Immedica MAH for Ztalmy® (ganaxolone) in the EU

Stockholm, Sweden – June 12, 2025 – Immedica Pharma AB today announced that Immedica became the Marketing Authorisation Holder (MAH) for the orphan medicinal product Ztalmy® in the European Union. The European Commission adopted the decision to transfer the marketing authorization of Ztalmy to Immedica Pharma AB on June 2, 2025 and this represents a significant regulatory milestone for Immedica.

This follows Immedica's acquisition of Marinus Pharmaceuticals, Inc. earlier this year, through which Ztalmy became a core asset in Immedica's expanding portfolio focused on rare diseases.

"We are very pleased to assume the MAH responsibilities for Ztalmy in the EU," said Anders Edvell, CEO of Immedica Pharma AB. "This marks an important step in our commitment to improving the lives of patients with CDD across Europe."

Ztalmy is not yet commercially available in the EU. The MAH transfer became effective as of the European Commission's decision date. Immedica now holds full regulatory responsibility for the product within the EU.

The company is also working closely with the UK Medicines and Healthcare Products Regulatory Agency (MHRA) to finalize the MAH transfer for the UK market.

About CDKL5 Deficiency Disorder (CDD)
CDKL5 deficiency disorder 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 ZTALMY®
ZTALMY (ganaxolone) is a medicine approved in the EU and Great Britain 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. ZTALMY is also approved in US and China.

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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