ZTALMY®
The first FDA-approved treatment for seizures associated with CDD in patients 2 years of age and older

About ZTALMY® (ganaxolone)
ZTALMY is the first and only U.S. Food and Drug Administration-approved treatment specifically for seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients two years of age and older.1,2

ZTALMY Mechanism of Action
ZTALMY is a neuroactive steroid anticonvulsant that enhances GABAergic inhibitory effects beyond the synapse by modulating both synaptic and extra GABAA receptors.3,4,5 The precise mechanism of action of how ZTALMY treats seizures in CDD is unknown.5

Phase 3 Marigold Trial
The Marigold study is a Phase 3 double-blind placebo-controlled trial in which patients were randomized and treated with ZTALMY or placebo. Participating patients suffered from approximately 16 or more major motor seizures per month that were not controlled by anti-seizure medications.

Pivotal population
Evaluated in a controlled study of 101 patients, aged 2 to 19 years, with refractory seizures associated with CDD.3

Proven efficacy
Significantly reduced the frequency of monthly major motor seizures vs placebo over 17 weeks.3

Demonstrated safety profile
Most common adverse reactions (incidence ≥5% and ≥2x placebo) were somnolence, pyrexia, salivary hypersecretion, and seasonal allergy.3

About CDD
CDD is a serious and rare genetic disorder caused by a mutation of the cyclin-dependent kinase-like 5 (CDKL5) gene, which is located on the X chromosome and encodes proteins essential for normal brain function.5

Incidence is approximately 1:40,000 live births and predominantly affects females.6

Diagnosed by genetic testing to determine if there is a mutation in the CDKL5 gene.6

Characterized by early-onset, difficult-to-control seizures and severe neurodevelopmental impairment.5

References

Please see Important Safety Information on page 2
ZTALMY is indicated for the treatment of seizures associated with cyclin-dependent kinase like 5 (CDKL5) deficiency disorder (CDD) in patients 2 years of age and older.

**INDICATION AND USAGE**

ZTALMY can cause somnolence and sedation. In a clinical study somnolence and sedation appeared early during treatment and were generally dose related. Other CNS depressants, including opioids, antidepressants, and alcohol, could potentiate these effects. Monitor patients for these effects and advise them not to drive or operate machinery until they have gained sufficient experience on ZTALMY to gauge whether it adversely affects their ability to drive or operate machinery.

**Suicidal Behavior and Ideation:** Antiepileptic drugs (AEDs), including ZTALMY, increase the risk of suicidal thoughts or behavior. Monitor patients taking ZTALMY for the emergence or worsening of depression, suicidal thoughts or behavior, or any unusual changes in mood or behavior. Advise patients, caregivers, and their families to be alert for these behavioral changes and report behaviors of concern immediately to healthcare providers. When considering ZTALMY, or any other AED, balance the risk of suicidal thoughts or behaviors with the risk of untreated illness. If these symptoms emerge during treatment, consider whether it may be related to the AED or the underlying illness.

**Withdrawal of Antiepileptic Drugs:** As with most AEDs, withdraw ZTALMY gradually to minimize the risk of increased seizure frequency and status epilepticus. If withdrawal is needed because of a serious adverse event, rapid discontinuation can be considered.

**ADVERSE REACTIONS**

The most common adverse reactions (incidence of at least 5% and at least twice the rate of placebo) were somnolence, pyrexia, salivary hypersecretion, and seasonal allergy.