

**Summary:** A 26-week treatment, multicenter, randomized, double-blind, double-dummy, placebo-controlled, adaptive, seamless, parallel-group study to assess the efficacy, safety and tolerability of two doses of investigational drug in patients with COPD (Chronic Obstructive Pulmonary Disease).

**Inclusion Criteria:**

- Male or female adults aged  $\geq 40$  years
- Patients with a diagnosis of COPD
- Smoking history of at least 20 pack years

**Exclusion Criteria:**

- Patients requiring long term oxygen therapy ( $>15$  h a day)
- Pregnant or nursing (lactating) women
- Patients who have been hospitalized for a COPD exacerbation or had a upper respiratory infection in the last 6 weeks
- Patients who do not maintain regular day/night, waking/sleeping cycles (e.g., night shift workers)
- Patients who have had treatment with investigational drugs at the time of enrollment, or within the last 30 days
- Patients with pulmonary disease, pulmonary tuberculosis (unless confirmed by chest x-ray to be no longer active) or clinically significant bronchiectasis
- Patients with a history of asthma
- Patients with Type I diabetes or uncontrolled Type II diabetes (including patients with a history of blood glucose levels consistently outside the normal range or HbA<sub>1c</sub>  $>8.0\%$ )
- Any patient with lung cancer or a history of lung cancer.
- Any patient with active cancer or a history of cancer with less than 5 years disease free survival time

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