burning pain or pain shooting through the body like electricity persists even after cure of herpes zoster. It is regarded as one of the intractable pains, which cause muscle weakness and paralysis in rare cases. PHN is reported to affect 10-25% of the 500-600 thousand Japanese who develop herpes zoster annually.