

September 22, 2017

Toray Industries, Inc.
Japan Tobacco Inc.
Torii Pharmaceutical Co., Ltd.

Toray Receives Japanese Approval for an Additional Indication of Pruritus Treatment REMITCH[®] CAPSULES 2.5μg and REMITCH[®] OD Tablets 2.5μg

Toray Industries, Inc. (head office: Chuo-ku, Tokyo; President: Akihiro Nikkaku; hereinafter referred to as "Toray") today announced that it received approval on September 22, 2017 for partial change to the manufacturing and marketing approval of its pruritus treatment REMITCH[®] CAPSULES 2.5μg and REMITCH[®] OD Tablets 2.5μg as a treatment of pruritus in dialysis and chronic liver disease patients (use only when sufficient efficacy is not obtained with the existing therapies or treatments) by adding the indication of treating pruritus in peritoneal dialysis patients (use only when sufficient efficacy is not obtained with the existing therapies or treatments). Toray already has obtained manufacturing and marketing approval for REMITCH[®] CAPSULES 2.5μg and REMITCH[®] OD Tablets 2.5μg, which are being distributed by Torii Pharmaceutical Co., Ltd. (head office: Chuo-ku, Tokyo; President: Shoichiro Takagi; hereinafter referred to as "Torii Pharmaceutical") as a treatment for 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 are 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 three companies expect that the approval of the additional indication would offer a new treatment option to peritoneal dialysis patients experiencing pruritus and significantly contribute to their treatment.

The outline of REMITCH[®] CAPSULES 2.5μg and REMITCH[®] OD Tablets 2.5μg is as follows:

[Product outline]	
Product name	: REMITCH [®] CAPSULES 2.5μg, 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): dialysis 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 an additional indication: September 22, 2017	
NHI drug price standard: 1,346.30 yen per one 2.5μg capsule and tablet	
Manufacturer/distributor	: Toray Industries, Inc.

REMITCH®

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.

Pruritus experienced by peritoneal patients, even if there is no inflammation on the skin, is known to cause severe itching all over the body. Although multiple factors are believed to be affecting the pruritus experienced by such patients, the exact cause is yet to be identified. Existing treatments for itching fail to sufficiently control this pruritus and development of effective treatments have been sought.

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 June, 2017)

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 June, 2017)

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