Efficacy and Tolerability of 39 Weeks of ITCA 650 (Continuous Subcutaneous Exenatide) in Poorly Controlled T2DM With High Baseline A1C (≥10%)

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BACKGROUND
• A large segment of treatment-naïve patients with type 2 diabetes mellitus (T2DM) remain poorly controlled due to:
  - The progressive nature of the disease
  - Limitations of current therapies, clinical inertia
  - Poor compliance and adherence rate

• The benefits of GLP-1 therapy in a class include lowering HbA1c, weight loss, and hypoglycemic risk
  - The potential roles include parallel achievement of weight loss and glycemic targets in type 2 diabetes in treatment and the cost of poor adherence overall

• ITCA 650 osmotic mini-pump: an injection-free GLP-1 receptor agonist, currently in Phase 3 development, that can deliver exenatide subcutaneously for up to 12 months (Figure 1)

OBJECTIVES
• To evaluate the efficacy, safety, and tolerability of ITCA 650 60 mcg/day in poorly controlled patients with T2DM
• To evaluate for safety reasons, and background treatment for type 2 diabetes was not modified

RESULTS
• ITCA 650 resulted in:
  - Statistically and clinically significant reductions of HbA1c and FPG were observed and maintained over 39 weeks (Figure 2, Table 1, Figure 3: ITCA 650 treatment resulted in statistically significant reductions in HbA1c and FPG over 39 weeks)
  - N=59

• The most common adverse events were consistent with the known profile of exenatide and those expected from a minor procedure (hematoma, bruising, bleeding)
  - The incidence of nausea was <1% except for the week before the pump placement (Figure 6: Incidence of Nausea by Study Period (Safety Population))
  - No pancreatic events, thyroid cancer or major hypoglycemia
  - Of those ITCA 650 ≥10% of patients experienced nausea

• The incidence of serious adverse events was 22%

CONCLUSIONS
• ITCA 650 is a once-daily injectable, noninsulin, microdialysis-controlled study of ITCA 650 in patients with HbA1c >10% and ≤12.0%

ITCA 650 60 mcg/d (N=60) vs. Baseline

Table 1: Incidence of Treatment-Emergent Adverse Events (Safety Population)

Table 2: Baseline Characteristics

Table 3: Incidence of Treatment-Emergent Adverse Events (Safety Population)