

**FOOD AND DRUG ADMINISTRATION (FDA)**  
**CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)**  
***Pulmonary-Allergy Drugs Advisory Committee (PADAC)***  
FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center (Rm. 1503)  
Silver Spring, MD  
March 8, 2011

**Questions to Committee**

1. Discuss the efficacy data of indacaterol considering the following
  - a) Dosing regimen or dosing frequency
  - b) Total daily dose lower than 75 mcg
  - c) Are there advantages of 150 mcg once-daily dose over 75 mcg once-daily dose
  - d) Claim that 150 mcg once-daily dose improves St. George's Respiratory Questionnaire (SGRQ) considering the totality of the SGRQ data
  
2. Discuss the overall safety profile of indacaterol considering the following
  - a) Safety data from asthma studies
  - b) Proposed indication specific to chronic obstructive pulmonary disease (COPD) including chronic bronchitis and/or emphysema
  - c) Comparative safety assessment of 75 mcg and 150 mcg dose for balancing safety risk relative to efficacy
  
3. Considering the totality of the data, has indacaterol demonstrated substantial evidence of efficacy for the long term, once-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and/or emphysema
  - a) For the 75 mcg dose? **(Vote)**
  - b) For the 150 mcg dose over the 75mcg dose? **(Vote)**
  - c) If not, what further data should be obtained? **(Discuss)**
  
4. Is the safety profile of indacaterol adequate for approval for the long term, once-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and/or emphysema
  - a) For the 75 mcg dose? **(Vote)**
  - b) For the 150 mcg dose? **(Vote)**
  - c) If not, what further data should be obtained? **(Discuss)**
  
5. Does the totality of the data provide substantial evidence to support a claim that indacaterol improves health-related quality of life as measured using St. George's Respiratory Questionnaire (SGRQ)
  - a) For the 75 mcg dose? **(Vote)**
  - b) For the 150 mcg dose? **(Vote)**
  
6. Do the efficacy and safety data provide substantial evidence to support approval of indacaterol inhalation powder for the long term, once-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and/or emphysema? **(Vote)**  
If yes, should the dose be
  - a) 75 mcg once-daily? **(Vote)**
  - b) 150 mcg once-daily? **(Vote)**
  - c) If not, what further data should be obtained? **(Discuss)**