

May 26, 2015

Press Release

Mitsubishi Tanabe Pharma Corporation
Ube Industries, Ltd.

Approval for Additional Pediatric Indications in Japan Received for TALION[®] Tablets and TALION[®] OD Tablets, Anti-Allergic Agents

Osaka and Ube, Japan, May 26, 2015 - Mitsubishi Tanabe Pharma Corporation (President & Representative Director, CEO: Masayuki Mitsuka, hereinafter "Mitsubishi Tanabe Pharma") and Ube Industries, Ltd. (President & Representative Director: Yuzuru Yamamoto, hereinafter "Ube Industries") announced today that Mitsubishi Tanabe Pharma has received approval of a partial change of approved information (hereinafter "approval of a partial change") for TALION[®] Tablets and TALION[®] OD Tablets (generic name: bepotastine besilate), Anti-Allergic Agents. The partial change is related to additional pediatric indications (for children at least seven years of age).

Since its launch in October 2000 as a second-generation non-sedating anti-histamine, TALION[®] has been used in many medical institutions because of its excellent clinical effectiveness for adult allergic rhinitis, urticaria, and pruritus accompanying dermatitis (eczema/skin inflammation, prurigo, itching) with assurance of a high level of safety, and minimal effect on daily activities due to absence of impaired performance*.

Clinical trials for children proved the same level of efficacy and safety as in adults. This led to the approval of a partial change and use in pediatric patients with allergic disease.

TALION[®] was discovered by Ube Industries and has been developed jointly by Mitsubishi Tanabe Pharma and Ube Industries. Mitsubishi Tanabe Pharma received approval for TALION[®] Tablets in 2000, and received approval for TALION[®] OD Tablets for additional formulation in 2007, and has since marketed the product.

Mitsubishi Tanabe Pharma and Ube Industries will contribute to a higher quality of life for patients by providing a new choice in the treatment of pediatric allergic disease.

*Use of antihistamines may lead, without awareness of drowsiness, to impaired concentration, judgement or performance of tasks. Such conditions are called impaired performance.

(Reference: Practice Guideline for the Management of Allergic Rhinitis in Japan, 2013, the revised seventh edition)

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