

July 10, 2025

Notification Regarding a Joint Development and Distribution Agreement with TOYO Pharmaceutical for the Pain Treatment Drug for Postherpetic Neuralgia

Hisamitsu Pharmaceutical Co., Inc. (Head Office: Tosu City, Saga Prefecture; President and CEO: NAKATOMI, Kazuhide) is pleased to announce that it has entered into a joint development and licensing agreement in Japan with TOYO Pharmaceutical Co., Ltd. (Head Office: Osaka City, Osaka Prefecture; Representative Director and President: NISHIMURA, Hidekatsu) for a gel formulation (development code: TH-004; generic name: lidocaine) used to relieve pain associated with postherpetic neuralgia.

In Japan, topical formulations containing lidocaine (such as tapes, sprays, and gels) have been approved. However, formulations with efficacy against postherpetic neuralgia have not yet been applied. Although topical lidocaine formulations are sometimes prepared as in-hospital formulations, reports on their efficacy and safety are limited*1, and there are issues such as crystallization of the raw drug.

Against this background, the Japan Pain Clinic Society requested the development of a lidocaine formulation (gel 10%) to relieve pain associated with postherpetic neuralgia. A Review Meeting on Unapproved Drugs and Off-label Drugs with High Medical Needs, held on March 11, 2021, recognized the medical necessity. Following this, the Ministry of Health, Labour and Welfare recruited development companies, and TOYO Pharmaceutical undertook drug development.

The estimated number of patients with postherpetic neuralgia in Japan is approximately 106,000*2, and the introduction of this drug provides a new treatment option for patients suffering from pain. We aimed to enhance the pipeline in transdermal drug delivery system formulation and pain treatment, contributing to improving the patients' QOL.

Overview of TOYO Pharmaceutical Co. Ltd.

Company name	TOYO Pharmaceutical Co., Ltd.
Business details	Manufacturing and sales of pharmaceuticals and chemical industrial products
Location	1-5, Doshomachi 2-chome, Chuo-ku, Osaka City
Date of establishment	March 1918
Representative	Representative Director and President: NISHIMURA, Hidekatsu
Website	https://toyo-pharma.com/

*1: Survey on the Utilization of In-Hospital Formulation 10% Lidocaine Gel for Neuropathic Pain Jpn. J. Drug Inform., 25(3): 115-123 (2023)

*2: The Ministry of Health, Labour and Welfare: Request for Unapproved and Off-Label Drugs with High Medical Necessity Request for Unapproved and Off-Label Drugs (Target for Recruitment (1) (2)) IV-96 (Attached Form 1-1)