REPORT SUMMARY

A Non-GLP 3-Day Oral Tolerability Evaluation of d8PLAT in Sprague Dawley Rats

Testing Facility Study No. 461-01
Sponsor Study No. 001-01

TESTING FACILITY
Hera Biolabs
2277 Thunderstick Dr #500
Lexington, KY 40505

SPONSOR
3C Labs dba 3CHI
8500 E. 116th St
Ste 443
Fishers, IN 46048

The objective of this study was to evaluate the tolerability of platinum delta8-THC (d8PLAT), a 99% pure delta8 THC, when administered once by oral gavage at five different dose levels to male and female Sprague Dawley rats. Animals received a single dose of d8PLAT at 1.03, 2.58, 5.17, 10.33, or 51.67 mg/kg by oral gavage in 100% MCT oil. d8PLAT dosages were calculated based on human equivalent doses (HED) for a 60 kg human for the following HED: 10, 25, 50, 100, and 500 mg. General health, body weight, and food consumption were monitored daily for 3 days. At the end of the 3-day observation period, animals were terminated, and a gross necropsy was performed.

There was no moribundity or mortality observed in any group throughout the observation period. There were no clinical signs in animals dosed with d8PLAT at 1.03 or 2.58 mg/kg (Groups 1 and 2, respectively). Clinical signs in animals dosed with d8PLAT at 5.17 mg/kg (Group 3) consisted of mild hypoactivity after dosing which resolved by the day after dosing. Clinical signs in animals dosed with d8PLAT at both 10.33 and 51.77 mg/kg (Groups 4 and 5, respectively) consisted of severe hypoactivity after dosing, and mild hypoactivity the day following dosing. No other clinical signs were observed in any animal.

Animals in all groups exhibited mild weight loss ($\leq$ 4.0% for Groups 1-4, $\leq$ 8.0% for Group 5) the day after dosing (Day 2). From Study Day 2-4, body weight increased for all groups. Overall, there were no significant concerns with body weight throughout the observation period.

Group 1 (d8PLAT, 1.03 mg/kg, HED 10 mg) males had a mean body weight change of -1.53% the day after dosing, which resolved to +1.58% at termination, relative to pre-dose value. Group 1 females had a mean body weight change of -0.31% the day after dosing and overall body weight change of -0.62% from dosing initiation to termination.

Group 2 (d8PLAT, 2.58 mg/kg, HED 25 mg) males had a mean body weight change of -2.07% after dosing, and -1.36% at termination. Group 2 females had a mean body weight change of -0.76% the day after dosing, and overall body weight change of +0.14% from dosing initiation to termination.

Group 3 (d8PLAT, 5.17 mg/kg, HED 50 mg) males had a mean body weight change of -3.62% after dosing, and -1.06% at termination. Group 2 females had a mean body weight change of -2.66% the day after dosing, and an overall body weight change of -2.15% from dosing initiation to termination.

Group 4 (d8PLAT, 10.33 mg/kg, HED 100 mg) males had a mean body weight change of -5.03% after dosing, and -1.99% at termination. Group 2 females had a mean body weight change of -2.30% the day after dosing, and an overall body weight change of -3.06% from dosing initiation to termination.

Group 5 (d8PLAT, 51.77 mg/kg, HED 500 mg) males had a mean body weight change of -6.44% after dosing, and -4.31% at termination. Group 2 females had a mean body weight change of -8.44% the day after dosing, and an overall body weight change of -5.42% from dosing initiation to termination.

Food consumption was similar for all dosing groups throughout the pre-dosing and post-dosing observation period. There was a decrease in food consumption on Day 2, the day after dosing, for all groups. On Study Days 3 and 4, food consumption increased to levels similar to pre-dose values.

In conclusion, one time administration of d8PLAT by oral gavage to male and female Sprague Dawley rats at a dose level of 1.03, 2.58, 5.17, 10.33, and 51.67 mg/kg were tolerated without significant adverse events.