SNAP 101: Randomized, Crossover, Active/Placebo-Controlled, Safety and Pharmacokinetic/Pharmacodynamic Study of 3 Ascending Doses of POD® Olanzapine

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Objective: To evaluate the pharmacokinetics and pharmacodynamics of olanzapine (OLZ) ODT in a single dose oral administration in subjects with agitation in the emergency setting.

Methods: This was a Phase 1, randomized, double-blind, parallel-group, placebo- and active-controlled, active comparator, washout study. Subjects were randomized to receive OLZ ODT 5 mg (n=6), OLZ ODT 10 mg (n=6), or placebo (n=5) at a dose of 15 mg. Mean ± standard deviation; BMI – body mass index.

Results: The mean maximum change (± standard deviation) in sedation/cognition (VAS) score at 15 minutes showed greater sedation/cognition (negative change = desired, calming effect) with INP105 10 mg and 15 mg doses versus OLZ ODT and placebo. A significant difference was observed in subjects receiving INP105 10 mg versus OLZ ODT 5 mg (p=0.003) and 10 mg (p=0.004) and OLZ 5 mg IM (p=0.003) (Figure 5).

Introduction: The incidence of agitation in the emergency setting is high, often due to untreated psychiatric illness, and may be associated with agitation in the emergency setting.