SUMMARY
- Exposure to CBD and its metabolites increased in a dose-proportional manner.
- N-desmethylclobazam (N-CLB) levels increased in patients on CBD, except for those on concomitant stiripentol, which may reflect prior saturated inhibition of CYTP3A4 by stiripentol.
- There was no demonstrable effect on other antiepileptic drugs (AEDs) tested (valproic acid, topiramate, stiripentol, or levetiracetam).
- CBD resulted in more adverse events than placebo, but it was generally well tolerated at all doses examined.
- 20 mg/kg/day was approved by the Data Safety Monitoring Committee for further investigation.

INTRODUCTION
- The randomized, double-blind, placebo-controlled trial evaluated safety, tolerability, and pharmacodynamics of oral CBD in children with Dravet syndrome (DS).
- Data from Part A were used to determine the dose for Part B, which assessed safety and efficacy in a larger population.

PATIENT DISPOSITION AND BASELINE DEMOGRAPHICS

PHARMACOKINETIC RESULTS

Mean percentage change in plasma concentrations of CLB, N-CLB, and valproic acid at Day 22

SAFETY RESULTS

Treatment-emergent adverse events (TEAEs)

METODS
- Patients were aged 6-18 years and had a documented history of DS with at least one qualifying AED (CLB).
- After an 8-week baseline period, patients with fewer than 4 convulsive seizures within 4 weeks had CLB levels increased. Patients had completed the trial were eligible to continue into an open-label extension study.
- Treatment-emergent adverse events (TEAEs) were monitored for the duration of the trial.
- An independent Data Safety Monitoring Committee reviewed unblinded safety data during Part A of the trial in order to recommend the dose and dose schedule.
- Chlorophyllin of natural types were approved by the Epihealth Board Committee.
- Patients who completed the trial were eligible to continue in an open-label extension study.