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Company:	KYORIN Holdings, Inc.
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Kyorin Pharmaceutical obtains approval for additional indication for pediatric use of ***Flutiform*®** 50 Aerosol, a combination drug for asthma treatment

TOKYO, JAPAN (June 29, 2020) — Kyorin Pharmaceutical Co., Ltd. (Head office: Chiyoda-ku, Tokyo; Representative Director, President: Shigeru Ogihara; "Kyorin Pharmaceutical"), a subsidiary of KYORIN Holdings, Inc., obtained approval from the Ministry of Health, Labour and Welfare for a partial change in dosage and administration to add an indication for the pediatric use of ***Flutiform*®** 50 Aerosol - 56 inhalations and ***Flutiform*®** 50 Aerosol - 120 inhalations, a combination drug for asthma treatment.

***Flutiform*®** is a fixed-dose combination of the active ingredients fluticasone propionate (an inhaled steroid: ICS[1]) and formoterol fumarate (a long-acting inhaled β2 agonist: LABA[2]) in a pressurized metered-dose inhaler (pMDI[3]). Kyorin Pharmaceutical entered into a license agreement on ***Flutiform*®** with SkyePharma PLC (London, United Kingdom, currently Vectura Group) in April 2008, conducted clinical developments in Japan, obtained manufacture and sales approval in dosage and administration for adults, and released the product in November 2013. Regarding the indication for pediatric use, Kyorin Pharmaceutical has received additional approval of ***Flutiform*®** 50 Aerosol - 56 inhalations and ***Flutiform*®** 50 Aerosol - 120 inhalations in the treatment of pediatric patients, based on the results of a phase III clinical study conducted in Japan in Japanese pediatric patients with bronchial asthma. This approval will provide a new treatment option for pediatric patients with bronchial asthma.

Kyorin Pharmaceutical is determined to contribute to better patient care by appropriately providing information.

***Flutiform*®**, also marketed under the brand name "flutiform®" and other brand names, has been approved in 64 countries and regions including Europe for patients with bronchial asthma, as well as in 34 countries and regions including the United Kingdom for use in pediatric patients with bronchial asthma (as of April 2020).

The sales estimate is factored into the projected sales of ***Flutiform*®** published on May 12, 2020.

[1] ICS: Inhaled corticosteroid
[2] LABA: Long acting β_2 agonist
[3] pMDI: Pressurized metered-dose inhaler

(Product information)
Brand name: ***Flutiform*®** 50 Aerosol - 56 inhalations, ***Flutiform*®** 50 Aerosol - 120 inhalations
Active ingredient: Fluticasone propionate (inhaled corticosteroid) and formoterol fumarate (a long-acting inhaled β2 agonist)
Indication: Bronchial asthma (when a combination of an inhaled steroid and a long-acting inhaled β2 agonist is necessary)
Dosage and administration: Pediatric patients should use ***Flutiform*®** 50 Aerosol (50μg fluticasone propionate and 5μg formoterol fumarate) 2 times per day (2 inhalations per application).
*Description of dosage and administration for adult patients is omitted.