

- This material is an English translation of the press release announced on February 23, 2011 in Japanese, and the Japanese release is given priority about the content and the interpretation.

February 23, 2011

Announcement of the acquisition of marketing approval for transdermal long-acting chronic pain “NORSPAN® TAPE ”(development code: BTDS)

Hisamitsu Pharmaceutical Co., Inc. (HQ: Tosu, Saga, Japan; President/CEO: Hirotaka Nakatomi; hereinafter referred to as Hisamitsu) is pleased to announce that we were notified by Mundipharma K.K. that they have received as of today (February 23, 2011) a marketing approval for “NORSPAN® TAPE” (development code: BTDS), a buprenorphine patch developed by the company.

“NORSPAN® TAPE” is a long-acting transdermal patch indicated for analgesia of chronic pain associated with osteoarthritis and low back pain not being controlled sufficiently with non-opioid analgesics.

In August 2007, Hisamitsu acquired from Mundipharma the exclusive right to distribution of the product in Japan, for which Mundipharma K.K. filed an application for marketing approval in October 2008. We will receive a supply of products from Mundipharma K.K. and distribute them to customers.

In collaboration with Mundipharma K.K., we will further contribute to improving the quality of life of patients suffering from chronic pain through providing appropriate information and establishing the system to promote the proper use of the product.

<Reference >

Product name:	NORSPAN® TAPE 5 mg, NORSPAN® TAPE 10 mg, NORSPAN® TAPE 20 mg
Generic name:	Buprenorphine
Indication:	Relief of chronic pain associated with the following diseases of which the pain can not be controlled sufficiently with non-opioid analgesics: - Osteoarthritis - Low back pain
Dosage and administration:	Usually for adults, apply this product onto prothoracic part, upper part of back, outside of upper arm or side chest and change it every 7 days. The initial dose applied is set at 5 mg as buprenorphine, and the subsequent dose to be applied should be adjusted according to the symptom of patient as appropriate but should not exceed 20 mg.
Approval requirements	Appropriate actions should be taken at the time of marketing so that NORSPAN® TAPE will be prescribed/used by physicians who know how to make a diagnosis of and treat chronic pain accompanying osteoarthritis and low back pain; NORSPAN® TAPE will be used only at pharmacies and medical institutions where a physician or supervising pharmacist can sufficiently control and explain the risks of NORSPAN® TAPE, etc; and NORSPAN® TAPE will be dispensed at the pharmacies after the concerned physician/medical institution has confirmed its use.

