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AstraZeneca K.K. Receives a Japanese Marketing Approval of Symbicort[®] Turbuhaler[®] for the Treatment of Adult Bronchial Asthma

Tokyo, Japan, October 16, 2009 - AstraZeneca K.K. (headquarters: Tokyo; President and CEO: Masuhiro Kato) today announced that it received a Japanese manufacturing and marketing approval for Symbicort[®] Turbuhaler[®] 30 doses and Symbicort[®] Turbuhaler[®] 60 doses for the treatment of adult bronchial asthma. The product will be manufactured and developed by AstraZeneca K.K. and distributed and sold by Astellas Pharma Inc., while promotion will be jointly carried out by both companies (co-promotion).

Symbicort Turbuhaler is a twice-daily treatment for adult bronchial asthma combining budesonide, an inhaled corticosteroid (one dose containing $160\mu g$) and formoterol fumarate dihydrate, a rapid and long acting $\beta 2$ agonist (one dose containing $4.5\mu g$), and the product is administered by an inhaler (Turbuhaler).

Characteristics of Symbicort Turbuhaler are as follows:

- -The Product alone shows good efficacy in countering both of the causes of bronchial asthma, airway inflammation and airway narrowing
- By administering two medications in one product, in addition to the convenience for controlling bronchial asthma, due to the fast onset of bronchial dilation effect of formoterol, patients can easily feel the effect of the treatment. As a result, improvement in adherence (continuation of treatment) can be expected.

The results of Phase III study in Japan show that in Japanese adult bronchial asthma patients Symbicort Turbuhaler shows clinical usefulness compared to combination therapy of budesonide and theophylline sustained release. In terms of safety profile both treatment groups show favorable tolerance. Further, it has been reported that a long-term (52 weeks) study demonstrated favorable tolerance and efficacy.

Symbicort Turbuhaler was first approved in Europe in 2000, and is now approved in more than 100 countries and regions.

In Japan, the number of bronchial asthma patients is estimated to total approximately 5 million, and approximately 2,500 patients die annually due to this disease, and this mortality is one of the highest among advanced countries. While it has been pointed out that use of inhaled corticosteroid is lower in Japan compared to overseas, we believe that Symbicort Turbuhaler will contribute to further enhancing adult bronchial asthma treatment in Japan.

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