

# ABSTRACT

## Poster Presentation 954

### Pharmacokinetics of Technosphere® Insulin Unchanged in Patients with Chronic Obstructive Pulmonary Disease

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**Background and aims:** The rate and extent of insulin exposure have been shown to be decreased by approximately 20% to 50% in subjects with chronic obstructive pulmonary disease (COPD) with the use of inhaled insulin.

**Materials and methods:** The pharmacokinetics (PK) of Technosphere® Insulin (TI), a rapid-acting insulin for pulmonary delivery, was evaluated in an open-label, single-dose, euglycemic glucose clamp study in 37 non-diabetic, non-smoking healthy subjects (n = 19; Baseline mean ± SD aged 51 ± 14 years; BMI 29 ± 3 kg/m<sup>2</sup>; forced expiratory volume in 1 second [FEV<sub>1</sub>] 3.5 ± 1 L) and subjects with COPD (n = 17; aged 60 ± 9 years; BMI 29 ± 5 kg/m<sup>2</sup>; FEV<sub>1</sub> 2.6 ± 0.8 L).

**Results:** Thirty-four subjects were age-, gender-, and BMI-matched. One COPD subject was excluded. Each subject received a single dose of 30 U of TI via inhalation. Serial blood samples were drawn for insulin and C-peptide concentration determination until 480 minutes post-dose. Insulin concentrations were C-peptide corrected to account for endogenous insulin, and C-peptide corrected values were used for PK parameter estimation. There was no statistically significant difference in absorption in the two groups. Mean peak insulin was 34.7 and 39.5 µU/mL (p = 0.285) with a median time to maximum insulin concentration of 15 and 12 minutes (p = 0.241) in the COPD and non-COPD groups, respectively. Mean insulin exposure from time 0 to 240 minutes post-dose (AUC<sub>0-240</sub>) was 2037 and 2270 µU/mL·min (p = 0.469) for the COPD and non-COPD groups, respectively. Dosing was well tolerated.

**Conclusion:** These results indicate that the characteristic absorption pattern of TI is not significantly altered in the COPD population.

