

This material is an English translation of the press release announced on September 25, 2017 in Japanese, and the Japanese release is given priority about the content and the interpretation.

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September 25, 2017

**Notification of the commencement of the Phase II clinical study  
of Investigational HP-5000 in the USA (an analgesic transdermal drug)**

Hisamitsu Pharmaceutical Co., Inc. (Head Office: Tosu city, Saga prefecture, Japan; Chairman and CEO: Hirotaka Nakatomi, hereinafter referred to as Hisamitsu) hereby announces that it has commenced the Phase II clinical study in the USA for an analgesic transdermal patch (Development code: HP-5000, Active pharmaceutical ingredient: Diclofenac, hereinafter referred to as “the investigational product”).

In the Phase II clinical study, the efficacy and safety of the investigational product will be compared to placebo in patients with Osteoarthritis knee pain.

The clinical trial 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. We expect the investigational product to be a safe and effective new treatment option for Osteoarthritis knee pain demonstrating higher drug delivery to the affected area as one of the transdermal formulation attributes.

We aim to initiate Phase III clinical study during FY 2019.



## **Delivering Patch Culture Hand by Hand**

Hisamitsu Pharmaceutical Co., Inc. was established in 1847 and has marked its 170th anniversary since its foundation thanks to the support of many people.