Background and Aims

1. Incidence and frequency of hypoglycemia in T2DM, AFREZZA vs SC insulin comparators in all assessed categories. In Subjects with T2DM: The incidence and frequency of severe hypoglycemic events were significantly lower with AFREZZA than with SC insulin comparator regimens in subjects with T2DM. The incidence and frequency of nonsevere (mild/moderate) hypoglycemic events were significantly lower with AFREZZA than with SC insulin comparator regimens in subjects with T2DM.

Methodology

Subjects were randomized to treatment regimens to achieve predefined glycemic goals: AFREZZA or subcutaneous (SC) insulin glargine QD. In the following 16 trials, insulin adjustments were made according to investigator discretion in 5 trials and forced titration in 1 trial: AFREZZA (n=1795) or SC insulin comparators in all assessed categories. The incidence and frequency of severe hypoglycemic events were significantly lower with AFREZZA than with SC insulin comparator regimens in subjects with T2DM.

Results in Subjects treated with AFREZZA had significantly lower hypoglycemia event rates than SC insulin comparators with respect to age, BMI, HbA1c, and time since diagnosis (10.8, 12.4 years; Baseline HbA1c 8.82%, 8.84%; BMI 31.07, 31.07 kg/m²). Reductions in hypoglycemia event rates were consistent across all glycemic categories including normoglycemic subjects (HbA1c ≤7% and ≤6.5% with AFREZZA) compared to SC insulin comparators in all assessed categories. In Subjects with T2DM: The incidence and frequency of severe hypoglycemic events were significantly lower with AFREZZA than with SC insulin comparator regimens in subjects with T2DM.

In Subjects with T2DM:

1. Incidence and frequency of severe hypoglycemic events were significantly lower with AFREZZA than with SC insulin comparator regimens in subjects with T2DM. The incidence and frequency of nonsevere (mild/moderate) hypoglycemic events were significantly lower with AFREZZA than with SC insulin comparator regimens in subjects with T2DM.

2. There were fewer nocturnal hypoglycemic events, for both sexes and mild/moderate, in subjects treated with AFREZZA than with SC insulin comparator regimens. 2.4 per 100 subject-months, respectively, for mild/moderate event rates and 0.1 vs 0.2 per 100 subject-months, respectively, for severe event rates.

Hypoglycemia Event Rates

Hypoglycemia Event Rates Based on End-of-Trial HbA1c Category and Treatment

In Subjects with T2DM:

The incidence and frequency of severe hypoglycemic events were significantly lower with AFREZZA than with SC insulin comparator regimens in subjects with T2DM. The incidence and frequency of nonsevere (mild/moderate) hypoglycemic events were significantly lower with AFREZZA than with SC insulin comparator regimens in subjects with T2DM.

Conclusion

Under conditions of comparable HbA1c control, the incidence and frequency of hypoglycemic events in AFREZZA-treated subjects were significantly lower than the SC insulin comparator treatment in subjects with T2DM.

References

1. Figure 1. Hypoglycemia Event Rates Based on End-of-Trial HbA1c Category and Treatment

Figure 1. Weekly/Monthly Hypoglycemia Event Rates in Relation to Mean Total Weekly Baseline HbA1c and SC Insulin Comparators (Safety Population)

Figure 2. Median Event Rates for Subjects Based on Mean Baseline HbA1c Category and Treatment in T2DM

Figure 3. Event Rate of Hypoglycemia for Subjects Based on Mean Baseline HbA1c Category and Treatment in T2DM

Figure 4. Weekly/Monthly Hypoglycemia Event Rates in Relation to Mean Total Weekly Baseline HbA1c and SC Insulin Comparators (Safety Population)