15 April 2021

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

Request for maintenance of Orphan Designation for Efmody® withdrawn

European Efmody® launch, planned for Q3 2021, remains unchanged following earlier positive CHMP opinion supporting drug approval

Granted European Efmody® patents provides protection until 2033

Diurnal Group plc (AIM: DNL), the specialty pharmaceutical company targeting patient needs in chronic endocrine (hormonal) diseases, announces that it has decided to withdraw its application for maintenance of Orphan Designation in Europe for Efmody® (hydrocortisone modified-release hard capsules – development name Chronocort®). This follows feedback from the Committee for Orphan Medicinal Products (COMP), an advisory committee to the European Medicines Agency (EMA). Diurnal has decided that continuing pursuit of an Orphan Designation for the drug would be likely to cause a significant delay in its European commercial launch. First commercial launch is currently anticipated to be in Q3 2021.

As previously announced by the Company on 26 March 2021, the Committee for Medicinal Products for Human Use (CHMP), an advisory committee of the EMA, issued a positive opinion to the European Commission recommending Efmody® as treatment of adult and adolescent patients (12 years and older) with the rare condition congenital adrenal hyperplasia (CAH). The formal approval of marketing authorisation from the European Commission for Efmody®, which is not dependant on the maintenance of Orphan Designation, continues to be anticipated in June 2021, in accordance with the 67-day mandated timeline following the adoption of a positive opinion by the CHMP. In anticipation of this and commercial launch shortly thereafter, market access activities in the Company's target European territories are underway.

Orphan Designation provides for market exclusivity for 10 years from launch. However, the Company currently holds granted European patents for Efmody® for the treatment of patients with both CAH and adrenal insufficiency (AI) and believes these patents provide sufficient protection for Efmody® until at least 2033 in all designated states covered by the European Patent Convention. In addition, while Orphan Designation can be used to support premium pricing in certain territories, Diurnal does not believe that this is critical to the overall commercial potential of the product given the significant clinical need for new therapies in CAH.

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 41,000 patients in Europe.

Martin Whitaker, Chief Executive Officer of Diurnal, commented:
"Following the recent positive opinion from the CHMP we are focussed on the timely launch of Efmody® in Q3 2021. Orphan Designation for Efmody® in Europe is not critical to the commercial potential of the product in this market. There remains a strong clinical rationale for the drug's use to address the significant need for new therapies to improve outcomes for adult patients with CAH. This was highlighted recently in the paper in the Journal of Clinical Endocrinology and Metabolism that detailed our pivotal clinical trial data and results from a long term extension study. Additionally, a robust, granted European patent estate provides market exclusivity for the drug until at least 2033."

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

Diurnal Group plc **+44 (0)20 3727 1000**

Martin Whitaker, Chief Executive Officer
Richard Bungay, Chief Financial Officer

Panmure Gordon (UK) Limited (Nominated Adviser and Sole Broker) **+44 (0)20 7886 2500**
Corporate Finance: Freddy Crossley, Emma Earl
Corporate Broking: Rupert Dearden

FTI Consulting (Media and Investor Relations) **+44 (0)20 3727 1000**
Simon Conway
Victoria Foster Mitchell
Alex Davis

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, 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 positive opinion from the CHMP 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
Founded in 2004, Diurnal is a UK-headquartered, European specialty pharma company developing hormone therapeutics for the global market for the life-long treatment of chronic endocrine conditions, including congenital adrenal hyperplasia, adrenal insufficiency and hypogonadism. 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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