

This material is an English translation of the press release announced on November 26, 2019 in Japanese, and the Japanese release is given priority about the content and the interpretation.

November 26, 2019

**Notification of the results of Phase II clinical study of HP-5000 in the U.S.
(Transdermal, pain relief and anti-inflammatory patch)**

Hisamitsu Pharmaceutical Co., Inc. (Head Office: Tosu city, Saga Prefecture, Japan; President and CEO: Kazuhide Nakatomi, hereinafter referred to as “Hisamitsu Pharmaceutical”) announces the results of the Phase II clinical trial in the U.S. for transdermal, pain relief and anti-inflammatory patch (Development code: HP-5000, generic name: Diclofenac Sodium, hereinafter referred to as “the investigational product”), involving patients with Osteoarthritis of the knee.

In this study, the efficacy and safety of the investigational product was compared to placebo in patients with Osteoarthritis of the knee. The study results suggested the investigational product was efficacious 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 Pharmaceutical expects the investigational product to be new treatment option for Osteoarthritis of the knee demonstrating efficacy and safety by achieving higher drug delivery to the affected area as one of the transdermal formulation attributes.

In the future, we aim to initiate Phase III clinical study during FY 2020.