

This material is an English translation of the press release announced on Dec 7, 2020 in Japanese, and the Japanese release is given priority about the content and the interpretation.

Dec 7, 2020

Notification of the results of Phase III clinical study of HP-3150 for “low back pain, humeroscapular peri-arthritis, cervico-omo-brachial syndrome and tenosynovitis” in Japan (transdermal, pain treatment NSAID patch)

Hisamitsu Pharmaceutical Co., Inc. (Head Office: Tosu city, Saga Prefecture, Japan; President and CEO: Kazuhide Nakatomi, hereinafter referred to as Hisamitsu) announces that the transdermal, pain treatment NSAID patch (Development code: HP-3150, generic name: diclofenac sodium, hereinafter referred to as “the investigational product”) achieved the primary endpoint of the LP03 study, Phase III clinical study for “low back pain” and the LP04 study, Phase III clinical study for “humeroscapular peri-arthritis, cervico-omo-brachial syndrome and tenosynovitis” in Japan.

In the LP03 study, the efficacy and safety of administration of the investigational product once per day were compared with a placebo in patients with low back pain. As a result, there was a statistically significant difference in the primary endpoint when compared the investigational product group with the placebo group. In addition, no adverse reactions were observed that could cause major concerns in development.

In the LP04 study, the efficacy and safety of administration of the investigational product once per day were compared with a placebo in patients with humeroscapular peri-arthritis, cervico-omo-brachial syndrome and tenosynovitis. As a result, the efficacy of the investigational product was confirmed in the primary efficacy endpoint. In addition, no adverse reactions were observed that could cause major concerns in development.

The investigational product is a transdermal formulation developed using Hisamitsu’s TDDS (Transdermal Drug Delivery System) technology. Hisamitsu expects it to be a new option for the treatment of low back pain, humeroscapular peri-arthritis, cervico-omo-brachial syndrome and tenosynovitis to realize its long-lasting effect by means of maintaining a stable blood drug concentration.

In the future, Hisamitsu aims to apply for manufacturing and marketing approval during FY2021.