Reduced Incidence and Frequency of Hypoglycemia in an Integrated Analysis of Pooled Data from Clinical Trials of Subjects with Type 1 Diabetes Using Prandial Inhaled Technosphere Insulin

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Abstract

Background and Aims

The integrated analysis of a phase 2b/3 randomised controlled trial compared AFREZZA (TPA-2361) inhalation powder with sc insulin treatment in subjects with type 1 diabetes mellitus (T1DM). The event rate of glucose ≤36 mg/dL (≤2.0 mmol/L) was lower in the AFREZZA group (Table 3). Subjects treated with AFREZZA + basal insulin had a lower overall incidence of hypoglycemia than sc insulin comparator regimens in subjects with T1DM. Severe hypoglycemic event rates decreased over time after the initial drug titration period. The incidence of total hypoglycemia was significantly lower with AFREZZA + basal insulin than with sc insulin comparator regimens in subjects with T1DM.

Methodology

In Subjects with T1DM:

The integrated analysis of a phase 2b/3 randomised controlled trial compared AFREZZA (TPA-2361) inhalation powder with sc insulin treatment in subjects with type 1 diabetes mellitus (T1DM). The event rate of glucose ≤36 mg/dL (≤2.0 mmol/L) was lower in the AFREZZA group (Table 3). Subjects treated with AFREZZA + basal insulin had a lower overall incidence of hypoglycemia than sc insulin comparator regimens in subjects with T1DM. Severe hypoglycemic event rates decreased over time after the initial drug titration period. The incidence of total hypoglycemia was significantly lower with AFREZZA + basal insulin than with sc insulin comparator regimens in subjects with T1DM.

Conclusions

Under conditions of comparable HbA1C control, subjects treated with AFREZZA + basal insulin had a lower incidence of hypoglycemia and an improved odds ratio relative to sc insulin comparators for severe, mPMB, and total hypoglycemia, including those events with a BG ≤36 mg/dL (≥2.0 mmol/L) and ≥36 mg/dL (<2.0 mmol/L).

Treatment with AFREZZA + basal insulin is associated with a reduced risk for hypoglycemia relative to sc insulin comparators.

References


Figure 1. Severe Hypoglycemia Event Rates, Time-Stratified Randomization: Subjects Treated with AFREZZA + Basal Insulin vs SC Insulin Comparator (Safety Population)

Figure 2. Table 1: Baseline Characteristics of T1DM Subjects (Safety Population)

Table 2: Incidence of Hypoglycemia in T1DM, AFREZZA vs SC Insulin Comparator (Safety Population)

Table 3: Hypoglycemia Event Rates in T1DM, AFREZZA vs SC Insulin Comparator (Safety Population)