

August 10, 2012

**Astellas and AstraZeneca announce the approval in Japan of the dry-power inhaler Symbicort<sup>®</sup> Turbuhaler<sup>®</sup> for the additional indication of chronic obstructive pulmonary disease (COPD)**

**Tokyo, Japan, August 10, 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<sup>®</sup> Turbuhaler<sup>®</sup> has been approved for the additional indication of chronic obstructive pulmonary disease (COPD).

COPD is a chronic, inflammatory lung disease caused by long-term, regular inhalation of harmful agents contained in tobacco smoke and other substances. The principal symptoms are coughing, sputum, shortness of breath and difficulty in breathing. COPD is the fourth most common cause of death worldwide and the number of potential patients in Japan is estimated to exceed 5.3 million.

Symbicort<sup>®</sup> Turbuhaler<sup>®</sup> is a combination product containing a long-acting  $\beta_2$  agonist (LABA) with a bronchodilating action that is the mainstay of drug-based COPD therapy, and an inhaled corticosteroid (ICS), which reduces exacerbations of COPD. Symbicort<sup>®</sup> Turbuhaler<sup>®</sup> can reduce exacerbations of COPD and has a rapid onset of action, substantially contributing to an improved quality-of-life (QOL) for COPD patients.

In the case of COPD patients, Symbicort<sup>®</sup> Turbuhaler<sup>®</sup> needs to be inhaled four times per day (twice in the morning and twice at night) from the inhalation device (Turbuhaler<sup>®</sup>). The daily dose is 640 $\mu$ g of budesonide and 18 $\mu$ g of formoterol fumarate hydrate.

Symbicort<sup>®</sup> Turbuhaler<sup>®</sup> was launched in Japan in January 2010 as a twice-daily, dry-power inhaler combination product for the treatment of bronchial asthma. As of April 2012, it is approved as a treatment for asthma in 114 countries and for COPD in 106 countries.

The approval of Symbicort<sup>®</sup> Turbuhaler<sup>®</sup> for COPD alongside the existing adult bronchial asthma indication will allow Astellas and AstraZeneca to maximize the value of the product and further promote its appropriate use so as to improve the treatment of COPD in Japan.

## PRODUCT SUMMARY

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|----------------------------|--|
| Product name:              | Symbicort® Turbuhaler® 30 doses<br>Symbicort® Turbuhaler® 60 doses   |
| Generic name:              | Budesonide<br>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:      | <ol style="list-style-type: none"><li>1. Bronchial asthma (when a combination of an inhaled steroid and a long-acting inhaled <math>\beta_2</math> agonist is necessary)</li><li>2. Relief of various symptoms of chronic obstructive pulmonary disease (chronic bronchitis, pulmonary emphysema) (when a combination of an inhaled steroid and a long-acting inhaled <math>\beta_2</math> agonist is necessary)</li></ol>   |
| Dosage and administration: | <ol style="list-style-type: none"><li>1. Bronchial asthma<br/>The usual maintenance dose is one inhalation (equivalent to 160 <math>\mu\text{g}</math> budesonide and 4.5 <math>\mu\text{g}</math> 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 <math>\mu\text{g}</math> budesonide and 36 <math>\mu\text{g}</math> formoterol fumarate dihydrate).<br/>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.<br/>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 <math>\mu\text{g}</math> budesonide and 54 <math>\mu\text{g}</math> formoterol fumarate dihydrate) can be used temporarily.</li><li>2. Relief of various symptoms of chronic obstructive pulmonary disease<br/>The usual adult dosage is two inhalations (equivalent to 320 <math>\mu\text{g}</math> budesonide and 9 <math>\mu\text{g}</math> formoterol fumarate dihydrate) twice daily via inhalation.</li></ol> |
| Producer and distributor:  | AstraZeneca K.K.   |
| Sales agency:              | Astellas Pharma Inc.   |

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