

Immedica regains commercial rights in the MENA region for Ztalmy® (ganaxolone)

Stockholm, Sweden – June 12, 2025 – Immedica today announces that the company and its partner Biologix FZCo have decided to mutually terminate their marketing and distribution agreement for ganaxolone in the Middle East and North Africa (MENA). That means that Immedica regains the commercial rights to ganaxolone in this region.

Ganaxolone is approved in Europe as well as in the U.S for the adjunctive treatment of epileptic seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients two to 17 years of age. CDD is a serious and rare genetic disorder. Biologix will suspend all ganaxolone-related activities in MENA.

"We thank Biologix for the collaboration and their efforts to make ganaxolone available to patients with CDD in the region. With the commercial rights now returned to us, we look forward to pursuing regulatory approval and exploring new opportunities to ensure that patients in MENA can access this important treatment," says Anders Edvell, CEO of Immedica.

About CDKL5 Deficiency Disorder (CDD)

CDD is a serious and rare genetic disorder that is 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. CDD predominantly affects females and is characterized by early-onset, difficult-to-control seizures and severe neuro-developmental impairment. Many children diagnosed with CDD also experience scoliosis, visual impairment, sensory problems, gastrointestinal difficulties, and sleeping disorders.

About Ztamly® (ganaxolone)

Ganaxolone is a medicine approved in the EU, Great Britain, the U.S and China for the adjunctive treatment of epileptic seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients 2 to 17 years of age. ZTALMY may be continued in patients 18 years of age and older.

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 and specialty care. Immedica was founded in 2018 and employs today around 140 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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