ITCA 650 Improves Glycemic Control and Reduces the Need to Advance Antidiabetes Therapy

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ABSTRACT

In patients with type 2 diabetes, Phase 3 studies with ITCA 650 demonstrated significant improvement in change from baseline HbA1c (ITCA 650, 0.9% ± 0.9; sitagliptin, 1.1% ± 1.1; placebo, 1.9% ± 1.9) that provides continuous, subcutaneous delivery of exenatide SC for up to 6 months. Exenatide plasma levels are maintained as long as the ITCA 650 device is in situ, and no action is required on the part of patients.

In this post hoc analysis of pooled data from 2 randomized, double-blind, double-dummy Phase 3 studies from the FREEDOM-2 trial, add-on therapy with ITCA 650 20/60 mcg/d significantly improved glycemic control without the need for advancement of antidiabetic therapy in patients who were poorly controlled on optimal doses of antidiabetic drugs, greater efficacy (HbA1c, weight, and glycemic control) was achieved with ITCA 650 compared to sitagliptin, and there was no increase in the incidence of patients requiring advanced therapy.

METHODS

 Patients were randomized 1:1:1 to ITCA 650 20/60 mcg/d, sitagliptin 40 mcg/d, or placebo, and followed for up to 52 weeks. Data were analyzed up to Week 39. The majority of ITCA 650 treated patients who advanced therapy achieved and maintained glycemic control below the threshold for advancement.

RESULTS

• The majority of ITCA 650 treated patients who advanced therapy achieved and maintained glycemic control below the threshold for advancement.

Table 1. Description of Efficacy Studies Included in the FREEDOM Program

Table 2. 13-Wk Mean Change From Baseline to Endpoint in FREEDOM-1 and FREEDOM-2 (mITT Population)

Table 3. Baseline Demographic and Clinical Characteristics for the Advancing Therapy Population vs. Overall Study – mITT Population

CONCLUSION

A progressive increase in the incidence of patients advancing therapy was observed in the sitagliptin and placebo groups after Week 39. Cumulatively, 26% of sitagliptin and 39% of placebo treated patients needed to advance therapy by Week 39.

In this analysis of patients who were poorly controlled on optimal doses of antidiabetic drugs, greater efficacy (HbA1c, weight, and glycemic control) was achieved with ITCA 650 compared to sitagliptin, and there was no increase in the incidence of patients requiring advanced therapy.