ZYN002 does not contain THC. THC may increase the risk of anxiety and a constellation of behavioral symptoms in children and adolescents with 22q when added to a stable standard of care.

Dysfunction in the ECS may be present in all 3 syndromes (22q, FXS, and ASD) affecting children with neurodevelopmental disorders (22q, FXS, and ASD). ZYN002 does not contain delta-9-tetrahydrocannabinol (THC) or 5-HT1A, GABA, or dopamine receptor agonists affecting children with neurodevelopmental disorders (22q, FXS, and ASD). ZYN002 also does not contain delta-9-tetrahydrocannabinol (THC) or 5-HT1A, GABA, or dopamine receptor agonists affecting children with neurodevelopmental disorders (22q, FXS, and ASD).

ZYN002 does not contain THC. THC may increase the risk of anxiety and a constellation of behavioral symptoms in children and adolescents with 22q when added to a stable standard of care.

Method:

1. **Participants**: A total of 20 patients with ≥35% improvement in the ABC-C total score and all 5 subscales of ADAMS were included in the efficacy analysis for Period 1. The efficacy analysis for Period 2 included 11 patients; 1 patient who completed Week 38 stopped drug prior to Baseline (n=16).

2. **Efficacy Measures**: The efficacy analysis for Period 1 included 16 patients for ADAMS (1 patient did not have a valid assessment at Baseline). The efficacy analysis for Period 2 included 11 patients; 1 patient completed Week 38 and was included in the analysis. The efficacy analysis for Period 1 included 15 patients for PARS-R (2 patients did not have valid assessments at Baseline).

3. **Statistical Analysis**: The efficacy analysis for Period 1 included 15 patients for PARS-R (2 patients did not have valid assessments at Baseline). The efficacy analysis for Period 2 included 11 patients; 1 patient completed Week 38 and was included in the analysis.

4. **Significant Improvements**: Clinically meaningful improvements in CGI-I were reported in 17 patients (85%). Statistically significant improvements were reported in 16 patients (80%). The PARS-R is a clinical interview that assesses symptoms of anxiety disorder in children and adolescents (adolescence/adulthood).

5. **Conclusions**: The findings warrant further study of ZYN002 in children and adolescents with 22q.

**REFERENCES**