



# Immedica announces first marketing authorization approval in the MENA region for Ztalmy® (ganaxolone) for CDKL5 deficiency disorder

**Stockholm, Sweden, April 1, 2026** – Immedica today announced that the Kuwait Ministry of Health (MOH) has granted Marketing Authorization (MA) approval for Ztalmy® (ganaxolone) for the treatment of seizures associated with CDKL5 deficiency disorder (CDD) in Kuwait. This marks the first approval for Ztalmy in the Middle East and North Africa (MENA) region.

“This is an important milestone for Immedica and for the expansion of Ztalmy in the MENA region,” said Ashraf Attia, General Manager MENA. “We are particularly pleased that patients in Kuwait will now be able to benefit from this important treatment option”.

This approval underscores Immedica’s commitment to improving access to innovative therapies for patients with rare diseases across underserved regions.

## **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 and China. Ztalmy, a neuroactive steroid anticonvulsant that acts as a positive allosteric modulator of GABA<sub>A</sub> 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](http://www.immedica.com).

## **Immedica contact:**

Linda Holmström  
Head of HR & Communication

[linda.holmstrom@immedica.com](mailto:linda.holmstrom@immedica.com)

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Immedica Pharma AB  
Solnavägen 3H  
SE-113 63 Stockholm