METHODS CONT.

STUDY CONDUCT
- Transdermic Synthetic Cannabidiol for the Treatment of Epilepsy (STAR 1) was a Phase 2A, randomized, double-blind, placebo-controlled study of the efficacy and safety of ZYN002 in adults with focal seizures.
- STAR 2 is the open-label extension study for completers of the 12-week STAR 1 study (Figure 3).
- All patients from STAR 1 who exited double-blind and continued in STAR 2 were permitted to titrate to 390 mg (390 mg) or to 195 mg (195 mg) daily.
- Patients were taken on a wide range of antiepileptic drugs (AEDs), and the most commonly used AEDs were levetiracetam, carbamazepine, lamotrigine, lacosamide, and gabapentin.
- One patient died following the Month 15 visit; the causality is suspected SUDEP.

RESULTS

EFFICACY
- Among all treated patients, there was a significant increase in efficacy of ZYN002 over placebo from STAR 1 baseline at Months 3, 6, 9, 12, 15, and 18 of STAR 2 (as of July 31, 2018). Safety assessments: Clinical labs, physical examination, and adverse events (AEs) as of July 31, 2018.
- The cohort group is defined as patients included in the Month 18 analysis.

SAFETY
- ZYN002 was well tolerated, with good skin tolerability in STAR 2 (Table 3). Three serious adverse events were considered possibly related to ZYN002 in STAR 2: seizures (n=2) and increased anxiety (n=1).
- No abnormal liver AEs were observed (ie, alanine aminotransferase/aspartate aminotransferase levels > 3 times the upper limit of normal — were observed).

REFERENCES

CONCLUSIONS — ALL PATIENTS
- ZYN002 is safe and well tolerated at doses of 390 mg to 780 mg over 18 months of treatment
- ZYN002 390 mg dose demonstrates consistent apparent efficacy across STAR 2
- Higher doses of 585 mg and 780 mg only provided limited additional benefit
- No abnormal liver AEs were observed (ie, alanine aminotransferase/aspartate aminotransferase > 3 x upper limit of normal — were observed).