

October 14, 2011

For immediate release

Toray Industries, Inc.
Mitsubishi Tanabe Pharma Corporation

Toray, Mitsubishi Tanabe Pharma Reach North American License Agreement on Antipruritic Agent, TRK-820

Toray Industries, Inc. (headquarters: Chuo-ku, Tokyo; President, CEO and COO: Akihiro Nikkaku; hereinafter referred to as “Toray”) and Mitsubishi Tanabe Pharma Corporation (headquarters: Chuo-ku, Osaka; President and CEO: Michihiro Tsuchiya; hereinafter referred to as “Mitsubishi Tanabe Pharma”) today announced that the companies signed an agreement regarding exclusive development and marketing of TRK-820 (Toray development code; generic name: nalfurafine hydrochloride), an innovative antipruritic agent developed by Toray, in North America.

TRK-820 is a highly selective κ (kappa) opioid receptor agonist. In Japan, it was launched in March 2009 as a treatment for hemodialysis-related uremic pruritus under the brand name REMITCH® CAPSULES 2.5 μ g (manufactured and marketing approval held by Toray; distributed by Torii Pharmaceutical Co., Ltd.; in alliance with Japan Tobacco Inc.). Clinical development is currently underway also for a treatment of pruritus caused by chronic liver disease and atopic dermatitis.

Toray and Mitsubishi Tanabe Pharma agreed to start clinical development in North America for a treatment of hemodialysis-related uremic pruritus, an indication for which the drug already has been approved and marketed in Japan.

Pruritus experienced by hemodialysis patients is non-inflammatory but generalized and severe, and it is known to be less related to histamine, a generally known substance for causing itching. Some patients suffer from lack of sleep due to severe itching, which worsens their quality of life (QOL). In addition, scratching results in skin inflammation and infections, which aggravate systemic symptoms. It is well known that conventional antipruritic agents including antihistamines cannot fully suppress this itching; and development of an effective drug has been long awaited also in North America.

By licensing in TRK-820, Mitsubishi Tanabe Pharma enhances its development pipeline in North America for renal diseases area, and will actively drive forward its clinical development to bring it to the market as early as possible.

Toray hopes that TRK-820 will become a successful global product by synergistic effect

with Mitsubishi Tanabe Pharma's business strategy in the renal disease area in North America.

See an accompanying material for TRK-820 details.

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<Accompanying material>

1. Pruritus

Pruritus is the severe itching caused by certain diseases or background. Primary diseases which often cause such itching include chronic renal failure, chronic liver diseases such as cholestatic cirrhosis and atopic dermatitis.

2. TRK-820 features

TRK-820 is a novel selective κ (kappa) opioid receptor agonist, with a different mechanism from existing antipruritic drugs such as antihistamine. The drug is thought to suppress the pruritus mediated by the opioid-related mechanism and hence is expected to be effective in treating itching that is resistant to existing treatments such as antihistamine drugs. It is also thought to significantly contribute to improvement in the quality of life (QOL) of hemodialysis patients.

3. Opioid receptors

Receptors are the molecules located on the cell membranes. When receptors are bound by the medical compounds, a biological response is triggered. There are a wide variety of receptors in the human body and each of them has a different specificity to its binding compounds and pharmacological functions expressed by such bindings. An opiate is one such medical compound that binds to a receptor and expresses a response, and its receptors are known as opioid receptors. Whereas it was thought that there was only one type of opioid receptor when it was initially discovered, the subsequent evolution of the research in the area revealed that it is largely classified into three receptor types indicated as μ (mu), δ (delta) and κ (kappa).

4. Agonists

Pharmacological molecules which target receptors are divided into agonists and antagonists. An agonist activates or stimulates, and thereby induces either an increase or decrease in the biological activities by the cell.