A Phase 1, Randomized, Open-Label, Single-Dose, 3-Period Crossover Study to Evaluate the Drug-Drug Interaction Between ZX008 (Fenfluramine Oral Solution) and a Regimen of Stiripentol, Clobazam, and Valproate in Healthy Volunteers

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Rationale
- An oral solution of fenfluramine (FFA), ZX008, is under development as a low-cost, non-sedating, non-addictive, and non-habit forming appetite suppressant.
- ZX008 is being developed for the treatment of obesity, with a focus on weight loss and weight maintenance.
- The study aims to evaluate the effects of combining ZX008 with a regimen of stiripentol (STP), clobazam (CLB), and valproate (VPA) on the pharmacokinetics of these drugs.

Methods
- Study design: Open-label, randomized, single-dose, 3-period crossover study
- Subjects: Male or non-pregnant, non-lactating female subjects, 18-50 years old
- Treatment regimens: STP regimen, STP regimen + ZX008

Results
- Pharmacokinetics: ZX008 did not have a significant impact on any of the PK profiles in the combination regimen compared to the individual agent (STP + VPA) (Table 2).
- The STP regimen had a significant effect on the PK of FFA, with a decrease in the geometric mean of FFA AUC and Cmax.

Conclusions
- ZX008 did not have any significant impact on the PK of the individual agents in the STP regimen. Clobazam, and VPA.
- The STP regimen had a significant effect on the PK of FFA, with a decrease in the geometric mean of FFA AUC and Cmax.

Disclosure
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