

May 31, 2017

Toray Industries, Inc.  
Japan Tobacco Inc.  
Torii Pharmaceutical Co., Ltd.  
Sumitomo Dainippon Pharma Co., Ltd.

**Toray's Pruritus Treatment REMITCH<sup>®</sup> OD Tablets 2.5 µg to Be Introduced in Japan**

Toray Industries, Inc. (head office: Chuo-ku, Tokyo; President: Akihiro Nikkaku; hereinafter referred to as "Toray") today announced that on May 31, 2017 REMITCH<sup>®</sup> OD Tablets 2.5 µg (hereinafter referred to as the "OD tablets") received a National Health Insurance (NHI) drug pricing and the drug will become available for sale on Tuesday, June 13, 2017. Toray already has obtained manufacturing and marketing approval for REMITCH<sup>®</sup> CAPSULES 2.5 µg, which is being distributed by Torii Pharmaceutical Co., Ltd. (head office: Chuo-ku, Tokyo; President: Shoichiro Takagi; hereinafter referred to as "Torii Pharmaceutical") as a treatment of pruritus in hemodialysis and chronic liver disease patients (use only when sufficient efficacy is not obtained with the existing therapies or treatments) in Japan (tie-up with Japan Tobacco Inc. (head office: Minato-ku, Tokyo; President: Mitsuomi Koizumi)) and is being promoted by Sumitomo Dainippon Pharma Co., Ltd. (head office: Osaka; President: Masayo Tada; hereinafter referred to as "Sumitomo Dainippon Pharma") for treating pruritus in chronic liver disease patients. Toray received approval for the OD tablets as an additional orally disintegrating tablets formulation of REMITCH<sup>®</sup> CAPSULES 2.5 µg on March 30, 2017.

The OD tablets, which were put on the NHI drug price list this time, can be taken with or without water and therefore is convenient for patients whose swallowing capabilities have deteriorated or those who have restrictions on water intake, and is expected to lead to improved drug intake compliance.

The four companies expect that the addition of the orally disintegrating tablets formulation would offer a new treatment option and significantly contribute to the treatment of pruritus in hemodialysis and chronic liver disease patients.

The outline of REMITCH<sup>®</sup> OD Tablets 2.5µg is as follows:

[Product outline]	
Product name	: REMITCH <sup>®</sup> OD Tablets 2.5µg
Generic name	: Nalfurafine hydrochloride
Indications	: Improvement of pruritus in the following patients (use only when sufficient efficacy is not obtained with the existing therapies or treatments): hemodialysis patients, patients with chronic liver disease
Dosage and administration	: The recommended dose for adults is 2.5µg of nalfurafine hydrochloride once daily, administered orally after an evening meal or before bedtime. The dose can be increased in accordance with the symptoms and the maximum dose is 5µg once daily
Date of approval for the additional formulation	
	: March 30, 2017
Date of NHI drug price listing	: May 31, 2017
Date of launch	: June 13, 2017
NHI drug price standard	: 1,346.30 yen per one 2.5µg tablet
Manufacturer/distributor	: Toray Industries, Inc.

## **REMITCH<sup>®</sup> OD Tablets 2.5 $\mu$ g**

REMITCH<sup>®</sup> is the world's first highly selective kappa opioid receptor agonist developed by Toray and has been distributed in Japan since March 2009 by Torii Pharmaceutical as a treatment for pruritus in hemodialysis patients. It controls itching based on a mechanism that is different from antihistamines and anti-allergy drugs and, therefore, was developed with the expectation that it would be effective for pruritus which could not be controlled with existing treatments. In addition, REMITCH<sup>®</sup> was also approved for treating pruritus in chronic liver disease patients in May 2015, and Sumitomo Dainippon Pharma formed an alliance promoting it for this indication.

REMITCH<sup>®</sup> has been available only as a soft capsule until now. Toray developed the OD tablets version, which can be administered without water, so as to improve convenience for patients whose swallowing capabilities have deteriorated or those who have restrictions on water intake.

### **Corporate Profiles**

#### Toray Industries, Inc.

Head office	:	1-1, Nihonbashi-Muromachi 2-chome, Chuo-ku, Tokyo
President	:	Akihiro Nikkaku
Capitalization	:	147,873 million yen (as of the end of March, 2017)

#### Japan Tobacco Inc.

Head office	:	2-1, Toranomom 2-chome, Minato-ku, Tokyo
President	:	Mitsuomi Koizumi
Capitalization	:	100,000 million yen (as of the end of December, 2016)

#### Torii Pharmaceutical Co., Ltd.

Head office	:	Torii Nihonbashi Building, 4-1, Nihonbashi-Honcho 3-chome, Chuo-ku, Tokyo
President	:	Shoichiro Takagi
Capitalization	:	5,190 million yen (as of the end of December, 2016)

#### Sumitomo Dainippon Pharma Co., Ltd.

Head office	:	[Osaka] 6-8, Doshomachi 2-chome, Chuo-ku, Osaka, Osaka [Tokyo] 13-1, Kyobashi 1-chome, Chuo-ku, Tokyo
President	:	Masayo Tada
Capitalization	:	22,400 million yen (as of the end of March, 2017)

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