This material is an English translation of the press release announced on Jan 9, 2020 in Japanese, and the Japanese release is given priority about the content and the interpretation.

Jan 9, 2020

# Notification of the commencement of Phase III clinical study of HP-3150 for “low back pain, humeroscapular periarthritis, cervico-omo-brachial syndrome and tenosynovitis” in Japan (transdermal, pain treatment NSAID patch)

Hisamitsu Pharmaceutical Co., Inc. (Head Office: Tosu city, Saga Prefecture, Japan; President and CEO: Kazuhide Nakatomi, hereinafter referred to as Hisamitsu) announces that the transdermal, pain treatment NSAID patch (Development code: HP-3150, generic name: diclofenac sodium, hereinafter referred to as “the investigational product”) has commenced of the LP03 study, Phase III clinical study for “low back pain” in Japan. Hisamitsu also announces that the investigational product has commenced of the LP04 study, Phase III clinical study for “humeroscapular periarthritis, cervico-omo-brachial syndrome and tenosynovitis” in Japan.

In the LP03 study in patients with low back pain and in the LP04 study in patients with humeroscapular periarthritis, cervico-omo-brachial syndrome and tenosynovitis, the efficacy and safety of administration of the investigational product once per day are compared with a placebo.

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 low back pain, humeroscapular periarthritis, cervico-omo-brachial syndrome and tenosynovitis 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 FY2021.