



Immedica announces marketing authorization approval in the UAE for Ztalmy® (ganaxolone) for CDKL5 deficiency disorder

Stockholm, Sweden, June 23, 2026 – Immedica today announced that the Emirates Drug Establishment (EDE) has granted Marketing Authorization (MA) approval for Ztalmy® (ganaxolone) for the treatment of seizures associated with CDKL5 deficiency disorder (CDD) in the United Arab Emirates (UAE). This marks an important milestone in making Ztalmy available to eligible patients in the UAE.

“The approval of Ztalmy in the UAE is an important step in expanding access to treatment options for patients living with CDD,” said Ashraf Attia, General Manager MENA. “We are very pleased that eligible patients in the UAE will now have access to this important treatment option.”

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 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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