ITCA 650 Significantly Reduces the Need to Advance Antidiabetes Therapy Compared to Sitagliptin

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ABSTRACT
Background: the need to advance antidiabetes therapies is a salient indicator of the effectiveness and sustainability of a treatment approach. ITCA 650, a once-weekly osmotic mini-pump for type 2 diabetes (T2D) continuously delivers exenatide SC for up to 6 months after subcutaneous placement. ITCA 650 dosing for 2 weeks followed by a maintenance dose of 60 mcg/day every 6 months was tested in a double-blind, randomized, double-blind study (FREEDOM-2) compared to sitagliptin (SITA) 100 mg (1.5%, 0.8%, 0.7%) and weekly weight loss.

Methods: This exploratory analysis from FREEDOM-2 assessed the need for further therapy in addition to SITA or ITCA 650 in ARMS (a randomized ITCA 650 [maximal placebo (MPL)]) group. Further therapy was pre-defined as metformin or other antidiabetic that increases observed in real-world setting.

Figure 2. Study Design for FREEDOM-2

OBJECTIVE
To assess the need to advance antidiabetes therapy, a meaningful measure of the effectiveness and sustainability of antidiabetes therapy, in patients with type 2 diabetes treated with ITCA 650 vs. SITA (Fig. 2).

RESULTS: FREEDOM-2, a 52-week, double-blind, double-blind, double-blind study comparing ITCA 650 and sitagliptin (Fig. 2).

Table 1. Baseline Demographic and Clinical Characteristics for Population Requiring Advancement of Therapy—Overall Study—ITT Population

- In the global study of patients who were poorly controlled on oral doses of metformin, proteinuria (HbA1c, weight loss, and postprandial weight was achieved with ITCA 650 compared to sitagliptin.
- Near 25% of patients treated with sitagliptin + metformin entered to advance therapy compared with 15% of patients treated with ITCA 650 + metformin.
- The need to advance therapy with sitagliptin was minimal and improvement over time compared to ITCA 650.
- Substantial percentage of patients treated with the ITCA 650 group remained on monotherapy compared to nearly 25% of patients in the sitagliptin group.
- This is consistent with sustained efficacy over time of ITCA 650 compared to sitagliptin.


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Figure 5. Percent of Patients Who Advanced Therapy by Week of Treatment (ITT Population)

CONCLUSION
In this proposed analysis of a randomized, controlled trial in inadequately controlled type 2 diabetes patients treated to near-normal levels of glycemia, add-on therapy with ITCA 650 resulted in significantly improved and sustained glycemic control without the need to advance antidiabetes therapy in most patients.


Figure 4. Persist of Patients Who Achieved Therapy by Week of Treatment (ITT Population)

Table 2. WBW and Body Weight Prior to Advancement of Therapy (ITT Population)

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