

This material is an English translation of the press release announced on October 28, 2022 in Japanese, and the Japanese release is given priority about the content and the interpretation.

October 28, 2022

**Notification of the Results of the Phase III Clinical Study of HP-5000
for Osteoarthritis Pain of the Knee in the U.S.
(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 the results of the Phase III clinical study of the 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 the U.S. was obtained.

This study was a 12-week, placebo-controlled, randomized, double-blind, parallel-group study in patients with osteoarthritis pain of the knee, to evaluate the efficacy and safety of the investigational product compared to placebo. The study did not meet its primary endpoint of statistically significant improvement in the osteoarthritis knee pain score (WOMAC) from baseline to week 12.

Hisamitsu Pharmaceutical will assess whether or not to continue further development of the drug through investigation of the results obtained from this study.