



## Press Release

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### **Daiichi Sankyo Announces Marketing Approval in Japan of “Tarlige® Tablets” for Pain Treatment**

**Tokyo, Japan (January 8, 2019)** – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced the receipt of marketing approval in Japan for Tarlige® Tablets 2.5 mg, 5 mg, 10 mg, 15 mg (generic name: mirogabalin besylate; hereafter, the drug) for the treatment of peripheral neuropathic pain (PNP)\*1

This drug, an  $\alpha_2\delta$  ligand\*2 created by Daiichi Sankyo, was submitted for marketing approval in February 2018 on the basis of the results of 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. Both trials were conducted in Asia and including Japan.

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

\*1. 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)<sup>\*3</sup> and postherpetic neuralgia (PHN)<sup>\*4</sup>.

\*2.  $\alpha_2\delta$  (Alpha<sub>2</sub> delta) ligand

$\alpha_2\delta$  ligand binds to the  $\alpha_2\delta$  subunits of voltage-dependent calcium channels.

\*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.

<Product Outline>

Brand name	“Tarlige® Tablets 2.5 mg, 5 mg, 10 mg, 15 mg”
Generic name	mirogabalin besylate
Date of approval for manufacturing and marketing	January 8, 2019
Indication	Peripheral neuropathic pain
Dosage and administration	Normally, the initial dose for adults is 5 mg of mirogabalin given orally twice daily, and then the dose is gradually increased by 5 mg at an interval of at least a week to 15 mg, given orally twice daily. A dose may be adjusted appropriately between 10 mg and 15 mg depending on ages and symptoms, given twice daily.