Background: Serdexamethylphenidate (SDX) is a prodrug of d-methylphenidate (d-MPH) currently being developed as a pharmaceutical ingredient in an investigational product for the treatment of ADHD.

Methods: To assess the human abuse potential of SDX after a single IV injection and to confirm the rational chemical design of the prodrug, a double blind, single dose, 3 treatment, randomized crossover study of IV administration of SDX API compared with d-MPH HCI API in recreational stimulant abusers was conducted.

Results: A total of 30 subjects (mean age=32, 80% male) completed all 3 treatment periods. SDX produced little or no increases in Drug Liking scores throughout the testing interval, with Emax (i.e., maximum response; median difference [95% CI] = 0.0 [2.59, 5.5], p<0.001) and non-inferior to placebo (median difference [95% CI] = 0.5 [5.5], p<0.001) (Figure 2). SDX produced little or no increases in Drug Liking scores throughout the testing interval, with Emax (i.e., maximum response; median difference [95% CI] = 0.0 [2.59, 5.5], p<0.001) and non-inferior to placebo (median difference [95% CI] = 0.5 [5.5], p<0.001) (Figure 2). Figure 2. Drug Liking VAS scores over time (left panel) and Drug Liking Emax scores (right panel) for IV SDX, d-MPH HCI, and placebo.

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Conclusions: SDX produced little or no increases in Drug Liking scores throughout the testing interval, with Emax (i.e., maximum response; median difference [95% CI] = 0.0 [2.59, 5.5], p<0.001) and non-inferior to placebo (median difference [95% CI] = 0.5 [5.5], p<0.001) (Figure 2). SDX produced little or no increases in Drug Liking scores throughout the testing interval, with Emax (i.e., maximum response; median difference [95% CI] = 0.0 [2.59, 5.5], p<0.001) and non-inferior to placebo (median difference [95% CI] = 0.5 [5.5], p<0.001) (Figure 2). Figure 2. Drug Liking VAS scores over time (left panel) and Drug Liking Emax scores (right panel) for IV SDX, d-MPH HCI, and placebo.