

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

Release of **Flutiform**[®], a combination drug for asthma treatment

TOKYO, JAPAN (November 19, 2013) — Kyorin Pharmaceutical Co., Ltd. (“Kyorin”) (Head office : Chiyoda-ku, Tokyo, President : Mitsutomo Miyashita), a wholly owned subsidiary of KYORIN Holdings, Inc., announced the release of **Flutiform**[®], a combination drug for asthma treatment.

Flutiform[®] is a new fixed-dose combination of the active ingredients formoterol fumarate and fluticasone propionate in a pressurized metered-dose inhaler (pMDI), developed by Skyepharma (Head office : London, United Kingdom, CEO : Peter Grant). In overseas markets, it is sold in 12 European countries to date under the brand name **flutiform**[®] (**flutiformo**[®] in Italy). Kyorin Pharmaceutical Co., Ltd. (“Kyorin”) has undertaken clinical developments in Japan and obtained manufacture and sales approval in September 2013. This has led to the NHI price listing and launch of the product today.

At present, there are estimated to be nearly 5 million adult patients with bronchial asthma. It is reported that 60 to 80 percent of patients who come under treatment steps 2 to 4 of the “Asthma Prevention and Management Guidelines 2012” have their symptoms insufficiently controlled, even if they are medicated for long-term control.*

Flutiform[®] combines fluticasone and formoterol and uses a pressurized metered-dose inhaler (pMDI) that is easy to use and facilitates inhalation irrespective of the flow of inhalation. By marketing this product, Kyorin hopes to contribute further to improved respiratory function in bronchial asthma patients and better symptom control.

Flutiform[®] has the following characteristics :

- (1) Facilitating the simultaneous inhalation of fluticasone, a substance that exerts a potent anti-inflammatory effect, and formoterol, a substance that rapidly dilates the bronchi.
- (2) A bronchodilating effect is able to be achieved from immediately after inhalation, allowing for long-lasting control of asthma symptoms.
- (3) The use of an aerosol formulation (pMDI) allows the drug to be taken easily, irrespective of a patient’s inhalation ability.

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. We expect sales of the drug in the initial year to reach nearly one billion yen.

Kyorin has launched a new website “Flutiform.jp”, for healthcare providers at www.flutiform.jp.

*Source : Kazuo.akiyama Allergology & Immunology, 19, 1120-1127 (2012)

(Product information)

Brand name : **Flutiform**[®] 50 Aerosol - 56 inhalations
Flutiform[®] 125 Aerosol - 56 inhalations

Active ingredient : fluticasone propionate (inhaled corticosteroid)
formoterol fumarate hydrate (a long-acting inhaled β 2 agonist)

Indication : Bronchial asthma (when a combination of an inhaled steroid and a long-acting Inhaled β 2 agonist is necessary)

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).

NHI price : ¥2,735.20 per an inhaler (**Flutiform**[®] 50 Aerosol - 56 inhalations)
¥2,193.10 per an inhaler(**Flutiform**[®] 125 Aerosol - 56 inhalations)

Date of Drug Price Listing : November 19, 2013
Date of initial marketing in Japan : November 19, 2013

(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.