This material is an English translation of the press release announced on January 4, 2021 in Japanese, and the Japanese release is given priority about the content and the interpretation.

January 4, 2021

Notification of the commencement of the Phase III 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 that it has commenced the Phase III clinical study 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"), for the treatment of Osteoarthritis knee pain.

In this study, the efficacy and safety of the investigational product will be compared to placebo in patients with Osteoarthritis of the knee.
The clinical study will be conducted by the U.S. subsidiary, Noven Pharmaceuticals, Inc. (Head Office: Florida, U.S.A.)

The investigational product is a transdermal formulation developed using Hisamitsu's TDDS (Transdermal Drug Delivery System) technology. Hisamitsu Pharmaceutical hopes the investigational product will be a 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 submit a NDA in the U.S. during FY 2023.