

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

Approval received for Eklira[®] Genuair[®], a treatment for COPD

TOKYO, Japan (March 26, 2015) — Kyorin Pharmaceutical Co., Ltd. (“Kyorin”) (Head office: Chiyoda-ku, Tokyo, President: Mitsutomo Miyashita), a wholly owned subsidiary of KYORIN Holdings, Inc., announced that Eklira[®] 400 µg Genuair[®] 30 inhalations and 60 inhalations, a treatment for COPD¹, received marketing authorization from the Ministry of Health, Labour and Welfare (“MHLW”) on March 26.

The product is an inhaler containing Acridinium Bromide, a new *long-acting* muscarinic antagonist, as the active ingredient discovered by Almirall,S.A. (Head office: Barcelona, Spain). It uses a novel dry powder inhaler named Genuair[®] with improved operability, and is already sold in 36 countries worldwide, including Europe and the United States. In Japan, Kyorin concluded a licensing agreement with Almirall,S.A. in February 2011 (exclusive development and marketing rights in Japan*) and, following clinical development in Japan, has now received approval.

COPD tends to occur in middle-aged and older persons who have / had smoking habits and is characterized by respiratory difficulties on exertion, a chronic and sustained cough, breathlessness and sputum. In recent years, an increase in the number of patients has been noted around the world, including in Japan, and, based on the results of a large epidemiology surveillance, the NICE study², it is estimated that there are more than five million COPD patients in Japan, claiming more than 16,000 lives annually, which makes COPD the *ninth* leading *cause of death*³. With the number of deaths caused by COPD expected to increase sharply in the future, measures to address the impact of smoking on health have also been recognized as an important issue in the MHLW’s “Health Japan 21” initiative. With twice-daily inhalations, the drug controls airway constriction associated with COPD all day, including nighttime and early morning, and improves respiratory function. It is expected to improve clinical symptoms (early morning, day-time and night-time) such as respiratory difficulties and breathlessness and improve patients’ QOL.

Kyorin has added Eklira[®] Genuair[®] 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.

*As a result of Almirall,S.A.’s transfer of its respiratory business to AstraZeneca UK Limited (Head office: U.K. President: Lisa Anson) in November 2014, Kyorin’s licensor for the drug changed from Almirall,S.A. to AstraZeneca UK Limited.

■About iF UNIVERSAL DESIGN award

Genuair[®], a dry powder inhaler received the “universal design expert favorite 2015” and “universal design consumer favorite 2015” in iF UNIVERSAL DESIGN award (Germany). For more details please see press release “Genuair[®], a dry powder inhaler for COPD treatment, selected for iF UNIVERSAL DESIGN award for 2015”, which we disclosed separately today.

1 COPD : Chronic Obstructive Pulmonary Disease
2 Source : Fukuchi Y. : NICE study. 2001;
3 Source : MHLW Vital Statistics 2013

■About 「Eklira® Genuair®」

Brand name	: Eklira® 400µg Genuair® 30 inhalations and 60 inhalations
Active ingredient	: Acclidinium Bromide
Indication	: Relief from symptoms arising from respiratory tract <i>obstruction</i> in COPD patients (chronic bronchitis, pulmonary emphysema)
Dosage and administration	: Adults should use Eklira® Genuair® (400µg Acclidinium Bromide) 2 times per day (1 inhalation per application).

