This material is an English translation of the press release announced on October 10, 2024 in Japanese, and the Japanese release is given priority about the content and the interpretation.

October 10, 2024

Notification of the start of clinical development for HP-3150 (transdermal nonsteroidal pain treatment) in the U.S.

Hisamitsu Pharmaceutical Co., Inc. (Head Office: Tosu City, Saga Prefecture; President: NAKATOMI, Kazuhide; hereinafter “Hisamitsu Pharmaceutical”) announces that clinical development of a transdermal patch formulation with nonsteroidal anti-inflammatory drugs for pain treatment (development code: HP-3150, generic name: diclofenac sodium; hereinafter referred to as "the investigational product") for chronic lower back pain in the U.S. has been determined to initiate.

The investigational product is a systemic transdermal patch containing diclofenac sodium as the active ingredient, developed using Hisamitsu Pharmaceutical's TDDS (Transdermal Drug Delivery System) technology. In Japan, the investigational product has been obtained for the manufacturing and market approval as "ZICTHORU® Tapes" in March 2021 for the indications of "analgesia in various cancers"*1 and "analgesia and anti-inflammation in low back pain, humeroscapular periarthritis, cervico-omo-brachial syndrome and tenosynovitis"*2 in June 2022.

In the U.S., we have developed a topical patch formulation with nonsteroidal anti-inflammatory drugs (development code: HP-5000, generic name: diclofenac sodium) for the treatment of osteoarthritis of the knee. However, to accelerate expanding ZICTHORU® Tapes globally, instead of HP-5000, we now start conducting clinical development of this investigational product in the United States for the indication of "pain relief in chronic lower back pain" and aim to provide a new treatment option for chronic lower back pain in the U.S.

As a next step, we will start a clinical pharmacology study, which is the first clinical trial of this investigational product in the U.S., in fiscal year 2025. Based on the results from this clinical pharmacology study and also non-clinical and clinical results obtained in Japan, we aim to start Phase III clinical study in the U.S. in fiscal year 2026.

By transdermal administration of the product once daily, the drug is absorbed directly into the blood of the whole body without going through the gastrointestinal tract, and it is expected to provide sustained pain relief by means of maintaining a stable blood concentration for 24 hours. Furthermore, because the product is a systemic transdermal system that exerts effect via systemic circulation of blood, it does not need to be continuously applied to the site of pain. Therefore, it can be applied not only to the site of pain, but also to any sites where the patient can apply it, which is expected to reduce the skin damage. In addition, because the product is a systemic transdermal system, it can also be administered to patients who have difficulty swallowing. The patient's medication status can be visually confirmed by family members and caregivers (to prevent forgetting to apply or overdosing) and there are no restrictions on timing of administration due to dietary influences, which is expected to improve medication adherence.

Hisamitsu will contribute to further improving the quality of life of patients around the world by expanding ZICTHORU® Tapes not only in Japan but also overseas, including the U.S.

※1：Notification of approval for manufacturing and marketing approval of ZICTHORU® Tapes for “cancer pain” in Japan (Transdermal, pain treatment NSAID patch, development code: HP-3150)
https://global.hisamitsu/pdf/news_release_E_210323.pdf

※2：Notification of approval for manufacturing and marketing approval of the additional indications of “low back pain, humeroscapular periarthritis, cervico-omo-brachial syndrome and tenosynovitis” for ZICTHORU® Tapes (Transdermal, pain treatment NSAID patch, development code: HP-3150) in Japan
https://global.hisamitsu/pdf/news_release_E_220620.pdf