March 30, 2017

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

Toray Receives Japanese Approval for an Additional Formulation of Pruritus Treatment REMITCH® OD TABLETS 2.5μg

Toray Industries, Inc. (head office: Chuo-ku, Tokyo; President: Akihiro Nikkaku; hereinafter referred to as "Toray") today announced that on March 30, 2017 it received approval for an additional orally disintegrating tablets formulation (REMITCH® OD Tablets 2.5 μg; hereinafter referred to as the "OD tablets") of REMITCH® CAPSULES 2.5 μg. Toray already has manufacturing and marketing approval for the drug, 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.

The OD tablets, for which Toray has obtained the approval this time, can be taken with or without water and therefore is convenient for the 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 approval of additional 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® OD Tablets 2.5μg is as follows:

[Product outline]

Product name:	REMITCH® 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, the maximum dose is 5μg once daily
Date of approval for the additional formulation:	March 30, 2017
Manufacturer/distributor:	Toray Industries, Inc.

REMITCH® OD Tablets 2.5μg

The agent 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® 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.

The agent had been available only as a soft capsule until now. Toray had been developing 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, 2016)

Japan Tobacco Inc.
Head office: 2-1, Toranomon 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 December, 2016)

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