Efmody® (modified-release hydrocortisone) granted extension of indication for adrenal insufficiency

Stockholm, Sweden – April 7, 2026 - Immedica Pharma AB is pleased to announce that the European Commission (EC) has granted extension of indication for Efmody® (modified-release hydrocortisone) to include treatment of adrenal insufficiency (AI) in adolescents aged 12 years and over and adults.

Adrenal insufficiency is a rare and serious condition in which the body does not produce sufficient amounts of cortisol. Patients require lifelong treatment and careful management to mimic the body's natural cortisol rhythm.

"The extension of Efmody indication represents an important milestone for patients living with adrenal insufficiency, who face a significant daily treatment burden", says Anders Edvell, CEO at Immedica. "We are committed to ensuring that patients across our regions gain access to innovative therapies that can make a meaningful difference in their lives."

The approval is based on final results from study DIUR-016-AI; a double-blind, double-dummy, two-way cross-over, randomised, phase II study of efficacy, safety and tolerability of modified-release hydrocortisones: Chronocort (Efmody) versus Plenadren (hydrocortisone), in AI.

About adrenal insufficiency (AI)
AI is a rare endocrine disorder in which the body's adrenal glands are unable to produce sufficient cortisol, a hormone essential for metabolic function and the physiological response to stress. The overall prevalence of adrenal insufficiency is estimated at approximately 41 per 100,000 people. Common daily symptoms include fatigue, low blood pressure, nausea, and reduced tolerance to physical and psychological stress. Treatment focuses on maintaining physiological cortisol levels to prevent acute adrenal crises, which can be life-threatening. Glucocorticoid replacement therapy, with hydrocortisone as the standard of care, is the cornerstone of treatment, with most patients requiring lifelong therapy.

About Efmody® (hydrocortisone modified-release hard capsules)
Efmody is indicated in adolescents aged 12 years and over and adults for the treatment of adrenal insufficiency (AI) and the treatment of congenital adrenal hyperplasia (CAH). Efmody is a modified-release preparation of hydrocortisone that has been specifically designed to replicate the natural circadian rhythm of cortisol when given in a twice-a-day "toothbrush" regimen (last thing at night before sleep and first thing in the morning on waking) and can thus provide a more physiological profile.

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 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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