



Press Release

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Daiichi Sankyo Initiates Phase 3 Trial of Mirogabalin in Asian Post-spinal Cord Injury Neuropathic Pain Patients Including Japan

Tokyo, Japan (March 27, 2019) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) announced administration of the pain treatment mirogabalin (brand name: Tarlige®) has begun in the first patient of a phase 3 clinical trial (AMELA Trial) on post-spinal cord injury neuropathic pain*¹.

The trial will evaluate efficacy and safety in 274 patients with post-spinal cord injury neuropathic pain, a typical type of central neuropathic pain (CNP)*², in Asia (Japan, Taiwan, and South Korea). The primary endpoint of the trial is to compare change in the average daily pain score (ADPS), weekly average of daily pain score measuring pain intensity, from baseline to Week 14 with placebo.

Daiichi Sankyo expects the drug to benefit diverse patients suffering from pain by providing a new therapeutic option.

***1: Post-spinal cord injury neuropathic pain**

In post-spinal cord injury neuropathic pain, neuropathy due to the spinal cord injury causes characteristic pain symptoms, including intense pain, burning pain, hyperalgesia and numbness, which greatly reduce quality of life of patients. In Japan, the number of patients with spinal cord injuries is reported to be approximately 100,000 and around 5,000 people are newly injured every year. Among them, about 75,000 patients are reported to be suffered from post-spinal cord injury neuropathic pain.

***2: Central neuropathic pain (CNP)**

CNP is pain that arises from injury or impairment of central nerves. A typical CNP disease is post-spinal cord injury neuropathic pain.

About Mirogabalin

Mirogabalin is a novel $\alpha\delta$ ligand created by Daiichi Sankyo for the treatment of chronic pain. The drug is considered to exhibit an analgesic action by suppressing increased release of neurotransmitters in nerve endings involved in pain. Approval for the indication of peripheral neuropathic pain was obtained in January, 2019, in Japan.