Notification of marketing of HARUROPI® TAPE in Japan (Transdermal, Parkinson's disease treatment patch, development code: HP-3000)

Hisamitsu Pharmaceutical Co., Inc. (Head Office: Tosu city, Saga Prefecture, Japan; President and CEO: Kazuhide Nakatomi, hereinafter referred to as "Hisamitsu Pharmaceutical") announces that Kyowa Kirin Co., Ltd., (Head office: Chiyoda-ku, Tokyo, Japan; President and CEO: Masashi Miyamoto, hereinafter referred to as "Kyowa Kirin") will launch HARUROPI⊚ TAPE, transdermal, Parkinson's disease treatment patch (Development code: HP-3000, generic name: ropinirole hydrochloride, hereinafter referred to as "the product") in Japan from December 17, 2019 following National Health Insurance (NHI) drug price listing on November 19, 2019.

The product is a systemic transdermal formulation developed using Hisamitsu Pharmaceutical's TDDS (Transdermal Drug Delivery System) technology and was approved for manufacturing and marketing in Japan on September 20, 2019. Hisamitsu Pharmaceutical expects its long-lasting effect by means of maintaining a stable blood concentration, and the product to be a new option for the treatment of Parkinson's disease.

Kyowa Kirin will be responsible for commercializing the product and providing medical information of the product based on an agreement for exclusive rights to commercialize the product in Japan executed in February 2019. Hisamitsu Pharmaceutical will receive milestone payments from Kyowa Kirin based on sales amount.

Hisamitsu Pharmaceutical and Kyowa Kirin will contribute to further improving the quality of life of patients who live with Parkinson's disease by providing proper medical information of the product.

(Product Information)

(Troduct Information)	
	HARUROPI® TAPE 8 mg
Trade name	HARUROPI® TAPE 16 mg
	HARUROPI® TAPE 24 mg
	HARUROPI® TAPE 32 mg
	HARUROPI® TAPE 40 mg
Generic Name	Ropinirole hydrochloride
Indication	Parkinson's disease
Dosage and Administration	Usually, for adults initially apply 8 mg formulation as
	Ropinirole hydrochloride once daily, observing the
	progress, increased as needed the daily dose by 8 mg at
	intervals of 1 week or more. For any dose, apply once
	daily to the skin of the chest, abdomen, flank, thigh or
	upper arm and replace every 24 hours. Further, the
	dosage can be adjusted according to the age and the
	symptoms, the daily dosage should not exceed 64 mg as
	Ropinirole hydrochloride.
Size of the formulation	5.33 cm ² (HARUROPI _® TAPE 8 mg)
	10.67 cm ² (HARUROPI _® TAPE 16 mg)
	16.00 cm ² (HARUROPI _® TAPE 24 mg)
	21.33 cm ² (HARUROPI _® TAPE 32 mg)
	26.67 cm ² (HARUROPI® TAPE 40 mg)
NIH drug price	404.90 yen/sheet (HARUROPI® TAPE 8 mg)
	623.00 yen/sheet (HARUROPI® TAPE 16 mg)
	801.50 yen/sheet (HARUROPI® TAPE 24 mg)
	958.40 yen/sheet (HARUROPI® TAPE 32 mg)
	1,101.00 yen/sheet (HARUROPI® TAPE 40 mg)
Date of approval for	September 20, 2019
manufacturing and marketing	
Date of NIH drug price listing	November 19, 2019
Manufacturer	Hisamitsu Pharmaceutical Co., Inc.
Distributor	Kyowa Kirin Co., Ltd.
Date of initial marketing in Japan	December 17, 2019