26 March 2021

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

European Medicine Agency issues positive opinion for Diurnal's second product in Europe

In preparation for commercial product launch in Europe, Chronocort® to be branded as Efmody®

Commercial launch anticipated in Q3 2021

Diurnal Group plc (AIM: DNL), the specialty pharmaceutical company targeting patient needs in chronic endocrine (hormonal) diseases, announces that the Committee for Medicinal Products for Human Use (CHMP), an advisory committee of the European Medicine Agency (EMA), has issued a positive opinion to the European Commission recommending 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). The formal approval of marketing authorisation from the European Commission is anticipated in June 2021, in accordance with the 67-day timeline following the adoption of the positive opinion by the CHMP, together with a decision on grant of Orphan Drug Status.

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.

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:
"We are delighted that the CHMP endorses Efmody® as a treatment option for adult and adolescent patients suffering from congenital adrenal hyperplasia. We look forward to expanding our commercial portfolio with the planned launch of Efmody® across Europe alongside our first product Alkindi®, to provide life-long treatment for patients with congenital adrenal hyperplasia, enabling Diurnal to continue to drive towards becoming a world-leading specialty endocrinology business."

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:

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	

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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VAULT PromoMats

Approval Certificate

Job Number CORP-GB-0110

Product Corporate

Item Name Press Release - EMA announce Chronocort decision

Objective

Intended Audience General Public, Investor

Certification and Release Declaration
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Medical Practitioner Certification I certify that I have re-examined the final form of the material and in my belief it is in accordance with the requirements of the relevant regulations relating to advertising and the ABPI Code and any other relevant code, is not inconsistent with the marketing authorization and the summary of product characteristics, and is a fair and truthful presentation of the facts about the medicine. I certify the above is true	John Porter johnporter@diurnal.co.uk Medical Practitioner 26-Mar-2021 11:42:38 GMT+0000
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