Abstract highlighting three-year ganaxolone data in CDD presented at EEC 2026

Stockholm, Sweden, Sept 10, 2026 – Immedica Pharma AB announced that data evaluating the long-term efficacy of ganaxolone in patients with CDKL5 deficiency disorder (CDD) was presented at the 16th European Epilepsy Congress (EEC), taking place in Athens, Greece, September 5-9, 2026. The poster presentation will feature results from a post-hoc analysis titled “Sustained clinical efficacy of ganaxolone in CDKL5 deficiency disorder: three-year follow-up.”

The analysis evaluated long-term seizure outcomes in patients who participated in the open-label extension phase following the pivotal, Phase III Marigold study (NCT03572933). 88 patients (aged 2 to 19) who completed the 17-week double-blind phase continued into the open-label extension study, where all participants received ganaxolone treatment. The study was completed after 233 weeks (~4.25 years; inclusive of the 17-week double blind phase) after FDA approval was granted in the United States in March of 2022.

Results demonstrated sustained reductions in major motor seizure frequency (MMSF) throughout the open-label extension period, with the proportion of participants with ≥50% reduction from baseline in 28-day MMSF consistently having met or exceeded that achieved in the ganaxolone group during the double-blind phase (24.5%) at all 3-month intervals for the first 3 years of treatment in the open-label extension. After 163 weeks (~3 years) of ganaxolone treatment in the Marigold open label extension, the median change from baseline in the 28-day MMSF was 35.6%, and 42.1% of participants demonstrated ≥50% reduction in the 28-day MMSF. No new safety findings were identified during the open label extension.

Poster Details

Title: *Sustained clinical efficacy of ganaxolone in CDKL5 deficiency disorder: three-year follow-up*

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About ZTALMY® (ganaxolone)
ZTALMY® is indicated specifically for seizures associated with cyclin-dependent kinase-like 5 deficiency disorder (CDD) in patients two years of age and older. ZTALMY® is approved in the United States, the European Union, United Kingdom, China, Kuwait and UAE. ZTALMY is a neuroactive steroid anticonvulsant, that acts as a positive allosteric modulator of $GABA_A$ receptors in the central nervous system.

About CDKL5 Deficiency Disorder
CDKL5 deficiency disorder (CDD) is a serious and rare genetic disorder that is caused by a pathogenic variant in the cyclin-dependent kinase-like 5 (CDKL5) gene, located on the X chromosome. CDD is characterized by early-onset, difficult-to-control seizures and severe neuro-developmental impairment.

About the Marigold Trial
ZTALMY was approved by the U.S. Food and Drug Administration in March 2022 based on data from the Phase 3 Marigold double-blind placebo-controlled trial of 101 patients with CDD, published in *The Lancet Neurology,* in which ZTALMY significantly reduced the frequency of monthly major motor seizures by a median of 30.7% compared with 6.9% for placebo (p=0.0036). In this trial, ZTALMY demonstrated efficacy, safety and tolerability with the most common adverse reactions (incidence ≥5% and at least twice the rate of placebo) in the ZTALMY group being somnolence, pyrexia, salivary hypersecretion and seasonal allergy.

About Immedica
Immedica is a pharmaceutical company, headquartered in Stockholm, Sweden, focused on the commercialization of medicines for rare diseases and specialty care products. Immedica's capabilities cover marketing and sales, compliance, pharmacovigilance, quality assurance, regulatory, medical affairs and market access, as well as a global distribution network serving patients in more than 50 countries. Immedica is fully dedicated to helping those living with diseases which have a large unmet medical need. Immedica's therapeutic areas are within RARE metabolic, RARE hematology & oncology, RARE neurology, RARE Endocrinology and specialty care. Immedica was founded in 2018 and employs today around 180 people across Europe, the Middle East and the United States. Immedica is backed by the investment firms KKR and Impilo.

For more information visit www.immedica.com.

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