



## Press Release

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### **Daiichi Sankyo Launches “Tarlige® Tablets” for Pain Treatment in Japan**

**Tokyo, Japan (April 15, 2019)** – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced the launch of Tarlige® Tablets 2.5 mg, 5 mg, 10 mg, 15 mg (generic name: mirogabalin besilate; hereafter, the drug) for the treatment of pain in Japan.

This drug, an  $\alpha_2\delta$  ligand<sup>\*1</sup>, created by Daiichi Sankyo, was approved for marketing in Japan in January 2019 on the basis of the results of phase 3 clinical trials conducted in Asia including Japan in patients with diabetic peripheral neuropathic pain (DPNP)<sup>\*2</sup> and postherpetic neuralgia (PHN)<sup>\*3</sup>, for the indication of peripheral neuropathic pain (PNP)<sup>\*4</sup>.

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

### Product Outline

Brand name	Tarlige® Tablets 2.5 mg, 5 mg, 10 mg, 15 mg
Generic name (JAN)	mirogabalin besilate
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.
Drug price	Tarlige® Tablets 2.5 mg: 78.00 yen/tablet Tarlige® Tablets 5 mg: 107.70 yen/tablet Tarlige® Tablets 10 mg: 148.70 yen/tablet Tarlige® Tablets 15 mg: 179.60 yen/tablet
Date of approval	January 8, 2019
Date of listing in the NHI price	February 26, 2019
Date of launch	April 15, 2019
Manufacture and Marketing	Daiichi Sankyo Company, Limited

#### \*1: $\alpha_2\delta$ (Alpha<sub>2</sub> delta) ligand

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

#### \*2: 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.

**\*3: 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.

**\*4: Peripheral neuropathic pain (PNP)**

PNP is caused by damage or functional abnormality of peripheral nerves due to various causes. Typical PNP are diabetic PNP (DPNP)<sup>\*2</sup> and postherpetic neuralgia (PHN)<sup>\*3</sup>.

**About Daiichi Sankyo**

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address diversified, unmet medical needs of patients in both mature and emerging markets. With over 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 15,000 employees around the world draw upon a rich legacy of innovation and a robust pipeline of promising new medicines to help people. In addition to a strong portfolio of medicines for hypertension and thrombotic disorders, under the Group's 2025 Vision to become a "Global Pharma Innovator with Competitive Advantage in Oncology," Daiichi Sankyo research and development is primarily focused on bringing forth novel therapies in oncology, including immuno-oncology, with additional focus on new horizon areas, such as pain management, neurodegenerative diseases, heart and kidney diseases, and other rare diseases. For more information, please visit: [www.daiichisankyo.com](http://www.daiichisankyo.com).