

This material is an English translation of the press release announced on May 24, 2019 in Japanese, and the Japanese release is given priority about the content and the interpretation.

May 24, 2019

Notification of the results of Phase III clinical study of HP-3150 in Japan for “cancer pain” (an analgesic transdermal drug containing NSAIDs)

Hisamitsu Pharmaceutical Co., Inc. (Head Office: Tosu city, Saga Prefecture, Japan; President and CEO: Kazuhide Nakatomi, hereinafter referred to as Hisamitsu) announces that the analgesic transdermal patch containing NSAIDs (Development code: HP-3150, generic name: diclofenac sodium, hereinafter referred to as “the investigational product”) achieved the primary endpoint of the Phase III clinical study for “cancer pain” in Japan.

In this study, the efficacy and safety of administration of the investigational product once per day were compared with a placebo in patients suffering from cancer 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.

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 cancer pain 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 FY2019.