

Company name: KYORIN Holdings, Inc.
Representative: Masahiro Yamashita
Representative Director, President
(Securities Code: 4569, TSE 1st Sec.)

Approval received for **Flutiform**[®], a combination drug for asthma treatment

TOKYO, JAPAN (September 20, 2013) — Kyorin Pharmaceutical Co., Ltd. (“Kyorin”) (Head office: Chiyoda-ku, Tokyo, President: Mitsutomo Miyashita), a wholly owned subsidiary of KYORIN Holdings, Inc., announced today that **Flutiform**[®], a combination drug for asthma treatment has received approval from the Ministry of Health, Labor and Welfare (“MHLW”).

Flutiform[®] is a new fixed-dose combination of the active ingredients formoterol fumarate and fluticasone propionate in a propellant-driven metered dose inhaler, developed by Skyepharma (Head office: London, United Kingdom, CEO : Peter Grant).

In overseas markets, it has to date been sold in 12 European countries under the brand name **flutiform**[®] (**flutiformo**[®] in Italy). In Japan, Kyorin signed a licensing agreement with Skyepharma (exclusive rights in Japan for clinical development, sales and marketing) on April 22, 2008, after which the clinical development of **Flutiform**[®] in Japan moved ahead. On September 25, 2012 Kyorin filed a new drug application for **Flutiform**[®] at the MHLW.

Currently, in the “Asthma Prevention and Management Guidelines 2012” of the Japanese Society of Allergology, the use of inhaled steroids and long-acting β 2-agonists as a single agent in combination with other drugs or as a combination drug is recommended for treatment steps 2 to 4.

Flutiform[®] contains fluticasone, which exerts a potent anti-inflammatory effect, and formoterol, which has a rapid and long-lasting bronchodilating effect. Further, it is contained in a propellant-driven metered dose inhaler that is easy to use, and it is expected to be a drug that meets the needs of patients and healthcare practitioners, such as improvement of respiratory function in patients with bronchial asthma and long-term control of asthma symptoms.

Kyorin has added **Flutiform**[®] to the line-up of its priority area of respiratory products, and is determined to contribute to better patient care by continuously providing up-to-date information.

The timing of the launch and sales projection will be announced at an appropriate time after the NHI price is listed.

(Product information)

Brand name : **Flutiform**[®] 50 Aerosol - 56 inhalations / 120 inhalations
Flutiform[®] 125 Aerosol - 56 inhalations / 120 inhalations
Active ingredient : fluticasone propionate (inhaled corticosteroid)
formoterol fumarate hydrate (a long-acting inhaled β 2agonist)
Indication : Bronchial asthma (when a combination of an inhaled steroid and a long-acting
Inhaled β 2agonist is necessary)
Originated by : Skyepharma PLC
Dosage and administration:
Adults should use **Flutiform**[®] 50 Aerosol (50 μ g fluticasone propionate and 5 μ g formoterol fumarate) 2 times per day (2 inhalations per application). Depending on the symptoms, **Flutiform**[®] 125 Aerosol (125 μ g fluticasone propionate and 5 μ g formoterol fumarate) can be used 2 times per day (2 to 4 inhalations per application).

(For Reference)

About Skyepharma PLC

Established in : March 1910 (renamed to present company name in January 1996)

CEO : Peter Grant

Location : 46-48 Grosvenor Gardens, London SW1W 0EB, United Kingdom

Revenue : £49.9 million (2012)

Number of employees: 85 (2012 average)

Features : Skyepharma, a London-based pharmaceutical company, is an expert drug delivery company which combines proven scientific expertise with validated proprietary drug delivery technologies to develop innovative oral and inhalation pharmaceutical products. The Group receives revenues from fourteen approved products in the areas of inhalation, oral, topical and injectable delivery as well as generating income from the development of further products and technology licenses. The Group's products are marketed throughout the world by leading pharmaceutical companies.