

Summary: A Phase 3, Open-Label, Three-Group Parallel Study to Evaluate the Efficacy and Safety of Human Insulin Inhalation Powder (HIIP) in Patients with Type 2 Diabetes Treated with Once-Daily Insulin Glargine

Inclusion Criteria:

- Age \geq 18 years
- Have had type 2 DM for at least 6 months
- A1C \geq 7.5 to \leq 10.5 %
- Are non-smokers, have not smoked for at least 6 months prior to screening
- Are able to perform pulmonary function test
- Have chest x-ray without evidence of clinically significant pulmonary abnormalities
- Been treated with the following regimen – one or more oral antidiabetic medications on a stable dose for at least 6 weeks (3 months for TZD's) AND Once-daily insulin glargine for at least 4 months

Exclusion Criteria:

- Are taking TZD dose greater than what is indicated in combination with insulin according to the TZD label in the respective country (for example, in US, rosiglitazone greater than 4 mg daily or pioglitazone greater than 45 mg is not currently indicated).
- Have had more than 2 episodes of severe hypoglycemia during the 6 months prior to study entry
- Have had a lower respiratory infection in the 3 months prior to screening
- Have received systemic glucocorticoid therapy within the 3 months prior to study entry
- Have abnormal hepatic and renal function test
- Have a history of renal transplantation, are currently receiving renal dialysis
- Have a history of unstable angina, myocardial infarction within the 6 months prior to study entry
- Have an active or untreated malignancy, or have been in remission from a clinically significant malignancy or current or past history of lung cancer
- Have a current diagnosis or past history of asthma, COPD, cystic fibrosis, bronchiectasis, or other clinically relevant pulmonary disease .
- Are taking or have taken exenatide (Byetta) within 6 weeks
- Require more than 150 U/day of insulin glargine

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