

This material is an English translation of the press release announced on Aug 20, 2021 in Japanese, and the Japanese release is given priority about the content and the interpretation.

Aug 20, 2021

Notification of application for manufacturing and marketing approval of the additional indications of “low back pain, humeroscapular peri-arthritis, cervico-omo-brachial syndrome and tenosynovitis” for ZICTHORU[®] Tapes (Transdermal, pain treatment NSAID patch, development code: HP-3150) in Japan

Hisamitsu Pharmaceutical Co., Inc. (Head Office: Tosu city, Saga Prefecture, Japan; President and CEO: Kazuhide Nakatomi, hereinafter referred to as “Hisamitsu”) announces that it has been submitted a new drug application for the additional indications of “low back pain, humeroscapular peri-arthritis, cervico-omo-brachial syndrome and tenosynovitis” for ZICTHORU[®] Tapes, transdermal, pain treatment NSAID patch (Development code: HP-3150, generic name: diclofenac sodium, hereinafter referred to as “the product”) in Japan as of today.

Hisamitsu has confirmed the efficacy and safety of the product in clinical trials in patients with low back pain and patients with humeroscapular peri-arthritis, cervico-omo-brachial syndrome and tenosynovitis.

The product is a systemic transdermal formulation developed using Hisamitsu’s TDDS (Transdermal Drug Delivery System) technology. By transdermal administration of the product once daily, the drug is transferred directly into the blood of the whole body without going through the gastrointestinal tract, and it is expected that the effect is maintained by means of maintaining a stable blood concentration for 24 hours. It can also be administered to patients who have difficulty swallowing, and the patient's medication status can be visually confirmed by family members and caregivers.

Hisamitsu obtained approval for manufacturing and marketing of the product for “Analgesia in various cancers” in March 2021. With this approval of the additional indications, Hisamitsu expects the product to be a new option for the treatment of low back pain, humeroscapular peri-arthritis, cervico-omo-brachial syndrome and tenosynovitis and contribute to further improving the quality of life of patients.

Hisamitsu Pharmaceutical aims to obtain a manufacturing and marketing approval of the additional indications during FY2022.