28 May 2021

Diurnal Group plc
("Diurnal" or the "Company")

Diurnal receives European Commission approval for Efmody®

First licensed treatment for European patients with CAH that mimics the physiological circadian rhythm of cortisol

Diurnal's second product to receive marketing authorisation

Commercial launch anticipated in Q3 2021

Diurnal Group plc (AIM: DNL), the specialty pharmaceutical company targeting patient needs in chronic endocrine (hormonal) diseases, announces the European Commission (EC) has approved the marketing authorisation for Efmody® (hydrocortisone modified-release hard capsules – development name Chronocort®) as treatment of adult and adolescent patients (12 years and older) with the rare condition congenital adrenal hyperplasia (CAH). This decision by the EC follows the positive opinion issued by the European Medicines Agency (EMA) in March 2021.

To facilitate timely commercial availability, Diurnal has already commenced market access activities in its target European territories, with the first commercial launch anticipated in Q3 2021. The Company intends to mirror its strategy for Alkindi® (hydrocortisone granules in capsules for opening) by commercialising the product itself in core European markets. The EC decision for Efmody® is valid in all countries of the European Union, and will also be adopted by Norway, Iceland and Liechtenstein.

Efmody® is a preparation of hydrocortisone that has been specifically designed for patients with CAH, an orphan condition caused by deficiency of adrenal enzymes, most commonly 21-hydroxylase. Approximately two-thirds of CAH patients are estimated to have poor disease control, leading to elevated androgen levels. The condition is estimated to affect a total of approximately 36,000 in the European Economic Area.

Professor Dr med Nicole Reisch, Professor of Internal Medicine, Endocrinology at the Ludwig-Maximilian-University Munich, commented:
"We welcome today's decision by the European Commission for Efmody® as treatment for adult and adolescent patients with the rare disease of congenital adrenal hyperplasia. Efmody® has been proven to provide control of the disease and the overall data shows an improved hormone balance, which will provide a well-tolerated and practical twice-daily treatment regimen for these patients where there is a significant unmet need. As the first licensed treatment for European patients with congenital adrenal hyperplasia that mimics the physiological circadian rhythm of cortisol, we look forward to having an additional therapeutic option for congenital adrenal hyperplasia patients in the near future."

Martin Whitaker, Chief Executive Officer of Diurnal, commented:
"We are delighted to have received European approval for Efmody®, a significant milestone for Diurnal as our second product to receive marketing authorisation. We look forward to expanding our adrenal portfolio with the European launch of Efmody® in Q3 2021 alongside our first product Alkindi®, to provide treatment for patients with congenital adrenal hyperplasia, enabling Diurnal to continue to drive towards becoming a world-leading specialty endocrinology business. "

This is a business press release containing financial information and/or data for the benefit of shareholders and potential investors. Data are included to allow informed investment decisions.

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) 596/2014 (MAR).

For further information, please visit www.diurnal.co.uk or contact:

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Notes to Editors

About Congenital Adrenal Hyperplasia
Congenital adrenal hyperplasia (CAH) is an orphan condition caused by deficiency of adrenal enzymes, most commonly 21-hydroxylase. This enzyme is required to produce the adrenal steroid hormone, cortisol. The block in the cortisol production pathway causes the over-production of male steroid hormones (androgens), which are precursors to cortisol. The condition is congenital (inherited at birth) and affects both sexes. The cortisol deficiency and over-production of male sex hormones can lead to increased mortality, infertility and issues during sexual development including ambiguous genitalia, premature (precocious) sexual development and short stature. Sufferers, even if treated, remain at risk of death through an adrenal crisis.

Current therapy for CAH uses a variety of generic glucocorticoid (steroids including hydrocortisone, dexamethasone, prednisolone and prednisone in the US) with no standard treatment regimen. Approximately two-thirds of CAH patients are estimated to have poor disease control, leading to elevated androgen levels. The condition is estimated to affect a total of approximately 41,000 patients in Europe and the United Kingdom, with over 400,000 in the rest of the world.

About Efmody® (hydrocortisone modified release hard capsules)
Efmody® is a preparation of hydrocortisone that has been specifically designed to mimic the circadian rhythm of cortisol when given in a twice-a-day "toothbrush" regimen (administered last thing at night before sleep and first thing in the morning on waking) to control androgen excess and chronic fatigue in patients with diseases of cortisol deficiency. The first indication for Efmody® is Congenital Adrenal Hyperplasia (CAH) in adults and adolescents (children older than 12 years of age). Efmody® has been extensively studied in 239 human subjects including 138 CAH patients who have taken part in clinical trials in Europe and the US.

The European Commission approval of Efmody® is based on a Phase 3 study conducted in a total of 122 patients enrolled across 11 clinical sites, the largest ever interventional clinical trial completed in CAH. The Phase 3 data was supported by detailed analysis of data from an open-label safety extension study for patients completing treatment in the Phase 3 study, which is assessing the impact of treatment with Efmody® over an extended period, with a number of patients on this trial having been treated for over 54 months. Patient retention rates in this study have been high and patients on this trial have, to date, shown sustained benefit from extended Efmody® treatment.

About Diurnal Group plc
Diurnal Group plc is a European, UK-headquartered, specialty pharmaceutical company dedicated to developing hormone therapeutics to aid lifelong treatment for rare and chronic endocrine conditions, including congenital adrenal hyperplasia, adrenal insufficiency, hypogonadism and hypothyroidism. Its expertise and innovative research activities focus on circadian-based endocrinology to yield novel product candidates in the rare and chronic endocrine disease arena.

For further information about Diurnal, please visit www.diurnal.co.uk

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