June 22, 2012

Symbicort® Maintenance And Reliever Therapy for Treatment of Adult Bronchial Asthma Approved in Japan

Tokyo, Japan, June 22, 2012 – Astellas Pharma Inc. ("Astellas", headquarters: Tokyo; President and CEO: Yoshihiko Hatanaka) and AstraZeneca K.K. ("AstraZeneca", headquarters: Osaka; Representative Director and President: Paul Hudson) today announced that Symbicort® Turbuhaler® for the treatment of adult bronchial asthma, currently used for maintenance therapy, has been granted additional approval in Japan for new dosage and administration on an as-needed basis used for reliever therapy.

Symbicort® Turbuhaler® was launched in January 2010 in Japan as a twice-daily dry-power combination inhaler for asthma treatment. In addition to its existing approval for regular twice-daily use, the approval for use as an as-needed reliever therapy specifies one inhalation at onset of an asthma attack with the ability for one further inhalation after a few minutes if the attack persists. This can be continued as needed to a maximum of six inhalations for each attack.

One dose administered by an inhaler (Symbicort® Turbuhaler®) combines 160μg of budesonide, an inhaled corticosteriod, and 4.5μg of formoterol fumarate hydrate, a rapid and long acting β_2 agonist.

Symbicort® Turbuhaler® is a single drug treatment that is highly effective in countering both of the causes of bronchial asthma, airway inflammation and airway narrowing. Many asthma patients report having experienced a worsening of inflammation causing manifestation or aggravation of symptoms due to irritation from triggers such as seasonal temperature changes and virus infections. Thanks to this approval for as-needed use in addition to regular use for maintenance therapy, it is now possible to rapidly and simultaneously intensify anti-inflammatory treatment and relieve symptoms such as coughing, wheezing and shortness of breath caused by worsened inflammation, permitting suffering asthma patients to exercise long-term control over their condition.

Symbicort® Turbuhaler® was first approved in Sweden in 2000, and is now approved in more than 100 countries and regions. Astellas and AstraZeneca are committed to further improve treatments for bronchial asthma.

PRODUCT SUMMARY

Product name:	Symbicort® Turbuhaler® 30 doses Symbicort® Turbuhaler® 60 doses
Generic name:	Budesonide Formoterol Fumarate Dihydrate
Approval date:	October 16, 2009
NHI pricing list date:	December 11, 2009
Launch date:	January 13, 2010
Dosage form:	Dry powder for inhalation
Indication and Usage:	Bronchial asthma (when a combination of an inhaled steroid and a long-acting inhaled β_2 agonist is necessary)
Dosage and administration:	The usual maintenance dose is one inhalation (equivalent to 160 μg budesonide and 4.5 μg formoterol fumarate dihydrate) twice daily via inhalation. The maintenance dose may be adjusted according to symptoms, but the maximum daily maintenance dose should not exceed 4 inhalations twice daily (8 inhalations in total: equivalent to 1280 μg budesonide and 36 μg formoterol fumarate dihydrate). Patients receiving a maintenance dose of 2 inhalations twice daily or lower, can take additional inhalations as needed in response to asthma attacks. Patients using this product as maintenance and reliever should take one inhalation in response to asthma attacks. If the attack persists after a few minutes, an additional inhalation should be taken. This is repeated as necessary, but not more than 6 inhalations should be taken on any single occasion. The maximum daily dose including maintenance dose and as-needed inhalations should be usually 8 inhalations in total, however a total daily dose of up to 12 inhalations (equivalent to 1920 μg budesonide and 54 μg formoterol fumarate dihydrate) can be used temporarily.
Producer and distributor:	AstraZeneca K.K.
Sales agency:	Astellas Pharma Inc.

Contacts for inquiries or additional information:

Astellas Pharma Inc.
Corporate Communications
Tel: +81-3-3244-3201
Fax: +81-3-5201-7473
http://www.astellas.com/jp

AstraZeneca K.K.
Corporate Communications
Tel: +81-6-6453-8011
Fax: +81-6-6453-8107
http://www.astrazeneca.co.jp